

A comparison of HES 6% 130/0.42 versus HES 6% 130/0.4 before spinal anaesthesia in Caesarean section patients: the effects on haemodynamics, haemoglobin, liver tests and thromboelastometry

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Abstract

Background. Prehydration before C-section is a controversial issue. As it was demonstrated in several studies starches may be better than crystalloids in increasing circulating volume and cardiac output. In the present study we wanted to evaluate the efficacy of two tetrastarch solutions on the incidence and severity of hypotension following a combined spinal-epidural anaesthesia (CSE) for elective C-section. **Method.** Of the 60 patients enrolled, 29 and 28 patients terminated the study in the HES 130/0.42/6:1 (Venofundin® or Venohes®, Ve group) and HES 130/0.4/9:1 (Voluven®, Vo group) respectively. Both groups received 500 mL of the solution and 1000 mL of Ringer's Lactate before the spinal injection as part of a CSE technique. We compared the haemodynamic parameters between the two solutions and their effect upon thromboelastometry, haemoglobin level and liver/kidney function tests. **Results.** There were no differences with respect to haemodynamic parameters such as lowest blood pressure values or vasopressor use. The only difference found, regardless of the group allocation, was a significantly higher 'lowest systolic blood pressure' in parturients receiving the spinal injection in the sitting position or those undergoing their delivery during the morning hours. Thromboelastometry and LDH concentration was affected more significantly following Voluven® use but there were no significant differences between both solutions. Haemoglobin level decreased more significantly in the Vo group while not in the Ve group. The difference between both colloids was significant as well. Alkaline phosphatase, γ GT and bilirubin decreased to the same extent with both colloids. **Conclusion.** There were no differences with respect to haemodynamics between the two colloids but that Voluven® had more effect on the thromboelastometry pattern and LDH while for the decrease of the haemoglobin concentration the difference was significant as compared to Venofundin®/Venohes®. Although significant changes were measured, the values remained within the normal reference range while it is unclear whether the extent of alterations was above and beyond the effect of haemodilution.

Key words: Anaesthesia: spinal, Caesarean section, colloids, starch, thromboelastography, thromboelastometry

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Introduction

Fluid prehydration before spinal anaesthesia in Caesarean section patients is rather controversial. Using crystalloids up to 10 mL/kg has been proven to be ineffective [1-3]. Increasing the volume or speed of administration did not improve haemodynamics.

Colloids on the other hand may be more effective as demonstrated by several trials [4, 5]. Especially starches, better than gelatines, may significantly decrease the incidence and severity of hypotension while reducing the need for vasopressor substances. Unfortunately the occurrence of hypotension cannot be avoided at all times which has been a sufficient reason for some authors to ignore the benefits of colloids.

In our department we use starch together with crystalloids for prehydration in elective Caesarean section. Especially the 6% starch solutions result in an increase of circulation volume larger than the infused volume but lasting only 30 minutes as opposed to the

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10% solution in which the intravascular fluid attraction lasts several hours, beyond the fading of local anaesthetic effect. Whereas 15 years ago starches with large molecular weights were used, actually starches with lower molecular weight may be safer and also decrease the antigenic properties of such substances.

There is a paucity of studies focusing on potential differences between the different starches. Differences with respect to haemodynamic parameters were hardly studied. Also the effects on platelet function and coagulation in general are not clearly elucidated. Prehydration with colloids may reduce the haematocrit by 20% [5] and probably also other substances required for optimal coagulation may be diluted regardless of direct effects of starch on platelet function.

In the present study we wanted to compare two Tetrastarch 130/0.4 solutions with respect to their effects on incidence and severity of hypotension, need for vasopressor substances, neonatal outcome and effects on coagulation for which thromboelastometry was used.

Methods

Following institutional ethics committee approval and informed patient consent, we included 60 ASA I pregnant woman undergoing elective caesarean section. Patients with pregnancy duration of less than 37 weeks, a history of diabetes, hypertension or pre-eclampsia or multiple pregnancy were excluded.

