

EFFECT OF APPLICATION OF LOWER LIMB VENOUS COMPRESSION ON MATERNAL BLOOD PRESSURE DURING CAESAREAN SECTION UNDER SPINAL ANAESTHESIA.

ABSTRACT

Background: Maternal hypotension from spinal anaesthesia poses significant risks warranting continued search for effective prophylaxis.

Aim: The study aims to compare the effects of knee high (KH) and thigh high (TH) sequential compression stockings (SCS) on maternal blood pressure during Caesarean section under spinal anaesthesia.

Method: Following Ethical approval, 150 consenting eligible parturients aged 18 – 45 years, of American Society of Anesthesiologists class I and II, scheduled for elective Caesarean, were randomized into KH, TH, and control (CT) groups, of 50 each. While groups KH and TH wore knee-high and thigh-high SCS respectively, including sham stockings, group CT wore sham stockings only. Following inflation of the SCS to 30-40 mmHg bilaterally, and 15 ml/kg 0.9% normal saline pre-loading, parturients received 2ml of hyperbaric bupivacaine 0.5% plus 25µg fentanyl, intrathecally, via L3/L4 intervertebral space in sitting position; post block heart rate, blood pressures were recorded. Hypotension was defined as > 20% decrease in baseline, or a systolic blood pressure < 90 mmHg.

Results: All 150 parturients completed the study. Hypotension occurred greatest [44 (37.9%)] in group CT, followed by group KH [40 (34.5%)] and least [32 (27.6%)] in group TH, $p < 0.001$, with significantly greatest ephedrine consumption in group CT, $p = 0.008$.

Conclusion: Knee-High and Thigh-High SCS application significantly reduced the incidence of maternal hypotension during Caesarean section under spinal anaesthesia, with superiority of the TH over the KH, and minimal side effects.

Keywords: *Hypotension, Sequential compression stockings, Spinal anaesthesia.*

INTRODUCTION

Subarachnoid block (SAB) remains the preferred anaesthetic technique for Caesarean section as it offers better maternal and foetal safety profile compared to general anaesthesia.¹ However, despite this advantage, the attendant hypotension and its sequelae on foeto-maternal physiology raises concern.² Theoretically, sympathetic blockade following SAB results in vasodilatation and consequent increase in venous capacitance, leading to pooling of blood in the lower extremities causing maternal hypotension.³ An associated high incidence of 75% in maternal hypotension from sympathetic blockade has been reported.³

Maintaining maternal cardiac output that ensures adequate utero-placental blood flow is vital, without which significant maternal complications and foetal compromise usually occur.⁴ It is documented that maternal hypotension is directly related to reduction in utero-placental blood flow.⁵ This understanding has necessitated the use of pharmacologic and non-pharmacologic methods to achieve increased venous return and mitigate maternal hypotension during SAB. Pre- and co-loading with crystalloids and colloids entail challenges of fluid overload, risk of pulmonary oedema, anaphylactic reactions and high cost.⁶ Ephedrine usage is limited by maternal tachyphylaxis and foetal acidosis, while phenylephrine is costly, associated with reflex bradycardia and consequent decrease in cardiac output.⁷

Sequential compression stockings (SCS), a type of sequential compression device (SCD), counters hypotension by exerting the greatest degree of compression at the ankle, with the force

of compression gradually decreasing up the garment, thereby establishing a pressure gradient which enhances venous return. While crepe bandages, though effective,⁸ have a flaw of inhomogeneity and poorly defined compression pressures, SCS exert clearly defined uniform pressures circumferentially on the limb, are simple, cost effective, and user friendly in application to prevent SAB induced maternal hypotension during Caesarean section.⁹

In healthy young volunteers SCS application to the lower limbs has been shown to pump about 125ml of venous blood to the heart during compression.¹⁰ Theoretically, applying same device in parturients may minimize or eliminate maternal hypotension following SAB for Caesarean section, as there is usually greater blood volume in maternal lower extremity at term.¹⁰ While Adsumelli et al.¹¹ found that thigh high sleeves support mean arterial pressure during Caesarean section under SAB, Tyagi et al,¹² showed that the difference in incidence of maternal hypotension during Caesarean section under SAB between the group of parturients who used a non-pneumatic anti-shock garment and those who used sequential compression device, was statistically insignificant. Therefore, the aim of this study was to evaluate the effect of lower limb venous compression, with Knee-High (KH) and Thigh-High (TH) SCS on maternal blood pressure changes during Caesarean section under SAB.

METHODOLOGY

Having registered and obtained Institutional Ethical Board approval from the University of Port Harcourt Teaching Hospital with reference no. UPTH/ADM/90/S. II/VOL.XI/717/2019 for a prospective, randomized, single blind, comparative study, 150 consenting parturients, aged 18 – 45 years, of ASA I and II, scheduled for elective Caesarean under SAB were randomized into 3 groups, KH, TH and control (CT), of 50 each. All the parturients recruited completed the study.

