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ORIGINAL ARTICLE

The effect of 0.5 L 6 % hydroxyethyl starch 130/0.42 versus 1 L Ringer's lactate preload on the hemodynamic status of parturients undergoing spinal anesthesia for elective cesarean delivery using arterial pulse contour analysis

Paraskevi Matsota · Agathi Karakosta · Ageliki Pandazi · Dimitra Niokou · Kalliopi Christodoulaki · Georgia Kostopanagiotou

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Abstract
Purpose Fluid loading attenuates the hypotensive response to spinal anesthesia (SA). This study aimed to compare the preload efficacy of 0.5 L hydroxyethyl starch (HES) versus 1 L Ringer's lactate (R/L) in the prevention of hypotension after SA for elective cesarean delivery (CD). Assessment of maternal hemodynamic variables using FloTrac/Vigileo^{TM} and neonatal outcome constituted secondary outcomes.
Methods Thirty-two ASA I/II parturients scheduled for elective CD were preloaded with either 1 L R/L (Group R/L, $n = 16$) or 0.5 L HES 6 % 130/0.42 (Group T, $n = 16$) approximately 25 min before SA. Hypotension, defined as a 20 % decrease of systolic arterial pressure (SAP) from baseline or SAP <100 mmHg, was treated with vasopressors according to a predetermined algorithm. The overall duration of hypotensive episodes and the total amount of vasopressors administered determined the severity of the hemodynamic instability.
Results The incidence of hypotension was 73.3 % in Group R/L and 46.7 % in Group T. HES compared to R/L preload was associated with a shorter overall duration of hypotensive episodes ($p < 0.001$), a significantly less usage of ephedrine and phenylephrine ($p = 0.015$ and $p = 0.029$, respectively) and a greater impact, although not statistically significant, on cardiac index (CI) and stroke volume index (SVI). Although no statistical difference was detected between groups over time, there was a significant drop in CI, SVI and SAP within groups ($p < 0.001$) up to 14 min after SA. No difference was recorded in neonatal outcome.
Conclusions Preloading with 0.5 L HES 130/0.42 produced more stable hemodynamics compared to 1 L R/L solution in obstetric patients.

Keywords Obstetric anesthesia · Preloading · Hemodynamic effect

Introduction

Spinal anesthesia (SA)-induced hypotension during cesarean delivery (CD) is a major concern. Certain interventions may reduce the incidence and severity of hypotension, including the use of vasopressors and pre- or co-loading with crystalloids or colloids. However, conflicting evidence exists regarding the time of fluid administration and the solution of choice. Loading with either hydroxyethyl starch (HES) or crystalloid solutions has traditionally been employed in obstetrics. According to recent literature reviews [1, 2], crystalloid co-loading seems more effective than preloading in preventing SA-induced hypotension in obstetrics, while HES co-loading appears as effective as HES preloading. Moreover, HES preloading is more consistently effective in reducing the incidence and severity of hypotension compared to both crystalloid pre- or co-loading [1]. On the other hand, other studies failed to distinguish between pre- or co-loading, suggesting that the time of fluid loading has no impact on the incidence of hypotension, both for colloid or crystalloid solutions [3].

P. Matsota and A. Karakosta contributed equally in the study design and motivated the study.

P. Matsota (✉) · A. Karakosta · A. Pandazi · D. Niokou · K. Christodoulaki · G. Kostopanagiotou
2nd Department of Anesthesiology, School of Medicine, University of Athens, "Attikon" Hospital, Rimini 1 Str, Chaidari, 12462 Athens, Greece
e-mail: matsota@yahoo.gr

Heart rate and blood pressure are routinely used as surrogate markers of maternal cardiac output (CO) in obstetric anesthesia. However, CO is a better indicator of uteroplacental perfusion than arterial blood pressure [4]. Minimally invasive techniques based on arterial pulse waveform analysis provide continuous CO assessment. To our knowledge, there is currently only one published pilot study concerning the use of the Vigileo device for arterial pulse waveform analysis in obstetric patients [5].

In our study, we tested the hypothesis that preloading with 0.5 L of balanced HES (6 % 130/0.42) is more effective than 1 L R/L solution in the prevention of hypotension after SA for CD. The incidence and severity of spinal-induced hypotension in parturients undergoing elective CD constitute the primary outcome.