Before starting the combined spinal-epidural anaesthesia (CSEA) technique, a sample of 10 ml of blood was withdrawn to check haemoglobin (Hb) level, baseline thromboelastometry (TEM), liver and renal function tests. Non invasive blood pressure was then measured 3 times and the lowest value taken as the baseline-reference. CSEA was performed with the patient either sitting or lying on the right side depending on the preference and discretion of the attending anaesthesiologist. For the spinal component 6.6 mg hyperbaric bupivacaine and 3.3 μ g sufentanil was injected intrathecally after infusing 1 L Plasmalyte and either 500 mL Venofundin/Venohes® 130/0.42/6:1 (B.Braun) or 500 mL Voluven® 130/0.4/9:1 (Fresenius Kabi). Although Venohes® is the trade name which is used in Belgium (alone), only the trade name Venofundin® will be used in the subsequent paragraphs. Both substances were administered in non-plasma adapted i.e. saline formulations.

Oxygen was given with face mask (3 L/min). Randomization was performed using computer listing. A third anaesthetist not involved in the study protocol administered the colloid which was covered with a bag for blinding purposes.

Vasopressor medication was administered if the patient became hypotensive, which was defined as a systolic blood pressure below 20% of the baseline value. Ephedrine (5 mg) was routinely administered to all patients before they were turned on their back and placed in a 10° left lateral tilt position. If the patient became nauseous, or developed hypotension with a heart rate less than 100 beats/min, ephedrine (5 mg) was injected. In case hypotension with tachycardia over 100 beats/min, phenylephrine (100 μ g) was given.

In case of insufficient analgesia epidural supplemental doses of ropivacaine 0.75% were administered starting with 2 mL per unanaesthetised dermatome or with at least 5 mL when occurred intraoperatively.

At the end of the operation haemoglobin level and thromboelastometry (see below) were checked. Two days later liver and renal function test were controlled as well.

Non invasive systemic arterial blood pressure was monitored every 2 minutes until delivery and the timing of the following events noted: intrathecal injection, incision, delivery and end of surgery.

The umbilical arterial pH (UApH) and oxygen content of umbilical arterial and venous blood samples were checked just following birth of the baby as was the Apgar score.

The roTEM (ro-tation Thrombo-Elasto-Metry) Coagulation Analyzer (Dynabyte medical) was used to measure the InTEM. This test uses partial thromboplastin derived from rabbit brain extract (ellagic acid) as activator. The InTEM was checked before and after colloid administration. This way of testing differs from the classical thromboelastography (TEG) during which the recipient rotates around the central axis whereas the opposite occurs with the roTEM analyzer. Normal ranges for this test are: clotting time (CT which corresponds with the r-value in TEG), 110-173 sec; clot formation time (CFT, corresponding with the k-value in TEG) i.e. the time required to reach an amplitude of 20 mm, between 34-108 sec; clot firmness after 10 minutes (A10), 53-73 mm; maximal clot firmness (MCF) or maximal amplitude (MA), 50-72 mm and finally the α -Angle, 66-86°. The different aspects of classical thromboelastography and thromboelastometry are highlighted in Figure 1.

Haemoglobin levels were measured using the Rapidpoint 405 analyser (Bayer Health Care).

Blood samples were collected in 3 mL tubes containing sodium citrate 3.2 % for the InTEM-test (Vacurette, Greiner Bio-One) and a 1 mL tube containing heparin for the determination of the Hb concentration (RapidLyte, Siemens). Analyses were performed within 15 minutes after collecting the blood sample.

For statistical analysis (SAS 9.2) the unpaired student-t test was used for continuous variable data