Randomization and blinding were ensured through recruitment of Research Assistants and picking of opaque sealed envelopes, keeping the Lead Researcher blinded to the subjects' group allocations and SCS applications. The subjects picked one out of 150 envelopes from a bag, on the morning of surgery, under the supervision of a Research Assistant and a Nurse. Each of these envelopes concealed a designation (KH, TH or CT) in it, with an equal number of 50 of each in the bag. The envelope picked was excluded from the rest and the patient allocated to the group so

designated. A different Registrar Anaesthetist (second Research Assistant), blinded to the outcome of the study, fixed the SCS and sham stockings according to group specification just prior to preloading and SAB. Groups KH and TH respectively had on knee-high and thigh-high SCS, covered with the sham stockings, while group CT had only the sham stockings on. The Lead Researcher administered the SAB drugs and recorded the parameters.

All patients had preoperative evaluation the previous day, as well as stopped solid food 6 hours, but took clear fluid up to 2 hours prior to surgery, and were premedicated with ranitidine 150 mg orally the previous night, and another 50mg with metoclopramide 10 mg intravenously on the morning of surgery. Parturients aged 18 – 45 years, of ASA class I or II scheduled for elective Caesarean under SAB, with ≤ 2 previous Caesarean and who gave consent for surgery and for study comprised the inclusion criteria, while subjects who refused to give consent for study, aged < 18 years or > 45 years, with ASA $> II$, ankle brachial pressure index (ratio of pressure in the ipsilateral leg to upper arm) < 1.0 , hypertensive/endocrine disorders, bleeding diathesis, lower limb peripheral vascular disease, haemoglobinopathy, multiple gestation, weight > 110 kg, allergy to intrathecal drugs, contraindication to SAB, failed SAB, COVID-19 patients and surgery duration > 90 minutes constituted the exclusion criteria.

On the morning of surgery, with parturients in the left lateral position, a multi-parameter patient monitor (Dash 4000®, GE Medicals) was attached to obtain and record the parturients' baseline heart rate (HR), noninvasive Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and peripheral arterial oxygen saturation (SpO₂) before and after inflation of the SCS (BWELL, model KBD AS002S), to 30 – 40 mmHg. Post-SCS inflation haemodynamic parameters were measured every minute and the average recorded at the 5th minute

Venous access secured with a 16-gauge cannula and 15ml/kg 0.9% normal saline preloading over 10 minutes, observing asepsis, a SAB was performed in the sitting position, with 2ml of hyperbaric bupivacaine plus 25µg of fentanyl injected over 15 – 20 seconds via a 25-gauge Whitacre point spinal needle advanced intrathecally at the L3/L4 intervertebral space after infiltration using 4ml of 1% plain lidocaine. Needle withdrawn and puncture site covered with sterile dressing, the parturients were returned to the supine position ensuring a 15 - 30° left

lateral tilt with the aid of a Crawford wedge. Supplemental oxygen was administered via face mask till foetal extraction, but continued thereafter if SpO₂ was < 95%. Surgery commenced at a sensory block height of T6 and Bromage score ≥ 3. Maintenance fluid was 0.9% normal saline infused as needed.

Post SAB, the following parameters were monitored intraoperatively:

- HR, SBP, DBP, MAP every minute for five minutes, then every 2 minutes for 10 minutes and, subsequently, at 5 minutes interval till end of surgery;
- continuous SpO₂ to ensure a value > 95%
- peripheral temperature

Hypotension was defined as a systolic blood pressure < 90mmHg or > 20% decrease from base line, with bradycardia considered as heart rate < 50 beats/minute or > 20% decrease from base line.⁵² Hypotension and bradycardia were treated with intravenous bolus doses of ephedrine 5 - 10mg and atropine 0.6mg, respectively. Similarly, temperature and sensory block assessment was done at 5 minutes' intervals, while continuous electrocardiography monitored cardiac rhythm, rate, waves, intervals and segments. Shivering was treated with warm fluids and regulation of the ambient temperature while pruritus was treated with intravenous dexamethasone. Neonatal wellbeing was assessed with Apgar score at the first and fifth minutes. The attending neonatologist who was also blinded to the groups (Registrar or Senior Registrar) collected 2ml of umbilical venous blood for pH measurements using pH meter (ISFET Mini Lab, Model IQ 120), immediately after the umbilical cord was clamped and the newborn separated from the mother. Intravenously, oxytocin 5 IU was administered slowly at the clamping of the cord to prevent postpartum haemorrhage.

Intraoperative maternal blood loss was carefully monitored and estimated by counting and weighing blood-soaked abdominal packs and gauzes, in addition to the quantity of blood in suction bottle and floor spillages. Parturients who had significant haemorrhage and developed severe intra-operative hypotension were excluded from the study. The occurrence of any adverse effects (pruritus, nausea and vomiting, shivering and depressed respiration) was also noted.

Postoperatively, parturients were monitored in the post anaesthesia care unit (PACU), till the ninetieth minute, and transferred to the ward on attainment of post recovery score of 9/10.