Materials and methods

Ethical approval for this study (protocol number 492/1-2-11) was provided by the Scientific Council of 'ATTIKON' University Hospital, Athens, Greece (Chairperson Prof. Christos D. Liapis) on February 1st 2011. The study is registered at ClinicalTrials.gov (ID NCT01835873).

Study design

Subjects—selection criteria

After obtaining individual written informed consent, thirty-two non-laboring ASA I and II parturients with a normal singleton pregnancy scheduled for CD under SA were enrolled in this prospective randomized clinical trial. Exclusion criteria included absolute contraindications to regional anesthesia, extremes of weight (<50 or >120 kg) or height (<150 or >180 cm), age <18 years or >40 years, baseline maternal heart rate (MHR) <60/min, active labor, multiple gestation or a gestation period <36 weeks, known fetal abnormalities, placental abruption, placenta previa/accreta, pregnancy-induced hypertension, anemia (hemoglobin <9 g/dl), cardiac, respiratory or renal disease, diabetes mellitus, spinal cord abnormalities, previous spinal surgery, or preexisting neurological dysfunction and known allergy to any protocol medication.

Randomization

Randomization was performed in the operating room using sealed envelopes sorted by computer-generated random allocation (Random Allocation Software). The randomization was single blinded; the anesthesiologist managing the intraoperative hemodynamics was aware of group assignment. All parturients were allocated to receive either 1 L crystalloid R/L solution preload (Group R/L) or 0.5 L colloid solution preload (HES 6 % 130/0.42—Tetraspan®; B. Braun, Melsungen, Germany) (Group T).

Parturient preparation and monitoring

Antepartum, intraoperative and postoperative management followed institutional standards. Intravenous access was established in the operating room by using two 18-gauge cannulas under local anesthesia and supplemental oxygen was administered via a face mask at flow rates between 5 and 8 L min. A 20-gauge radial arterial catheter was then placed under local anesthesia and connected to a Vigileo™ monitor via the FlowTrac™ pressure transducer (Edwards Lifesciences, Irvine, CA, USA). Standard noninvasive monitoring consisted of five-lead electrocardiography and pulse oximetry. Automatic oscillometric cuff blood pressure measurements were recorded at 3-min intervals until establishment of invasive blood pressure monitoring. Fetal heart rate (FHR) and uterine activity were monitored using the portable AN24 MHR/FHR/electrohysterography (EHG) recorder (AN24; Monica Healthcare Ltd. Nottingham, UK). Recording was allowed through five disposable electrodes positioned on the maternal abdomen in a standardized manner until cleansing and draping the patient. Ranitidine (50 mg) and metoclopramide (10 mg) were slowly administered intravenously approximately 25 min prior to the procedure.

Fluid administration

Intravenous crystalloid (1 L R/L) or colloid preload (0.5 L Tetraspan® 6 %) was rapidly infused approximately 25 min before SA. Fluid administration following preload was kept to a minimum until newborn delivery.

Regional anesthesia technique

A low-dose spinal via the needle-through-needle combined spinal−epidural (CSE) technique was employed. All patients received a mixture of ropivacaine 0.75 % and fentanyl (20 μg) with a total volume of ≤2 ml (Table 1). The CSE was performed in the sitting position at the L3/L4 or L4/L5 interspace, by the loss of resistance technique, using a Portex 18-gauge Tuohy needle and a 27-gauge pencil-point spinal needle. A mixture of local anesthetic (LA) plus opioid was administered slowly over a period of 20 s and the women were then positioned supine with at least 15° of left lateral tilt. Block height was assessed by cold sensitivity and confirmed by loss of pinprick discrimination. A sensory block to T4/T5 dermatome level was considered adequate for surgery. Failed SA or inadequate sensory block for surgery requiring a rescue epidural dose or conversion to general anesthesia would result in exclusion from the trial.

