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Indian Journal of Obstetrics and Gynecology Research

Journal homepage: www.ijogr.org

Original Research Article

Use of sequential compression device for prevention of hypotension associated with spinal anesthesia in elective caesarean section

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ARTICLE INFO

Article history:

Received 20-10-2021

Accepted 20-10-2021

Available online 14-02-2022

Keywords:

Spinal anesthesia

Sequential compression device

Hypotension

Obstetric anesthesia

Crystalloid

ABSTRACT

Background: A very high incidence of hypotension associated with spinal anesthesia (SA) is a matter of concern in obstetric anesthesia and a stable hemodynamic status is required to reduce morbidity furthermore to improve maternal safety. In this study we aim to evaluate the efficacy of sequential compression device for prevention of spinal anesthesia induced hypotension as compared to the standard crystalloid preloading.

Materials and Methods: In this prospective randomized study, total 80 patients with ASA grade I/II divided were enrolled after ethical approval. The patients were randomly allocated into two groups (40 patients in each group) using the computer generated random table. Mechanical Pump (Group M): Sequential compression device was applied and discontinuous compression was started at 60 mmHg and Crystalloid group (Group C) - Patients were preloaded with Ringer's lactate (RL) at dose of 10 ml/kg for not more than 10 minutes. Spinal block was given and RL was started at rate of 10-15 drops/min to keep venous line patent. The Chi Square test and Unpaired Student's 't' tests were used.

Results: Statistically significant differences were observed in heart rate, systolic BP, diastolic BP, mean arterial pressure. The percentage drop in systolic BP from baseline was significantly more in crystalloid group (p=0.043).

Conclusion: The sequential compression device is useful for prevention of hypotension in pregnant females undergoing elective caesarean section under spinal anesthesia.

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1. Introduction

Spinal anesthesia (SA) is a regular anesthetic technique to perform cesarean section.^{1,2} The reasons are multiple, like it is easy to perform, quick in onset, and avoids issue of difficult intubation present in pregnancy, maternal airway related complications, aspiration and neonatal depression.³ However, it is associated with a very high incidence of hypotension with reports as high as 83%.⁴ A systolic arterial pressure (SAP) drop by more than 20% of the baseline, or a pressure drop by less than 90–100 mmHg is considered as hypotension and this is dangerous to

mother, fetus, and newborn.⁵ To decrease chances of hypotension various strategies work like volume loading, inotropic agents and prevention of aortocaval compression. Regular blood pressure monitoring for early detection of hypotension and its management is paramount for risk reduction.

Prolonged maternal hypotension is harmful to the fetus as uterine blood flow is pressure-dependent. It was seen that spinal-induced hypotension leads to significant neonatal acidosis^{6,7} and hypotension of more than 2 min duration was associated with a significant increase in umbilical venous oxypurines and lipid peroxides, suggestive of ischaemia-reperfusion injury.⁸

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Hence, our main focus of clinical management is the maintenance of maternal blood pressure to avoid adverse effects of hypotension. There are various strategies to decrease SA-induced hypotension like use of intravenous fluids, Sequential Compression Device (SCD) and Vasopressors.

In Sequential Compression Device (SCD) method, intermittent pressure is applied above the knee. Previous studies say that almost 125 millilitre of blood is moved in compression phase. It is well known that at term, there is a high blood volume in the lower extremities, which is further increased by SA induced vasodilatation.^{9,10} Therefore, theoretically, the SCD method mobilizes more blood to the central [active] blood volume, and thus decreases chance of hypotension, whereas other methods are relatively short-term and temporary.

In view of the previous studies, the present study was designed to evaluate the efficacy of sequential compression device for prevention of spinal anesthesia induced hypotension as compared to the standard crystalloid preloading.