Sample size determination

Sample Size Determination

Sample size was determined using power analysis formula for interventional study:¹³

$$n = \frac{(Z_{\alpha} + Z_{\beta})^2 \times p(1-p)}{(P_1 - P_0)^2}$$

Where,

n = sample size

$Z_{\alpha} = 1.28$ with power of 90% for this study; $Z_{\beta} = 1.96$ at 5% significance level.

P_1 = proportion of outcome in intervention group; from similar study,¹⁴ proportion of hypotension among compression group was 25.0% (0.250).

P_0 = proportion of outcome in control group; proportion of hypotension among control group was 60.0% (0.600) from a related study.¹⁵

$$p = \text{average proportion} = \frac{P_1 + P_0}{2} = \frac{0.250 + 0.600}{2} = 0.425$$

Substituting,

$$n = \frac{2(1.28+1.96)^2 \times 0.425(1-0.425)}{(0.250-0.600)^2} = 2 \frac{(10.96) \times (0.425 \times 0.575)}{(-0.350)^2} = 42$$

With allowance for 10% attrition, adjusted sample size = 42 + 4.2 = 46.2, increased to 50 per group. Therefore, 150 parturients were recruited for the study.

DATA COLLECTION AND ANALYSIS

Data were entered into Excel spreadsheet and exported to the Statistical Package for Social Sciences (SPSS) version 20.0 (Armonk, NY: IBM Corp.) for statistical analysis. Statistical significance was set at $p < 0.05$.

RESULTS

The mean maternal ages (in years) of 29.76 ± 5.03 , 30.16 ± 6.05 and 29.58 ± 5.09 in the KH, TH and CT groups respectively with a range of 18 to 45 were comparable, $p = 0.0861$; their corresponding body mass indices (in kg/m^2) of 29.85 ± 1.57 , 30.17 ± 1.61 and 29.77 ± 1.59 were also not significantly different, $p = 0.058$. While only 2 (4%) out of 150 subjects were aged ≥ 20 years, 114 (76%) and 34 (20%) were in the age category of 21 – 35 years and ≥ 36 years respectively. There was no significant difference in the mean maternal baseline SBP, DBP and MAP (in mmHg) as well as in the heart rate changes (in beats/min) across the groups. (Table 1).

Across the groups, the mean parities of the subjects were comparable, $p = 0.480$ (Table 2).

SAB-delivery interval (in minutes) of 9.80 ± 2.82 for group KH, 10.56 ± 3.99 for group TH, and 8.68 ± 3.18 for group CT was observed, $p = 0.002$, as well as a significant difference across groups in the interval between foetal delivery and end of surgery with values of 42.92 ± 7.77 , 41.16 ± 8.14 and 37.16 ± 9.05 respectively, for the KH, TH and CT, $p = 0.001$. In the duration of surgery, the comparison of mean values recorded in the KH, TH and CT groups which correspondingly were 47.28 ± 8.09 , 45.92 ± 8.88 and 40.32 ± 9.77 respectively, showed significant difference, $p = 0.001$. The time to B2 sensory block according to modified Breen et al⁶⁰ score in minutes was 4.96 ± 0.83 for the KH group, 5.80 ± 0.75 for the TH group, and 4.96 ± 0.73 for the CT group, $p = 0.001$. Similarly, the surgical incision-delivery interval in minutes was 4.00 ± 0.80 for the KH group, 4.80 ± 1.12 for the TH group, 4.00 ± 0.80 and 4.08 ± 0.83 for the CT group, $p = 0.001$ (Table 3). Although it was greatest in the TH group (442.0 ± 101.7), followed by the KH group (426.0 ± 101.1) and least in the CT group (410.0 ± 90.4), the three groups were comparable in terms of the estimated blood loss in millilitres, $p = 0.266$. Mean maintenance fluid in litres used was 1.50 ± 0.40 , 1.26 ± 0.40 , and 1.49 ± 1.17 , for the KH, TH and CT groups, respectively, $p = 0.001$, with the least mean total volume of fluid administered intraoperatively (in litres) recorded in the TH group (2.54 ± 0.43), followed by the KH group (2.76 ± 0.43) and then the CT group (2.76 ± 0.46), $p = 0.016$ (Table 3).

There was a statistically significant difference in the mean systolic blood pressure across the three groups all through the study period except at the 20th and 25th minutes $p = 0.060$ and p

=0.127, respectively. The analysis showed that 36 (4.0%) of subjects had hypotension in the TH group compared to 82 (9.0%) and 192 (21.3%) in the KH and CT groups, respectively, $p = 0.001$ (Table 4).

Eight (16%) respondents in the TH group had a total of 25mg ephedrine while eighteen (36%) of the KH group had 70mg and twenty-two (44%) of the control group had a total ephedrine dose of 95mg (Table 5). This was statistically significant, with $p = 0.008$.