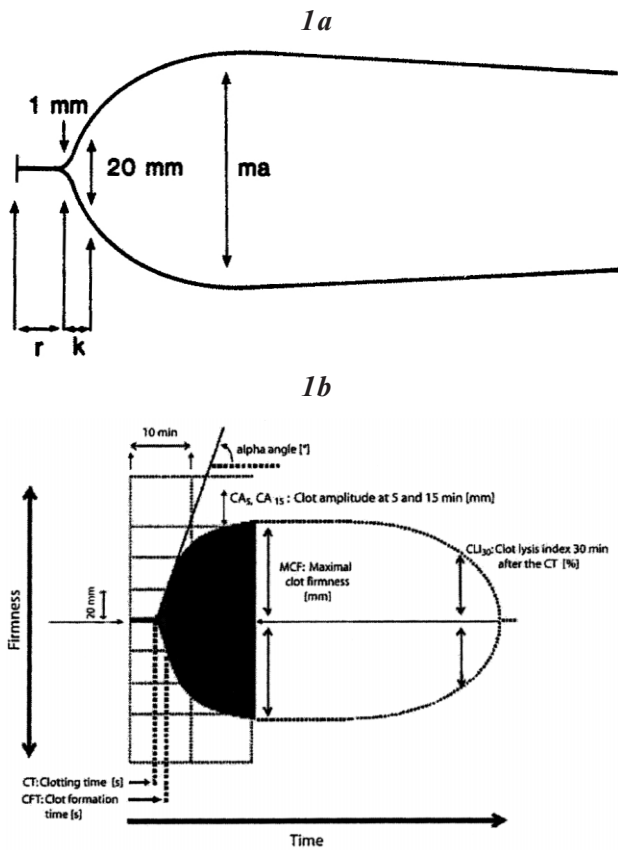


Fig. 1a and 1b. Normal thromboelastography (TEG) and rotation thromboelastometry (roTEM). r-value (in roTEM called Clotting Time: CT) is the interval between the start of the test and an amplitude of 1-2 mm (sec) and k-value is the time between the onset of coagulation and a 20 mm amplitude (in roTEM called Clot Formation Time: CFT). MA is the maximal amplitude (in roTEM called Maximal Clot Firmness: MCF)

and the chi-squared test for the categorical variable data. The ANOVA test for repeated measurements was used for comparisons between values obtained before and after administration of the colloids. The number of vasopressor doses was evaluated with the non-parametric Mann Whitney U test. A p value lower than 0.05 was considered to be significant.

Results

Of the 60 patients selected, three were excluded from further study participation i.e. one in the Ve group and two in the Vo group. Reasons for this exclusion were either protocol violation, malfunctioning or unavailability of the roTEM apparatus.

There were no differences with respect to patient demographics in terms of age, weight, height, duration of pregnancy and parity (Table 1). The interval between the spinal injection and incision or wound closure were comparable between both groups. The interval between surgical incision and delivery however was borderline significant with shorter time in the Vo group ($p = 0.03$). Approximately half of the patients in both groups (48% and 53% for the Ve and Vo groups respectively) received their spinal injection in the sitting position.

All anaesthetic procedures were uneventful from a technical point but six patients, three in each group i.e. 10%, required epidural supplementation after delivery of the baby or near the end of the operation.

Systolic blood pressure values decreased significantly but there were no significant differences between the two colloid groups ($p = 0.78$) neither were there any differences in the number ($p = 0.78$) and doses ($p = 0.43$) of vasopressor boluses and doses given (Table 2). Approximately 60% of the patients in both groups did not require more vasopressor support than the prophylactic ephedrine bolus of 5 mg. Less than 15% required more than two additional doses (Fig. 2).

Table 2. Haemodynamic data

	Ve group	Vo group	P value
Lowest SBP (mmHg)	110.5 ± 20	109.1 ± 16	0.78
Ephedrine use (mg)	8.0 ± 4.6	9.2 ± 6.4	0.43
Ephedrine bolus: n° (range)	1.6 (1-4)	1.7 (1-5)	0.78
Incidence of hypotension (%)	24.1	35.7	0.1
UApH	7.3 ± 0.48	7.3 ± 0.26	0.89

Table 1. Demographics. Data are expressed as mean ± SD or %. There were no significant differences

	Ve group n = 29	Vo group n = 28	P value
Age (yr)	33.1 ± 5.05	31.0 ± 3.81	0.096
Height (cm)	165.69 ± 6.75	162.12 ± 7.14	0.072
Weight (kgs)	77.75 ± 13.48	76.38 ± 16.09	0.741
Clot maximal amplitude before colloid infusion (mm)	67.5 ± 4.4	68.5 ± 4.0	0.38
Time CSE-incision (min)	19.07 ± 5.48	18.92 ± 4.42	0.913
Time CSE-end surgery (min)	58.48 ± 11.57	53.13 ± 10.40	0.094
Lateral/Sitting (%)	52/48	47/53	0.339