Table 1 Demographic characteristics, anesthetic and surgical data

	Group R/L ($n = 15$)	Group T ($n = 15$)	p
Demographic data			
Age (years)	31.66 (3.31)	30.8 (4.72)	0.56
BMI (kg/m^2)	30.99 (6.31)	31.12 (5.18)	0.95
BSA (m^2)	1.914 (0.14)	1.904 (0.13)	0.84
ASA I/II	12/3	10/5	0.68
Anesthetic data			
Preload time (min)	27 (23–34)	25 (22–34)	0.73
Intervertebral space (2nd/3rd)	1/14	4/14	0.33
Depth of epidural space (cm)	5.53 (1.14)	4.93 (1.26)	0.18
Depth of epidural catheter (cm)	10.66 (0.79)	10.3 (0.99)	0.27
Ropivacaine 0.75 % (mg)	10.25 (0.88)	10.8 (0.68)	0.06
Total volume of LA mixture (ml)	1.76 (0.11)	1.84 (0.09)	0.07
Level of sympathetic block (T4/T5)	12/3	14/1	0.59
Surgical endpoints timing from skin incision (min)			
Uterine incision (min)	5 (4–8)	5 (3–7)	0.34
Newborn delivery (min)	6 (5–9)	6 (4–9)	0.57
Placenta removal (min)	9.56 (3.64)	9.13 (2.42)	0.7

Results are presented as mean ± standard deviation or as median and interquartile range and as absolute frequencies, accordingly

ASA American Society of Anesthesiologists, *BSA* body surface area, *BMI* body mass index, *LA* local anesthetic

Vasopressor administration

The triggers for vasopressor administration were a 20 % decrease of systolic arterial pressure (SAP) from baseline or SAP <100 mmHg after induction of SA. Vasopressors were administered according to a predetermined algorithm; a bolus dose of 5 mg ephedrine was administered initially and repeated almost immediately in case of no or minimum hemodynamic response. Phenylephrine 0.1 mg bolus was administered in case of resistant hypotension after the second bolus dose of ephedrine and provided that MHR was >90 bpm. The choice of vasopressor thereafter was based on MHR and bolus doses of ephedrine (5 mg) and/or phenylephrine (0.1 mg) were administered until recovery of SAP within 20 % of baseline values. Bradycardia defined as MHR <60 bpm, was treated with bolus administration of 0.5 mg of atropine.

Data recording

Maternal hemodynamic measurements included SAP, diastolic arterial pressure (DAP), mean arterial pressure (MAP), cardiac index (CI) and stroke volume index (SVI). All hemodynamic data were recorded at predefined time points—before volume preload (baseline measurements [T0], immediately after volume preload [T1], immediately after SA [T2] and at 1-min intervals thereafter until delivery, followed by 10-min intervals until the end of the surgical procedure, i.e., last stitch). Skin incision, uterine incision, newborn delivery and placental delivery were considered specific time points of interest. Baseline hemodynamic data for each patient were obtained by averaging three consecutive measurements after calibration of CO and after a minimum 5-min period during which the women were lying supine with a 15° left lateral tilt.

Neonatal outcome was assessed by Apgar scores and umbilical arterial and venous blood gas values. Apgar scores were assessed by a pediatrician blinded to group assignment at 1 and 5 min, and blood was taken from a double-clamped segment of the umbilical cord for immediate blood gas analysis. Maternal satisfaction was also recorded before leaving the operating room using a 4-step ordinal scale (0, none; 1, little; 2, moderate; 3, much).

Outcome measurements

The incidence and the severity of spinal-induced hypotension constituted the primary outcome. Severity was assessed by both the total duration of the hypotensive episodes and the total amount of vasopressors administered. Secondary outcomes included maternal hemodynamic status monitored by FloTrac/Vigileo^{TM}, umbilical vessels blood gas values, neonatal Apgar scores, intraoperative side-effects (discomfort, nausea, vomiting, pruritus) and maternal satisfaction.