The mean umbilical cord venous blood pH though significantly different across the groups ($p < 0.001$), the Apgar scores in the first and fifth minutes were comparable, $p = 0.598$. Moderate birth asphyxia, though not significantly different, occurred more (16 neonates) in the CT and KH groups at the first minute, compared to 12 in the TH group, $p = 0.738$ (Table 6).

Figure I is a bar chart showing the incidence of hypotension in the study population. Forty (34.5%) parturients in the KH group had hypotension, while 32 (27.6%) and 44 (37.9%) developed hypotension in the TH and CT groups, respectively.

DISCUSSION

The application of thigh-high and knee-high SCS to parturients prior to instituting SAB for Caesarean section significantly reduced the incidence of arterial hypotension compared to its nonapplication as observed in this study; again, in comparison with the KH group, parturients in the TH group recorded significantly less hypotension. Furthermore, the interventional administration of ephedrine was significantly different across the groups, with the greatest total consumption noted in the control (CT) group, followed by the KH group, and the least observed in the TH group. Though there was significant difference in the umbilical cord venous and arterial blood pH values, the neonatal outcomes in the 3 groups were good and comparable.

Reduced incidence of maternal hypotension in association with the application of lower limb venous compression device has been reported. In their study of the effectiveness of medical lower limb compression with ordinary pressure of 20 to 30 mmHg via thigh-high sleeves on parturients, Peyronnet et al.¹³ observed a lower incidence (3.23%) of hypotension in the limb compression group 15 minutes following epidural analgesia, compared to 23.3% in the control

group. However, in this present study, while comparably recording significantly lower incidences of hypotension, 34.5% in the KH and 27.6% in the TH groups as opposed to 37.9% in the CT group, had higher incidence of hypotension compared to the findings of Peyronnet et al.¹³ The observed difference is understandable since less dense neuronal blockade with accompanying milder haemodynamic effects is associated with low-dose epidural block used by Peyronnet et al,¹³ compared to SAB in this study which is known to cause more profound sympathectomy and, consequently, greater haemodynamic derangement. The association between low-dose SAB and less dense motor block resulting in reduced incidence of maternal hypotension was documented by Santos et al.¹⁴

Hypotension following spinal anaesthesia results from sympathetic block, causing reduction in systemic vascular resistance leading to redistribution of central blood volume to the peripheral compartment, with a consequent decrease in preload, reduced left ventricular end-diastolic volume and eventually decreased cardiac output. SCS application to the lower limbs counters these negative circulatory effects of SAB by limiting the extent and duration of unopposed arteriolar and venous dilatation through pulsatile compressions, with the highest pressure at the ankles and the level of pressure decreasing upward the garment. Thus, SCD application over a greater lower limb surface area, theoretically, will achieve greater enhancement of venous return than one with equal compression pressure that is applied over a relatively smaller surface area. This relative difference in compressed lower limb surface area, between the knee-high and thigh-high SCDs, underpins the observed significantly lower incidence of hypotension in the TH group compared to the KH group in this current study.

A significantly higher incidence of hypotension requiring greater vasopressor therapy in the control (83%) compared with 16% in the group with legs wrapped in crepe bandage was noted by Bhagwanjee and co-workers.¹⁵ Crepe bandaging exerts on the limb a constant elastic pressure which is difficult to measure. In contrast, SCD is pulsatile, with a regular pulse interval of 20-60 seconds, as in this study, consequently, circumventing ischaemia of underlying tissues from unrelenting pressure. However, the intermittency of the SCD by allowing reflux of blood to the peripheral compartment during pauses, physiologically results in a less optimal venous return periodically. Thus, the combination of higher and constant non-pulsatile pressure from crepe bandaging will theoretically result in greater enhancement of venous return and reduction in the

incidence of hypotension, as observed by Bhagwanjee et al,¹⁵ with a lower reported incidence of hypotension in their leg crepe-banded group than that in the KH and TH groups in this study. This index study and that of Prajith et al¹⁶ showed greater vasopressor consumption in the control group, with significant hypotension in the first fifteen minutes following spinal anaesthesia. Although the current study did not evaluate the time to first administration of ephedrine, evidently, the use of lower limb venous SCS had significant favourable effects on maternal blood pressure during Caesarean section under SAB and, thereby, reduced the interventional need for vasopressors. In addition to utilizing higher compression pressure of 40 - 50 mmHg compared to 30 - 40 mmHg used in this current study, Prajith and colleagues¹⁶ administered their SAB in the lateral position. Available literature testifies that hypotension occurred less frequently when SAB was performed in the lateral position.¹⁷

The efficacy of combining crystalloid preloading at 20ml/kg for a period of 20 - 40 minutes and the use of venous compression device with higher pressure (54 mmHg) on the lower limb had been reported earlier by Agarwal et al,⁹ who noted decreased incidence of maternal hypotension comparable to this study, and an associated lower dose of ephedrine administration. This group of authors⁹ provides empirical evidence that lower limb venous compression using greater pressure, in combination with higher crystalloid prehydration has superior effectiveness in reducing the incidence of spinal-induced maternal hypotension, compared to the combination of a relatively smaller lower limb venous compression pressure and smaller crystalloid prehydration volume.