2. Materials and Methods

This prospective, randomized, interventional study was conducted after approval of the ethical committee of the university (Ref. code: 97th ECM II B- Thesis P27) and obtaining written informed consent from each patient. The study was conducted in non-laboring parturients aged 18–45 years belonging to ASA physical status I or II, and planned for elective cesarean section under spinal anesthesia. Exclusion Criteria were: contraindication of spinal anesthesia, emergency lower segment caesarean section, body mass index (BMI) >40 kg/m², history of hypertension or pregnancy-induced hypertension, multiple gestations, pregnancy pathology, heart diseases and gestational diabetes.

Patients were divided into 2 groups: Mechanical Pump (Group M) or Crystalloid group (Group C) with computer generated random number table. Group C (Crystalloid Group): Patients were preloaded with Ringer's lactate at dose of 10ml/kg for not more than 10 minutes. After that, spinal block was given and crystalloids were given at rate of 10-15 drops/min to keep venous line patent. Group M (Mechanical Pump Group): Sequential compression device was applied and discontinuous compression was started at 60 mmHg. (COVIDIEN Kendall SCD 700 Series: Ireland based company).

Patients were taken in operating room and an 18 G cannula was inserted in best vein available in hand or forearm. In operating room, pulse oximeter, electrocardiogram (ECG) and non-invasive BP cuff was applied and oxygen saturation, heart rate, and non-invasive BP was monitored in both groups. Patients in both groups were premedicated with Injection (Inj.) Emset 4 mg IV and

Inj. Rantac 50mg IV. Spinal anesthesia was given with the patient in sitting position. After skin infiltration with 2% xylocaine, 25G Quincke's needle was inserted at L3-4 vertebral interspace and 2ml of 0.5% hyperbaric bupivacaine (10mg) and fentanyl 25 µg was injected intrathecally without barbotage. Patients were immediately turned supine with 15-20 degree left lateral tilt. The block height was assessed by using the pinprick test every minute until maximum block height T6 was achieved. Oxygen at the rate of 5 L/min was administered by face mask.

Blood Pressure (BP) and Heart rate (HR) were measured at each min until delivery, every 3 min until 10 min, every 5 min until arrival to recovery room, and every 10 min until discharge from recovery room. Maternal hypotension if occurred [Systolic Blood Pressure (SBP) drop by >20% of baseline values or <90mmHg], was treated with Inj. Mephentermine 6mg and repeated at 2 min interval if hypotension persisted. If bradycardia occurred (HR<50 bpm), it was treated with Inj. Atropine 0.2mg IV. Occurrence of nausea and vomiting was recorded and treated accordingly. After delivery Inj. oxytocin was given (20 IU IV +10 IU IM). Infusion solution was stopped and compression device was removed and sensory and motor block levels were reexamined at the end of surgery. The study ended after the discharge of the patients from the recovery room.

2.1. Statistical analysis

The results were analyzed using descriptive statistics and making comparisons among various groups. Discrete (categorical) data were summarized as in proportions and percentages (%) and quantitative data were summarized as mean ± SD. Chi Square test and Unpaired Student's 't' tests were used. Level of Significance (p<0.05) was considered statistically significant.

2.2. Sample size

Sample size was calculated on the basis of a previous study¹¹ comparing proportion of hypotension after 5 minutes in the study group and assuming the null hypothesis of equality. The calculated sample size was 38 patients in each group (where $\alpha=0.05$ and $\beta=0.9$).

3. Results

The demographic profiles of the patients were similar in between group C (crystalloid) and group M (mechanical pump) (Table 1). The mean age was not significantly different between group C (32.10±4.96 years) and group M (30.05±4.66 years). The distribution of patients on the basis of socioeconomic status, ASA grade and gestational age were not significantly different between group C and group M. The mean number of previous cesarean section and Apgar score were not significantly difference in between