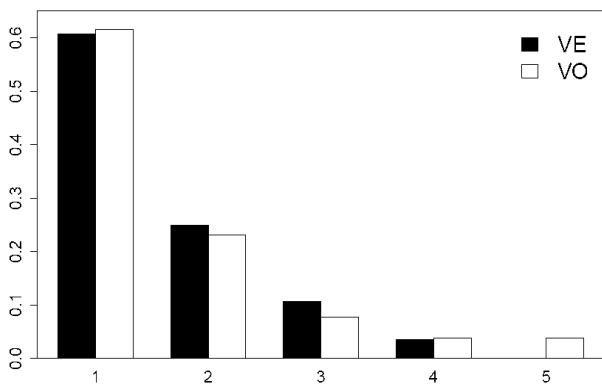


Fig. 2. Vasopressor use. Number of doses is represented in the horizontal axis. Incidences are mentioned as their part of 1.0 (representing 100%). No distinction was made between ephedrine of phenylephrine (100 µg was considered equivalent to 5 mg ephedrine). There were no significant differences

The only haemodynamic differences noticed were significantly better haemodynamics in parturients being punctured in the sitting position (lowest SBP 116 ± 18 vs $103 \text{ mmHg} \pm 17$, $p = 0.009$) or operated during the morning session (114.4 ± 16 vs $104.7 \pm 19 \text{ mmHg}$, $p = 0.046$). Six patients required epidural supplementation (4 in the Ve and 2 in the Vo group). All these patients had received the spinal injection in the sitting position.

Clotting time (r-value) decreased in both groups but only significantly in the Ve group as compared to prehydration values ($p = 0.04$) although no differences were found between both colloids (Table 3).

between both colloids. The CFT (k-value i.e. time to reach a 20 mm amplitude) was prolonged in both groups but only significantly in the Vo group ($p = 0.008$ vs 0.44 in the Ve group) but when comparing both colloids the difference was not significant.

Maximal amplitude (MA) values before the colloid infusion were $67.5 \pm 4.4 \text{ mm}$ for the Ve group and 68.5 ± 4.4 for the Vo group ($p = 0.38$). These values are consistent with values obtained in pregnant patients. After the infusion both values decreased to $65.4 \pm 4.5 \text{ mm}$ and $64.5 \pm 5.5 \text{ mm}$ respectively which however was only significantly different in the Vo group ($p = 0.014$). There were no differences between both colloids.

With both substances after 24 hours, when in fact a decrease of the amplitude should be expected because of fibrinolysis, in most of our patients a further widening of the amplitude was noticed.

In both groups haemoglobin decreased because of the dilution created by the prehydration. This decrease was significant for the Vo group ($p < 0.0001$) but not for the Ve group ($p = 0.37$). Also the difference between both substances was significant ($p = 0.007$).

Urea, creatinine and liver transaminase values did not change significantly. Alkaline phosphatase decreased in both groups without any noticeable difference between both colloids. Lactate dehydrogenase values increased but only significantly in Vo treated patients ($p = 0.0014$ vs 0.17 in the Ve group) but without difference between both substances. Other decreasing tests without any difference between both colloids were total bilirubine and gammaGT.

Table 3. Haemoglobin levels, liver tests and TEG results. Values were compared with pre-infusion values (*, **, *** = $p < 0.05, 0.01, 0.001$ resp.). Alkaline Phosphatase, γ GT and total bilirubine decreased in both study groups but no differences were found between the two colloids

	Ve group	Vo group	P value (Ve/Vo difference)
Clotting time (sec)	-24.6*	-11.9	0.44
CFT (sec)	+11.6	+18.7**	0.44
α -Angle (degree)	-1.92	-2.63*	0.66
A10 (mm)	-2.6*	-4.74***	0.17
MA (mm)	-2.0	-4.0*	0.6
Haemoglobin (g/dl)	-0.28	-1.53***	0.007
LDH (U/L)	+69.9	+154.3**	0.16

With respect to the α -Angle values, indicating the angle made towards maximal clot formation or amplification, in the Vo group this value decreased significantly although again this was not significantly different from the slight decrease which was noticed in the Ve group.

The amplitude after 10 minutes (A10) was significantly lower in both groups without any difference

Neonatal outcomes were comparable between both substances with almost equal UApH values (7.30 for both colloids, $p = 0.9$).