The incidence of post spinal hypotension in the TH group of the current study was 27.6% compared with 10% reported by Singh et al.¹⁸ The finding by the authors,¹⁸ thus testifies that a larger (20 ml/kg) crystalloid prehydration volume in combination with leg wrapping as well as with the use of phenylephrine as vasopressor achieves superior benefits in combating maternal hypotension under SAB. This study used 15ml/kg crystalloid preloading for all subjects. Prehydration achieves venous filling with some degree of hypervolaemia and is strategic in view of the veno-dilatation that will occur following pharmacological sympathectomy from subarachnoid block. Phenylephrine is a pure alpha-adrenergic receptor agonist with no beta-adrenergic receptor activity, hence exerts more specific vascular effect compared with ephedrine

that was utilized in the current study. The efficacy of phenylephrine in the treatment of postspinal hypotension is empirical finding.¹⁹

Contrary to the conclusions by many researchers as well as to the finding of this study, some studies have produced conflicting results. Adsumelli et al¹¹, in New York, noted no significant differences in the SBP, DBP and HR between the intervention and control groups, with a high (52%) incidence of hypotension in the parturients who wore SCD. Similarly, Tyagi et al¹² recorded 83% and 90% incidences in maternal hypotension in their SCD and control groups respectively.

The impact of spinal-delivery interval on the incidence of maternal hypotension, which usually manifests within six minutes following intrathecal injection is known, with its considerable influence on neonatal status.²⁰ The mean spinal-delivery interval was greater than eight minutes in this study, with the shortest and longest intervals observed in the CT and KH groups respectively. Inferentially, that the KH and TH groups, despite their longer spinal-delivery intervals, recorded less hypotension compared to the CT group signifies an anti-hypotensive effectiveness of the KH and TH applications of SCD.

Hassanin et al²¹ observed that lower umbilical cord arterial pH was associated with greater induction of spinal anaesthesia-delivery interval and prolonged duration of longest hypotension episode. This may explain the finding of lower umbilical cord arterial and venous blood pH values in the KH and TH groups which had longer induction-delivery interval compared to the control group. However, none of the neonates had Apgar scores < 7, reflecting no difference in the risk of low Apgar scores at 1 minute or at 5 minutes in the different groups. Apgar score of 7 occurred in 16 (32%) in the KH and CT groups compared to 12 (24%) in the TH group at the first minute, indicating a clinical correlation between the thigh-high SCS and more favourable neonatal outcome.

Although not studied in this present work, the use of compression stockings has been found to be safe in patients with compromised cardiac status. In one study²¹, it was demonstrated that there was no deterioration in cardiac function (transient or constant) during activation of the ISPC leg sleeves in patients with chronic congestive cardiac failure (systolic and diastolic). The main early haemodynamic changes observed included increased cardiac output, ejection fraction, and stroke volume, together with reduced SVR. However, toward the end of ISPC activation, cardiac

function returned to baseline. This technique should probably be applied with caution in patients with high right atrial pressures, severe tricuspid regurgitation, or severe right ventricular systolic dysfunction, because abruptly increasing venous return does not translate to improvement in left ventricular stroke volume and cardiac output, despite the decrease in systemic vascular resistance.

A limitation in this study was the lack of a beat-to-beat measurement of the blood pressure of the participants in this study. Therefore, the variations in blood pressure were not properly studied. Another limitation in this study was the lack of determination of the cord blood gases which could lead to a poor evaluation of the newborn delivered.

CONCLUSION

The use of knee high and thigh high sequential compression stockings significantly reduced the incidence of maternal hypotension with a corresponding decrease in vasopressor administration during Caesarean section under SAB, in comparison with the control group. Neonatal outcome was good across the groups, but comparatively better in the TH lower limb sequential compression group.

Conflict of Interest: None

REFERENCES

1. Madkour NM, Ibrahim SA, Ezz GF. General versus spinal anesthesia during elective Caesarean section in term low-risk pregnancy as regards maternal and neonatal outcomes: a prospective controlled clinical trial. *Res Opin Anesth Intensive Care* 2019; 6(1): 119-124
2. Choi DH, Ahn HJ, Kim MH. Bupivacaine-sparing effect of fentanyl in spinal anaesthesia for Caesarean delivery. *Reg Anaesth. Pain Med.* 2000; 25 (3): 240-245. Doi;10.1016/s1098-7339(00)90005-1