Table 1: Demographic profiles of the patients

Variable	Group C		Group M		p-Value	
	Mean	±SD	Mean	±SD		
Age (years)	32.10	4.96	30.05	4.66	0.06	
Socioeconomic status	No.	%	No.	%	0.343	
	Lower Middle Class	10	25.0%	6		15.0%
	Middle class	25	62.5%	25		62.5%
ASA Grade	Upper Middle Class	5	12.5%	9	22.5%	0.585
	I	10	25.0%	7	17.5%	
Gestational Age	II	30	75.0%	33	82.5%	0.113
	Preterm	15	37.5%	12	30.0%	
	Early Term	25	62.5%	24	60.0%	
No. of previous caesarean sections (mean±SD)	Full Term	0	0.0%	4	10.0%	0.274
	APGAR at 5 min (mean±SD)	1.25	0.71	1.45	0.90	
		8.73	0.64	8.50	0.75	0.153

ASA: American Society of Anaesthesiologists

groups.

The heart rate (HR) was 98.50 ± 10.83 b/min and 93.40 ± 13.59 b/min in group C and group M at baseline. The HR was slightly lower from baseline 55 min and after that it slight increased at discharge from recovery room (Figure 1). The significant differences in HR were observed among the groups at 3 min ($p=0.009$), 4 min ($p=0.029$), 5 min ($p=0.005$), 45 min ($p=0.001$), 50 min ($p=0.001$), 55 min ($p=0.020$), 60 min ($p=0.003$), 80 min ($p=0.009$), 90 min ($p=0.031$) and at discharge from recovery point ($p=0.042$).

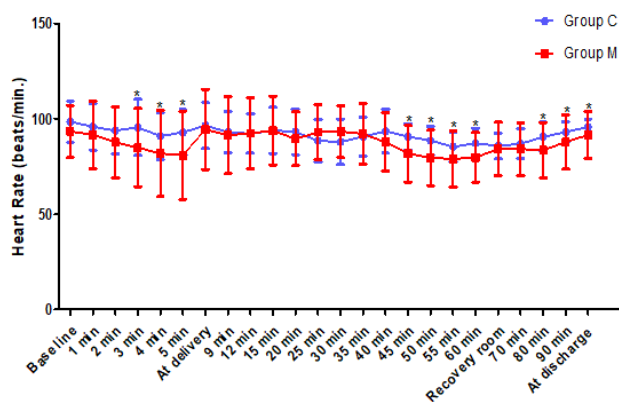


Fig. 1: Heart rates (beat/min) at various time points

The baseline means SBP was 125.13 ± 7.81 mmHg and 121.08 ± 10.73 mmHg group C and group M at baseline. The SBP was slightly lower from baseline to 15 min in group C and 3 min in group M, and after that it increases at discharge from recovery room (Figure 2). The significant differences in SBP was observed between the groups at 9 min ($p=0.026$) and 15 min ($p=0.022$).

The baseline means DBP was 80.25 ± 8.05 mmHg and 83.98 ± 10.28 mmHg group C and group M at baseline. The DBP was slightly lower from baseline to 12 min in group

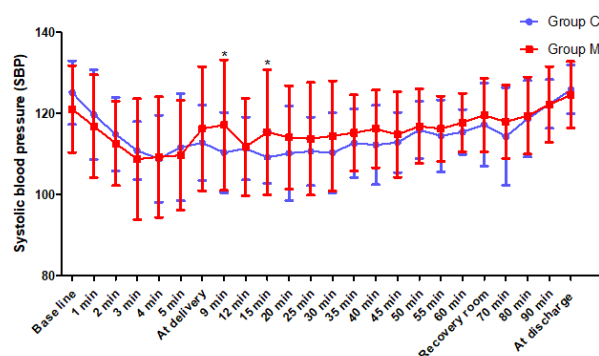


Fig. 2: Systolic blood pressure (mmHg) at various time points

C and 20 min in group M, and after that it increases at discharge from recovery room (Figure 3). The significant differences in DBP was observed between the groups at 1 min ($p=0.033$), 2 min ($p=0.021$), 3 min ($p=0.015$), 4 min ($p<0.001$), 5 min ($p=0.020$), 9 min ($p=0.005$), 12 min ($p=0.048$) 90 min ($p=0.047$) and at discharge from recovery room ($p=0.015$).