Discussion

The present study was unable to find any significant differences between the two starch solutions with

respect to the haemodynamic outcome parameters and neonatal outcome although the use of two vasopressors has made statistical comparisons more difficult. With respect to the laboratory tests several parameters changed for both substances as compared to pre-administration values but only significantly for the Vo group i.e. longer coagulation time, lower haemoglobin levels, decreased alpha values and longer CF Times, even if there were no differences when comparisons were made with the Vo group except for the haemoglobin content. All changes noticed remained within normal limits.

Prehydration is still subject of debate in patients undergoing a C-section under spinal anaesthesia. Whereas crystalloids do not seem to affect the incidence of hypotension [1-3], colloids have been found to be more effective, while starches more than gelatines [4-6]. The optimal volume of the colloid to be administered remains controversial. Two studies found that cardiac output increases, as found with any prehydration substance and volume, are only be maintained with 1000 mL but the results with respect to the incidence of hypotension were very contradictory ranging between 17% in the study by Ueyama et al and 65% found by Tamilselvan et al as opposed to 35% in the 500 mL group [6, 7].

Actually several starches are commercialized but meanwhile those with high molecular weight and substitution factor such as hetastarch and pentastarch (HES 200/0.5) have been abandoned for use as a prehydration agent in C-section. In addition the allergic potential may increase in relationship with the molecular weight. Actually HES 130/0.4 formulations are mostly used. In the present study two of these tetrastarches were compared. Voluven® (Fresenius) is made from waxy maize (corn) and has a more complex structure containing only the highly branched amylopectine and causing a more difficult breakdown than Venofundin® (B.Braun) which is made from potato and has a more linear structure due to 30% amylose which is easily metabolized by α -amylase. It has been shown that the latter will have a faster clearance from the circulation [8]. Coagulation testing has revealed quite conflicting results. Jamnicki et al found that during haemodilution (30% and 60%) potato starch derived HES compromised blood coagulation more significantly than the corn derived substance [9]. Sommermeyer et al suggested that the negatively charged phosphate-ester groups in potato derived starch may impair coagulation and liver function more than the corn starch-derived HES [10]. However, more recently Godier et al were unable to confirm these findings as they obtained similar effects of both substances on fibrin polymerization [11].

On a theoretical basis it may be suggested that the diluents of the starch may also play an important role

because the addition of a compound such as calcium may cause less disturbances in coagulation testing and platelet function. However the benefit of balanced HES i.e. plasma-adapted versus non-plasma-adapted (prepared in saline) was contested by Casutt et al [12]. However, it should be emphasized that in the latter study the blood was diluted by 33-66% which is much more extensive than in the present study. In addition, when comparing balanced HES 130/0.42 with unbalanced HES/0.4 it may remain unclear whether haemostatic differences, if any, are attributable to the HES substance per se or the electrolyte content. To rule out a possible effect of the diluents both solutions used in our study were dissolved in normal saline.

Although several measurements were significantly deviating from baseline values in the Vo group (whereas these differences were smaller and non significant for Ve treated patients) no statistical differences could be found between the two substances except for the haemoglobin level which was lower in the Vo treated subjects. This may signify that Venofundin® may cause less haemodilution. In a previous study we found that a 10 mL/kg colloid preload induced a decrease of haematocrit values of 14% increasing to > 20% when 1000mL of crystalloids were added to the colloid [5]. This may demonstrate that the contribution of the crystalloid should not be ignored.

Why haemoglobin content in the Ve group was higher than in the Vo group despite similar volumes administered is far from clear. If Venofundin® might have induced less haemodilution, then at least this did not affect the haemodynamics. The only differences found were better blood pressure values in subjects injected in the sitting position and those operated after 12 am. Although this was not the scope of the study, the high need for epidural supplementation in the sitting subgroup forced us to increase the spinal dose in future cases.