Statistical analysis

Sample size calculation was based on previously published data on the incidence of SA-induced maternal hypotension. A difference of 15 mmHg in SBP between groups was considered clinically significant [6]. With an standard deviation (SD) of 12.9 mmHg [6], we needed to include 15 patients in each group to show a mean difference in SBP of 15 mmHg with 85 % power and a significance level of 5 % (Russ Lenth's Power and Sample Size—www.stat.uiowa.edu/~rlenth/Power). To allow for potential dropouts, 16 women were included in each group. The Shapiro–Wilk test was performed to test for normal distribution of continuous variables. The results are given as mean ± SD, mean and 95 % confidence intervals or as median and interquartile range according to normality of continuous variables. All qualitative variables are presented as absolute or relative frequencies. Student's t test or its non-parametric equivalent Mann–Whitney U test was used to

Fig. 1 Patient flowchart

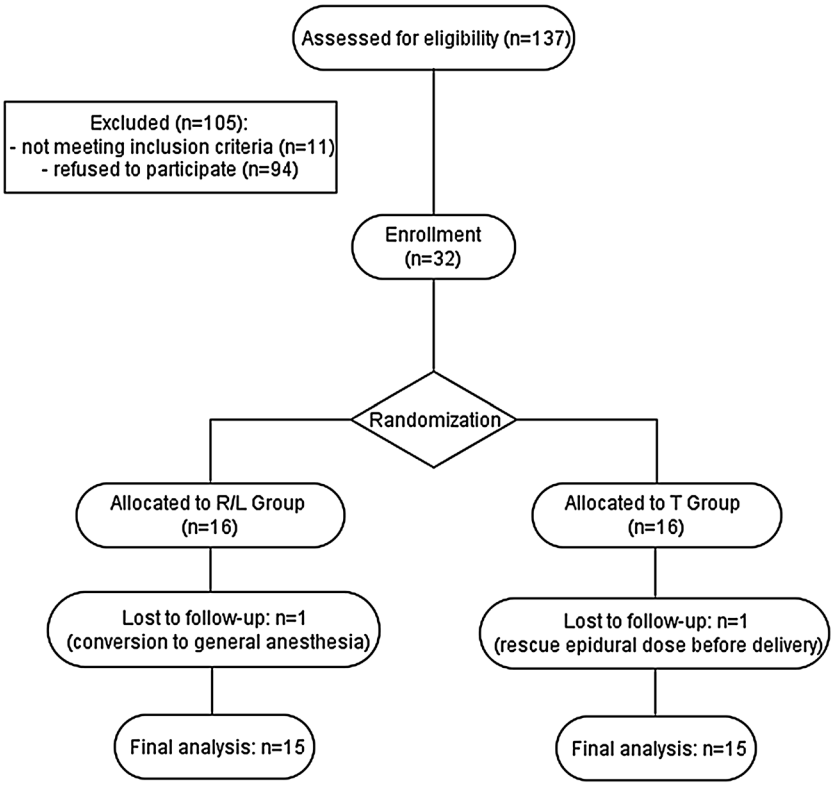

Table 2 Maternal hemodynamic variables at baseline (T0) and mean differences after preloading (T0 vs T1)

Hemodynamic variables	Group R/L ($n = 15$)	Group T ($n = 15$)	p
Baseline measurements (T0)			
SAP (mmHg)	126.5 (116.4 136.5)	135.1 (126.9 143.3)	0.16
DAP (mmHg)	69.5 (62.9 76.2)	71.9 (66.3 77.6)	0.56
MAP (mmHg)	88.5 (81.2 95.8)	93 (87.6 98.4)	0.29
CI (L/min/m^2)	4.1 (3.5 4.6)	3.95 (3.5 4.4)	0.67
SVI (ml/beat/m^2)	47.4 (41.8 52.9)	43.8 (38.5 49.1)	0.32
MHR (bpm)	83 (77.5 88.4)	85 (10.47) (79.3 90.8)	0.58
Mean differences (values at T1 minus values at T0 time points)			
SAP (mmHg)	12.8 (10.2 15.4)	10.5 (6.8 14.2)	0.62
DAP (mmHg)	9.6 (6.9 12.2)	3.5 (1.4 5.5)	0.08
MAP (mmHg)	10.7 (8.3 13.1)	5.9 (3.5 8.3)	0.17
CI (L/min/m^2)	0.65 (0.4 0.8)	0.94 (0.7 1.1)	0.26
SVI (ml/beat/m^2)	7.8 (5.6 10.1)	12.6 (10 15.2)	0.17
MHR (bpm)	3.7 (2.2 5.1)	3.9 (0.3 7.5)	0.47