3. Sklebar I, Rujas T, Habek D. Spinal Anaesthesia-Induced Hypotension In Obstetrics: Prevention And Therapy. *Acta Clin Croat.* 2019;58(1):90-95
doi:10.20471/acc.2019.58.s1.13
4. Somboonviboon W, Kyokong O, Charuluxananan S, Narasethakamol A. Incidence and risk factors of hypotension and bradycardia after spinal anesthesia for Caesarean section. *J Med Assoc Thai.* 2008; 91(2): 181-187.
5. Ueyama H, He YL, Tanigami H, Mashimo T, Yoshiya I. Effects of crystalloid and colloid preload on blood volume in the parturient undergoing spinal anaesthesia for elective Caesarean section. *Anesthesiology* 1999; 91(6): 1571-1576.
doi:10.1097/00000542-199912000-00006
6. Bajwa SJS, Kulshrestha A, Jindal R. Co-loading or pre-loading for prevention of hypotension after spinal anaesthesia! A therapeutic dilemma. *Anesth Essays Res.* 2013; 7 (2): 155-159 doi:10.4103/0259-1162.118943
7. Stewart A, Fernando R, McDonald S, Hignett R, Jones T, Columb M. The dose dependent effects of Phenylephrine for Elective Caearean Delivery under Spinal Anesthesia. *Anesth Analg* 2010; 111(5):1230-1237.
doi:10.1213/ANE.0b013e3181f2eae1.
8. Singh K, Payal YS, Sharma JP, Nautiyal R. Evaluation of hemodynamic changes after leg wrapping in elective Caesarean section under spinal anesthesia. *J Obstet Anaesth Crit Care* 2014; 4(1): 23-28. doi:10.4103/2249-4472.132818
9. 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
10. Zadeh FJ, Alqozat M, Zadeh RA. Sequential compression pump effect on hypotension due to spinal anesthesia for Caesarean section: A double blind clinical trial. *Electron Physician* 2017; 9(5): 4419-4424 doi:10.19082/4419
11. Adsumelli RS, Steinberg ES, Schabel JE, Saunders TA, Poppers PJ. Sequential compression device with thigh-high sleeves support mean arterial pressure during Caesarean section under spinal anaesthesia. *Br J Anaesth.* 2003; 91(5): 695 – 698. doi: 10.1093/bja/aeg248.

12. Tyagi A, Sethi AK, Salhotra R, Tyagi A. Nonpneumatic antishock garment versus intermittent sequential compression device for prevention of post spinal hypotension in patients undergoing Caesarean section. A randomized controlled study. *Anesth Essays Res.* 2019; 13(2): 383-388. doi: 10.4103/aer.AER_83_19
13. Peyronnet V, Roses A, Girault A, Bonnet MP, Goffinet F, Tsatsaris V, Lecarpentier E. Lower limbs venous compression reduces the incidence of maternal hypotension following epidural analgesia during term labor. *Eur J Obstet Gynecol Reprod Biol.* 2017; 219: 94 – 99. doi: 10.1016/j.ejogrb.2017.10.016.
14. Santos A, Pedersen H, Finster M, Edström H. Hyperbaric bupivacaine for spinal anesthesia in Caesarean section. *Anesth Analg.* 1994; 63 (11): 1009-1013
15. Bhagwanjee S, Rocke DA, Koovarjee RV, Brijball R. Prevention of hypotension following spinal anaesthesia for elective Caesarean section by wrapping of the legs. *Br J Anaesth.* 1990; 65(6): 819-822. doi: 10.1093/bja/65.6.819.
16. Prajith KR, Mishra G, Ravishankar M, Hemanth Kumar VR. Haemodynamic changes under spinal anesthesia after elastic wrapping or pneumatic compression of lower limbs in elective Caesarean section: A randomized controlled trial. *J Anaesthesiol Clin Pharmacol* 2020; 36(2): 244-250. doi: 10.4103/joacp.JOACP_72_18
17. Obasuyi BI, Fyneface-Ogan S, Mato CN. A comparison of the haemodynamic effects of lateral and sitting positions during induction of spinal anaesthesia for Caesarean section. *Int J Obstet Anesth.* 2013; 22(2): 124-128. doi: 10.1016/j.ijoa.2012.12.005
18. Singh PM, Singh NP, Reschke M, Kee WDN, 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
19. Eskandr AM, Ahmed AM, Bahgat NME. Comparative study among Ephedrine, Norepinephrine, and Phenylephrine infusions to prevent spinal hypotension during Caesarean section. A randomized controlled double - blind study. *Eg J Anaesth.* 2021; 37(1) 295-301. doi: 10.1080/11101849.2021.1936841
20. Hassanin AS, El-Shahawy HF, Hussain SH, Bahaa Eldin AM, Elhawary MM, Elbakery M, Elsafty MSE. Impact of interval between induction of spinal anesthesia to delivery on

umbilical arterial cord pH of neonates delivered by elective Caesarean section. *BMC Pregnancy Childbirth* 2022; 22(1): 216. doi: 10.1186/s12884-022-04536-y.

21. Bickel A, Shturman A, Sergeiev M, Ivry S, Eitan A, Atar S. Hemodynamic effect and safety of intermittent sequential pneumatic compression leg sleeves in patients with congestive heart failure. *J Card Fail.* 2014 Oct; 20(10): 739-746. doi: 10.1016/j.cardfail.2014.07.004.