The baseline means MAP was 95.21 ± 5.78 mmHg and 96.34 ± 7.89 mmHg group C and group M at baseline. The SBP was slightly lower from baseline to 4 min in group C and 20 min in group M, and after that it increases at discharge from recovery room (Figure 4). The significant differences in MAP was observed between the groups at 4 min ($p=0.001$) and 9 min ($p<0.001$).

The incidence of hypotension ($\%SBP$ change $< 20\%$) in group C was found to be 55.0%, while in group M it was 32.5% (Table 2). Overall incidence of hypotension was 43.8%. The incidence was significantly lower in group M as compared to group C ($p=0.043$).

Table 2: Incidence of hypotension and its intergroup comparison

Incidence of Hypo-tension	Group C		Group M		Significance		Risk reduction (Case)	
	No.	%	No.	%	chi sq	p-value	OR	95% CI
No	18	45.0%	27	67.5%	4.11	0.043	0.39	(0.16-0.98)
Yes	22	55.0%	13	32.5%				

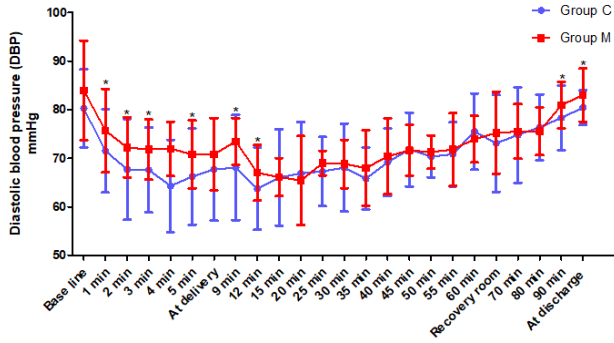


Fig. 3: Diastolic blood pressure (mmHg) at various time points

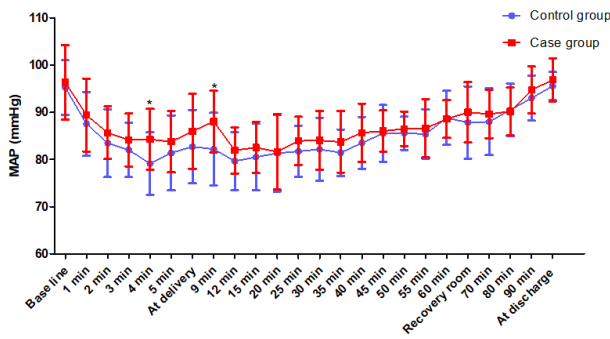


Fig. 4: Mean arterial pressure (mmHg) at various time points

4. Discussion

The incidence of hypotension during cesarean section under spinal anesthesia remains a frequent scenario in obstetric practice. Prevention of aortocaval compression also may not significantly prevent hypotension in most singleton pregnancies. Crystalloid pre-hydration also seems to be of little use. Thus, according to a previous study,⁴ the current focus is on timing of administration of fluids and the use of colloids. Various methods have been used to prevent or treat hypotension; since there is no treatment 100% effective by itself, thus a multimodal management has been suggested to achieve an optimum balance and avoidance of hemodynamic imbalance.¹² In our study, we have compared incidence of hypotension after spinal anesthesia using two groups: one group was preloaded with crystalloid and in another group, sequential compression device was applied.