Results are presented as mean and 95 % confidence interval

SAP systolic arterial pressure, *DAP* diastolic arterial pressure, *MAP* mean arterial pressure, *CI* cardiac index, *SVI* stroke volume index, *MHR* maternal heart rate

compare continuous variables between the two groups. Fisher's exact test was employed for comparison of categorical variables. A linear mixed random effects piecewise model (random intercept/random slope) was performed in order to assess changes in hemodynamic variables in the study groups over time. Specifically, the longitudinal analysis included values from induction of SA to placental delivery. All tests were two-tailed and statistical significance was established at 5 % ($p < 0.05$). Data were analysed using Stata^{TM} (Version 10.1 MP, Stata Corporation, College Station, TX 77845, USA).

Results

Thirty of the 32 women who initially enrolled in the study completed the study protocol and were included in the subsequent analysis. The patient flow diagram is illustrated in Fig. 1. The study population was homogenous regarding demographic, anesthetic, surgical characteristics (Table 1) and baseline hemodynamic variables (Table 2).

Preloading (T0 vs T1) increased CI from 3.95 (0.78) to 4.9 (0.56) L/min/m^2 and SVI from 43.8 (9.57) to 56.4 (7.95) ml/beat/m^2 in Group T. The corresponding increases in CI and SVI in Group R/L were 4.1 (0.93) to 4.7 (0.95) L/

min/m^2 and 47.4 (9.99) to 55.2 (10.85) ml/beat/m^2, respectively. However, no statistical difference in hemodynamic variables at T0 versus T1 was detected between groups (Table 2).

The incidence of hypotension in each group is shown in Table 3. Time elapsing between SA and the first hypotensive episode ranged from 2−16.5 min and from 2.5−12.5 min in Groups R/L and T, respectively. Nevertheless, none of the above demonstrated any statistical significance ($p > 0.05$) (Table 3). However, overall duration of hypotensive episodes was significantly prolonged in Group R/L compared to Group T ($p < 0.001$) (Table 3). Statistically significant differences were recorded regarding the total amount of vasopressor administered, with women allocated in Group R/L being administered a greater amount of both ephedrine and phenylephrine compared to women in Group T ($p = 0.015$ and $p = 0.029$, respectively) (Table 3). None of the parturients received atropine intraoperatively.

Table 3 Assessment of spinal-induced hypotensive episodes and use of vasopressors

Hypotension	Group R/L ($n = 15$)	Group T ($n = 15$)	*P*
Hypotension[a]	11/15 (73.3 %)	7/15 (46.7 %)	0.26
Duration of hypotensive episodes (min)[b]	1 (0–5.5)	0 (0–0.5)	0.0097
Total amount of ephedrine (mg)	10 (0–30)	0 (0–5)	0.015
Total amount of phenylephrine (mg)	0.1 (0–0.2)	0 (0–0)	0.029

Results are given as absolute/relative frequencies and as median and interquartile range

[a] Hypotension: 20 % decrease of systolic arterial pressure (SAP) from baseline or SAP <100 mmHg

[b] Duration of hypotensive episodes: sum of total duration of hypotensive episodes (min) recorded after induction of spinal anesthesia until newborn delivery

In the mixed random effects piecewise model, both linear and quadratic time effects revealed statistical significant differences ($p < 0.001$) within groups concerning MAP, SAP, DAP, SVI and CI up to 14 min after SA. However, no statistical difference between groups was detected concerning all hemodynamic variables over time. Figures 2, 3 and 4 demonstrate mean changes of SAP, CI and SVI over time. Measurements are demonstrated until 45 min after induction of SA.

Neonatal outcome did not differ between groups. There were no significant differences in Apgar scores, umbilical artery or vein pH, base excess and lactate concentration (Table 4). No neonate had fetal acidosis (defined by pH <7.2) apart from one woman in Group R/L who exhibited umbilical vein pH of 7.15.