UNDER PEER REVIEW

Table 1: Maternal demographics, baseline HR (b/m), SBP, DBP and MAP in mmHg.

Characteristics	K H	T H	CT	p value
	N = 50	N = 50	N = 50	
	Mean ± SD	Mean ± SD	Mean ± SD	
Age (years)	29.76±5.03	30.16±6.05	29.58±5.09	0.861
Age group (n [%])				
≤ 20	2 (4.0)	0 (0.0)	0 (0.0)	0.124
21 – 35	40 (80.0)	34 (68.0)	40 (80.0)	
≥ 36	8 (16.0)	16 (32.0)	10 (20.0)	
Weight (kg)	81.98±1.02	81.90±1.11	82.08±0.96	0.684
Height (m)	1.65±0.04	1.64±0.05	1.66±0.03	0.061
BMI (kg/m²)	29.85±1.57	30.17±1.61	29.77±1.59	0.058
Baseline SBP	122.12±8.32	125.08±11.36	124.32 ± 13.41	0.394
Baseline DBP	71.20 ± 6.01	73.56 ± 6.05	74.08 ± 10.38	0.145
Baseline MAP	88.08 ± 5.79	90.20 ± 6.35	90.52 ± 9.78	0.215
Baseline HR	84.92 ± 11.68	85.88 ± 12.16	88.36 ± 13.03	0.356

***Statistically significant**

Table 2: Obstetric History of the Study Population

Characteristics	K H = 50 Mean ± SD	N T H N = 50 Mean ± SD	CT N = 50 Mean ± SD	p value
Mean Parity	1.32 ± 1.02	1.56 ± 0.95	1.44 ± 0.99	0.480
Group Parity (n[%])				
Para 0	14 (28.0)	6 (12.0)	12 (24.0)	0.106
Para 1	12 (24.0)	20 (40.0)	10 (20.0)	
Para 2	18 (36.0)	14 (28.0)	22 (44.0)	
Para 3	6 (12.0)	10 (20.0)	6 (12.0)	
Gestational age (weeks)	37.44 ± 1.46	36.84 ± 0.98	36.68 ± 2.25	0.055
Mean Number of previous Caesarean sections	0.76 ± 0.72	1.12 ± 0.72	0.96 ± 0.78	0.054
Grouped Number of previous CS (n[%])				
None	30 (60.0)	40 (80.0)	34 (68.0)	0.309
1	8 (16.0)	4 (8.0)	6 (12.0)	
2	12 (24.0)	6 (12.0)	10 (20.0)	

n= Frequency,

% Percentage

Table 3: Time variable characteristics, estimated blood loss, maintenance fluid and total volume of fluid used in the Study Population

Characteristics (minutes)	K H N = 50 Mean ± SD	T H N = 50 Mean ± SD	CT N = 50 Mean ± SD	p value
T1	9.80 ± 2.82	10.56 ± 3.99	8.68 ± 3.18	0.021*
T2	42.92 ± 7.77	41.16 ± 8.14	37.16 ± 9.05	0.002*
T3	47.28 ± 8.09	45.92 ± 8.88	40.32 ± 9.77	0.001*
T4	4.96 ± 0.83	5.80 ± 0.75	4.96 ± 0.73	0.001*
T5	4.00 ± 0.80	4.80 ± 1.12	4.08 ± 0.83	0.001*
Estimated blood loss (ml)	426.0 ± 101.1	442.0 ± 101.7	410.0 ± 90.4	0.266
Maintenance fluid used (L)	1.50 ± 0.40	1.26 ± 0.40	1.49 ± 1.17	0.001*
Total vol. of fluid used (L)	2.76.0 ± 0.43	2.54.0 ± 0.43	2.76 ± 0.46	0.016*