Several studies have been done to determine the efficacy of mechanical devices in preventing hypotension after

spinal anesthesia. Previously, the effect of Thromboembolic Deterrent (TED) stockings was investigated to prevent hypotension during spinal anesthesia and no statistically significant difference was found in incidence of hypotension and mean arterial blood pressure at each time between the groups.¹³ In another study, a sequential compression mechanical pump with thigh-high sleeves was used with compression cycles set to venous refilling and hypothesized that this would recruit pooled venous blood from the lower limbs and maintain the central blood volume. No difference between groups in the time to onset of hypotension was seen.¹⁴

Several other studies have evaluated the effect of the lower leg compression technique for reducing spinal anesthesia-induced hypotension risks during cesarean delivery and found a highly statistically significant difference as hypotension affected a greater percentage of women in control group than those in the leg compression group.¹⁵⁻¹⁷ In our study too, the percentage drop in systolic BP from baseline was found to be more in control group and the incidence of hypotension with the use of sequential compression device was found to be significantly less. However, continuous pressure nonpneumatic anti-shock garment (NASG) proved to be a more effective device for prevention of postspinal hypotension when compared with application of SCD or no device.¹⁷ The hemodynamic effects of leg wrapping with elastic crepe bandage (CB) and pneumatic compression device (PCD) were also analyzed in another study in parturients undergoing for cesarean section under anesthesia and it was found that the incidence of hypotension was lower in group CB than group PCD.¹⁸ No significant difference was found in number of hypotensive episodes between SCD and control groups in our study as none of the patients required supplementation of vasopressors.

Several others investigated that multimodal approach decreases the incidence of hypotension following spinal anesthesia in parturients undergoing elective or urgent cesarean section. They applied maternal care bundle [consisting of fixed low dose of bupivacaine (7.5 mg + fentanyl 25 µg), co-loading with 15 ml/kg Ringer’s Lactate with patient in the supine wedged position, administration of 9 mg ephedrine sulphate IV after intrathecal injection, placement of graduated compression stockings (GCS) in the elevated leg position >45° and maintaining leg elevation at 20° following application of GCS] and found significantly decreased incidence of spinal induced hypotension in parturient undergoing cesarean section.^{19,20}

The effect of ondansetron, as a 5-HT₃ receptor antagonist, on the haemodynamic response following subarachnoid block in parturients undergoing elective caesarean section was also studied and it was seen that prophylactic intravenous ondansetron given before subarachnoid block significantly reduced hypotension and heart-rate fluctuations.^{21–23} In our study, patients in both groups were premedicated with ondansetron 4 mg IV.

Vasopressor requirements and maternal hemodynamics in women undergoing caesarean delivery with spinal anesthesia was compared among women who received either thromboembolic deterrent hose stockings (TEDs) or sequential compression mechanical devices (SCDs) and found that patients receiving either SCDs or TEDs have similar pressor requirements and hemodynamic indices during cesarean delivery.²⁴ In our study, SCD was no better than crystalloid preloading in term of vasopressors requirement.

Most trials reported hypotension requiring intervention and Apgar score of less than 8 at 5-minutes as the only outcomes.

Most studies assessed only women scheduled for elective caesarean sections and concluded that while interventions such as crystalloids, colloids, ephedrine, phenylephrine, ondansetron, or lower leg compression can reduce the incidence of hypotension but none have been shown to eliminate the need to treat maternal hypotension in some women.

Limitations of our study were small sample size, single center study, inclusion of only healthy parturients with uncomplicated pregnancies, and observer bias may be there due to non-blinding.

5. Conclusion

The sequential compression device is useful for prevention of hypotension in pregnant females undergoing elective caesarean section under spinal anesthesia and can also be used as a valuable tool in pregnant patients with compromised utero-placental blood flow as seen in pregnancy induced hypertension, preeclampsia or eclampsia. Although in our study, the percentages drop in systolic blood pressure was more in group C but none of the patients in any of the group required active intervention which was due to the inclusion of healthy parturients with uncomplicated pregnancies in our study. We further recommend that multicenter, larger sample size and double-blind studies should be undertaken to minimize the bias / error for generalization of the findings, and should also be undertaken on patients with multiple gestation and in patients of ASA grade > II.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.


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Cite this article: Agarwal A, Singh VK, Singh V, Singh GP. Use of sequential compression device for prevention of hypotension associated with spinal anesthesia in elective caesarean section. *Indian J Obstet Gynecol Res* 2022;9(1):48-53.