No difference was detected concerning various intraoperative complications and side-effects between the two groups ($p > 0.05$). Specifically, one woman in Group R/L complained of pruritus post delivery. Nausea was recorded in two women in Group R/L who at that point experienced severe hypotension (SAP <80 mmHg). Vomiting occurred in two women, one in Group R/L and one in Group T, both post delivery and related to ergometrine administration. Moreover, women in both groups demonstrated the same degree of overall satisfaction ($p > 0.05$).

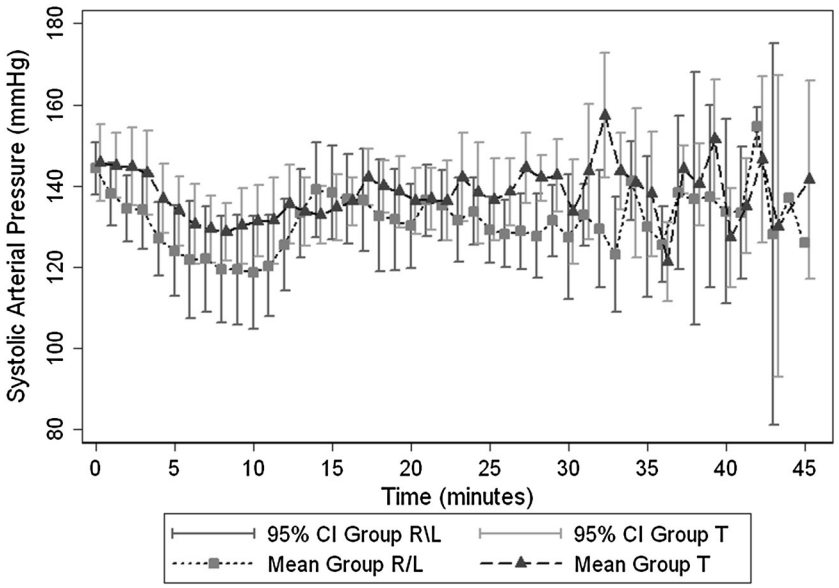

Fig. 2 Mean changes and 95 % confidence interval (CI) of systolic arterial pressure (SAP) over time in both groups (0 = T2, induction of spinal anesthesia)

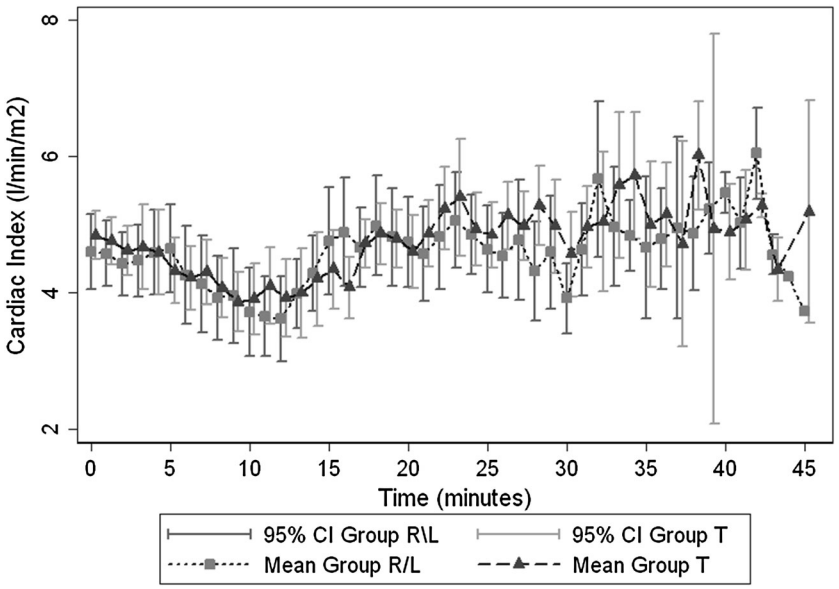

Fig. 3 Mean changes and 95 % confidence interval (CI) of cardiac index (CI) over time in both groups (0 = T2, induction of spinal anesthesia)