* **Statistically significant**

T1...SAB-Delivery interval

T2...Delivery-to-End-of-surgery interval

T3...Duration of surgery

T4...Time to B2 (Breen et al) Score

T5...Surgical incision – Delivery interval

Table 4: Comparison of the systolic hypotension among the study population

Time (minutes)	Hypotension Intervention group			p value
	K H	T H	CT	
	N = 50 (n[%])	N = 50 (n[%])	N = 50 (n[%])	
5	4 (8.0)	0 (0.0)	12 (24.0)	0.001*
10	4 (8.0)	8 (16.0)	14 (28.0)	0.029*
15	2 (4.0)	6 (12.0)	14 (28.0)	0.003*
20	12 (24.0)	4 (8.0)	12 (24.0)	0.060
25	12 (24.0)	6 (12.0)	14 (28.0)	0.127
30	12 (24.0)	2 (4.0)	16 (32.0)	0.002*
35	10 (20.0)	0 (0.0)	16 (32.0)	0.001*
40	8 (16.0)	0 (0.0)	12 (24.0)	0.002*
45	10 (20.0)	2 (4.0)	10 (20.0)	0.033*
50	6 (12.0)	0 (0.0)	10 (20.0)	0.005*
55	2 (4.0)	0 (0.0)	8 (16.0)	0.004*
60	0 (0.0)	4 (8.0)	10 (20.0)	0.003*
65	0 (0.0)	2 (4.0)	8 (16.0)	0.004*
70	0 (0.0)	2 (4.0)	8 (16.0)	0.004*
75	0 (0.0)	0 (0.0)	10 (20.0)	0.001*
80	0 (0.0)	0 (0.0)	8 (16.0)	0.001*
85	0 (0.0)	0 (0.0)	4 (8.0)	0.016*
90	0 (0.0)	0 (0.0)	6 (12.0)	0.002*
5 – 90 minutes	82 (9.1)	36 (4.0)	192 (21.3)	0.001*
5 – 90 mins (Mean±SD)	112.52 ± 10.99	118.11 ± 11.59	115.88 ± 13.67	0.001*

Table 5: Use of ephedrine in the study population

Characteristics	Intervention group			p value
	K H	T H	CT	
	N = 50	N = 50	N = 50	
	N (%)	N (%)	N (%)	
Total Ephedrine used (in mg)				
25 mg	0 (0.0)	8 (16.0)	0 (0.0)	
70 mg	18 (36.0)	0 (0.0)	0 (0.0)	0.008*
90 mg	0 (0.0)	0 (0.0)	22 (44.0)	

Statistically significant*

Table 6: Neonatal outcome by Apgar Score and umbilical venous blood pH of the study populations.

Characteristics	Intervention group		CT group	<i>p</i> value
	K H	T H	N = 50	
	N = 50 N (%)	N = 50 N (%)	N (%)	
APGAR score at 1st minute				
Good	34 (68.0)	38 (76.0)	34 (68.0)	0.598
Moderate asphyxia	16 (32.0)	12 (24.0)	16 (32.0)	0.738
APGAR score at 5th minute				
Good	50 (100.0)	50 (100.0)	50 (100.0)	1.000
Moderate asphyxia	0 (0.0)	0 (0.0)	0 (0.0)	Nil
Umbilical cord arterial blood pH (Mean ± SD)	7.27 ± 0.05	7.29 ± 0.07	7.30 ± 0.06	0.007*
Umbilical cord venous blood pH (Mean ± SD)	7.28 ± 0.04	7.31 ± 0.07	7.35 ± 0.05	<0.001

* Statistically significant

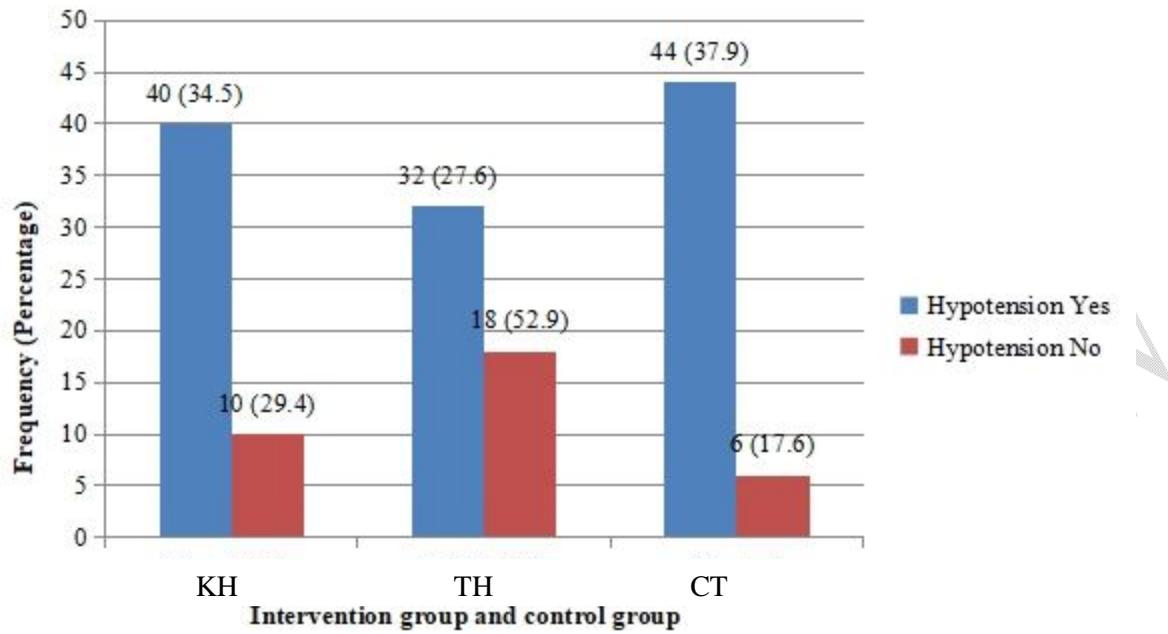


Figure I. Chart showing the incidence of hypotension in the study population.

UNDER PEER REVIEW