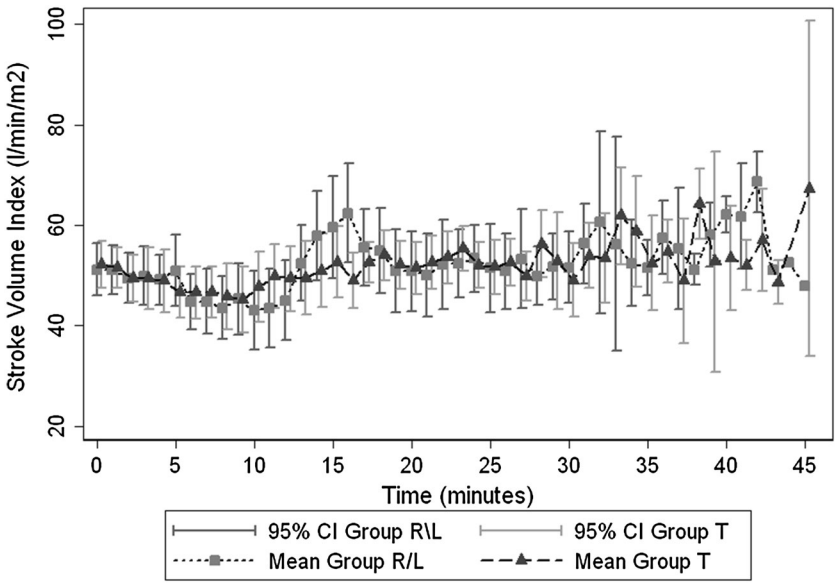

Fig. 4 Mean changes and 95 % confidence interval (CI) of stroke volume index (SVI) over time in both groups (0 = T2, induction of spinal anesthesia)

Discussion

This randomized clinical trial documents the hemodynamic response to SA for CD in healthy parturients preloaded with either 1 L crystalloid or 0.5 L colloid solutions. The incidence of maternal hypotension was high in both the crystalloid (73.3 %) and colloid (46.7 %) groups, and was similar to previous reports [7–9]. However, in our study, obstetric patients undergoing CD under SA preloaded with 0.5 L of balanced potato-derived 6 % HES 130/0.42 (Tetraspan®) exhibited better hemodynamic stability compared to patients preloaded with 1 L lactated R/L. Hemodynamic assessment was conducted via the FloTrac/Vigileo™ system, which has been considered a reliable method for monitoring hemodynamic changes after SA in obstetric patients [5].

In our study, despite the fact that Group R/L was administered twice the volume of fluid loading compared to Group T, the latter group exhibited better hemodynamic stability. In addition, HES preload produced a greater impact, athough not statistically significant, on CI and SVI than R/L preload (Table 2), indicating that the effect of preloading on maternal hemodynamics using 0.5 L HES may be greater than 1 L of crystalloid solution. This may be attributed to the intrinsic property of colloids having a greater intravascular persistence than crystalloids. Colloids

Table 4 Neonatal outcomes

	Group R/L ($n = 15$)	Group T ($n = 15$)	p
Apgar score and umbilical blood gas analysis			
Apgar score (1′)	9 (9–9)	9 (8–9)	0.29
Apgar score (5′)	10 (10–10)	10 (10–10)	0.32
Umbilical venous blood gas analysis			
pH	7.33 (0.06)	7.34 (0.03)	0.52
Base excess	1.74 (1.56)	1.15 (1.1)	0.23
Lactate (mmol/L)	1.43 (0.56)	1.34 (0.45)	0.64
Umbilical arterial blood gas analysis			
pH	7.31 (0.05)	7.32 (0.03)	0.44
Base excess	1.78 (1.37)	1.3 (1.08)	0.29
Lactate (mmol/L)	1.68 (1.09)	1.51 (0.47)	0.57

Results are given as mean ± standard deviation or as median and interquartile range

are known to induce a greater plasma volume expansion compared to crystalloids for the same administered volume [10, 11]. The 2:1 volume ratio of crystalloid versus colloid fluid loading used in our study is consistent with previously published data. Specifically, the reported fluid loadings administered for the prevention of SA-induced maternal hypotension are in the range of 1,000–1,500 ml for crystalloid or 500–1,000 ml for colloid solutions [3].

Maternal CO is a better indicator of uteroplacental perfusion than arterial blood pressure [4], and better correlated with umbilical arterial pH [12]. Therefore, the effect of fluid loading on CO is of particular interest as fluid loading seems to be beneficial in maintaining hemodynamic control. According to previously published data, colloid preloading, in contrast to crystalloid, consistently reduces the incidence and severity of SA-induced hypotension in an obstetric population [1, 2, 13].

A significant drop in hemodynamic measurements within the groups was recorded after SA and up to 14 min, but no statistically significant differences were detected between groups. The latter was attributed to continuous monitoring of arterial pressure and prompt administration of rescue hemodynamic treatment. However, women in the crystalloid group exhibited prolonged overall duration of hypotensive episodes and required administration of a significantly greater amount of vasopressors, despite the fact that no differences were detected regarding the level of sympathetic block and the total volume of LA administered.

In our study, no differences were observed between the two groups regarding neonate outcome, parturient adverse effects, including allergic reactions, nausea, vomiting, discomfort, epidural puncture and overall satisfaction.

A case of fetal acidosis was observed in Group R/L associated with prolonged maternal hypotension and excessive use of vasopressors (total dose of 35 mg ephedrine and 0.2 mg phenylephrine). In this case, the first hypotensive episode and subsequent vasopressor administration occurred during AN24 device application. No bradycardia or FHR abnormalities were documented during that time. The Apgar scores were 9 and 10 at 1 and 5 min, respectively. Severe and/or prolonged episodes of SA-induced hypotension have been associated with fetal acidosis [14]. According to Ngan Kee and Lee [15], ephedrine is more often associated with neonatal acidosis, especially at high doses [16, 17], as opposed to phenylephrine [18]. Although a high dose of phenylephrine is not associated with neonatal acidosis in healthy parturients, it causes reflex bradycardia and decreases cardiac output, which could compromise uteroplacental perfusion [13, 19, 20]. Ephedrine and phenylephrine have both been administered in equipotent doses in obstetric population according to previously documented data [21]. However, the optimal ratio of ephedrine/phenylephrine co-administration has not been determined. In our study, we followed an ephedrine/phenylephrine regimen for treating maternal hypotension. The β-mimetic effect of ephedrine, counteracting the phenylephrine-related maternal bradycardia has proven a beneficial combination in the prevention of maternal bradycardia [22]. In our study, the above combination was associated with normal umbilical blood gases and high Apgar scores in both groups.

Few studies monitor CO after SA in obstetric population. Most of them involve noninvasive ultrasonic techniques and intermittent measurement of CO [23–25]. Only a limited number of studies employ invasive techniques for continuous monitoring of maternal hemodynamics. Dyer et al. [26] used LiDCOplus for CO monitoring in 18 patients with severe preeclampsia. Langesaeter et al. [6] investigated the use of low-dose versus high-dose SA, with or without phenylephrine infusion, on maternal hemodynamics using the LiDCOplus devise. Auler et al. [5] used FloTrac/Vigileo^{TM} for maternal CO monitoring in a pilot study of ten women preloaded with crystalloid solution. Auler et al. observed a decrease of stroke volume (SV) and SVI up to 10 min after SA, whereas in our study SVI decrease occurred up to 14 min after SA.

SA-induced maternal hemodynamic instability is mainly attributed to sympathetic blockade-induced venodilation as well as to decreased systemic vascular resistance. Minimally invasive techniques designed to measure CO and SV-related parameters are known to be affected by these hemodynamic changes. Furthermore, the use of vasopressors and uterotonic agents act as confounders when it comes to CO measurements. Thus, the accuracy of pulse contour analysis techniques is still a matter of discussion,

and although studies have been performed to evaluate their clinical application [5], further validation in pregnancy is necessary. However, these devices have the advantage of providing beat-to-beat CO measurements, making them an excellent tool for measuring trends. Their use is strongly suggested in the setting of hemodynamic compromised parturients [26]. However, in our study, parturients displaying cardiovascular disorders or other systemic diseases were excluded due to the study design, constituting a potential limitation.

In conclusion, preloading with 0.5 L HES 6 % 130/0.42 (Tetraspan®) contributed to better hemodynamic stability compared to double the volume of R/L preload in parturients under SA for elective CD.

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Conflict of interest None declared.

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