Coagulation tested with TEM was affected more in the Voluven® treated patients, even if comparison with Venofundin® did not appear to offer significant differences as in this group results also deviated from baseline though not necessarily significantly. Nevertheless, this may be a warning that for some individuals the deviation may become clinically important whereas no bleeding or coagulation problems were reported during or after surgical delivery. Another remarkable finding may be that Venofundin decreased the coagulation time (r-value) representing the activation of clotting factors rather than platelets (being more responsible for the clot firmness) thus indicating some degree of hypercoagulability. As a consequence, its 'hypercoagulable' effect may be more pronounced than pregnancy itself, as from the second trimester, shorter CFT times and larger maximal amplitude / clot firmness (both 15% change) have been measured but

without any change in coagulation time [13]. Therefore our study does not agree with other studies suggesting more coagulation and liver disturbances with starches made from potato [9, 10]. On the contrary several liver tests did not change at all or were even decreasing.

TEG (or TEM) is not commonly accepted as the testing tool of choice in the parturient. TEG offers a general image of coagulation including the function of platelets and the coagulation cascade. In addition it is known that especially with volumes inferior to 1000 mL no or only little change should be expected. There is a lack of comparative studies using TEG in obstetric anaesthesia and results, both on obstetric and non-obstetric practice are mostly controversial with respect to differences among colloids on the thromboelastography pattern or the role of molecular weight [14, 15]. Not infrequently even a hypercoagulable condition may result, being similar to the shortening of the r-value in our study. It may be difficult to assess whether possible changes between pre and post administration are only to be explained by haemodilutional coagulopathy or a specific effect on clotting factors or platelet function.

Fries et al found that gelatine impaired coagulation less than HES 6% 130/0.4 when administered alone whereas no changes were measured when they were combined at a 1:1 ratio with Ringer's solution (as is the case in our study) [16]. Gordon et al found that gelatines 500 mL induced a significant shortening (enhanced coagulation) in r- and k-values but that this was also the case for patients not receiving any prehydration at all [17]. This finding contested previous suggestions that haemodilution itself may cause hypercoagulability. In children it was found that both gelatines and starch 130/0.42/6:1 impaired coagulation except for the r-value but that this impairment was not altered to an extent beyond the effect of haemodilution [18]. However, in another recent study 500 mL HES 6% prolonged the r- and k-times, though still within the normal reference range, as compared to 1500 mL of Ringer's lactate which did not affect these values [19].

In conclusion, there are no haemodynamic differences between the two colloids when used during spinal anaesthesia for Caesarean section. Both colloids exert an effect on coagulation but it needs to be determined whether the alterations measured are beyond the effect of dilution. However, following the use of Voluven® the coagulation was impaired more importantly, though still within normal reference values, while the haemoglobin content also decreased more significantly as compared to Venofundin®. As the latter leaves coagulation test and haemoglobin level more unaffected and breakdown and clearance may be faster, it may be a better choice for Caesarean section

patients in which only a short-lasting increase in circulating volume is aimed at. More studies are needed to evaluate possible differences with respect to coagulation effects of the actual available colloids.

Finally it should be recommendable that the B.Braun company should induce less confusion among anaesthetists when mixing different generic and trade names such as Tetrastarch, Venohes, Venofundin, Stereofundin and Stereofundin ISO.

Acknowledgement

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Conflict of interest

Nothing to declare

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O comparație între administrarea de HES 6% 130/0.42 și HES 6% 130/0.4 înainte anesteziei spinale la pacientele cu operație cezariană: efectele asupra hemodinamicii, hemoglobinei, testelor hepatice și trombelastometriei

Rezumat

Premize. Hidratarea înainte de operația cezariană este un subiect controversat. În mai multe studii s-a demonstrat că în comparație cu soluțiile cristaloidice administrarea de coloizi este mai eficientă pentru creșterea volumului circulant și a debitului cardiac. În

studiul de față s-au evaluat efectul celor 2 soluții asupra incidenței și severității hipotensiunii după anestezia combinată spinală-epidurală (CSE) pentru operația cezariană de elecție.

Metodă. Din cele 60 de parturiente înrolate în studiu, un număr de 29 și 28 au terminat studiul în grupurile HES 130/0.42/6:1 (Venofundin® sau Venohes® grupul Ve) și respectiv HES 130/0.4/9:1 (Voluven®, grupul Vo). La ambele grupuri s-au administrat 500 ml din soluția în studiu și 1000 ml soluție Ringer Lactat înainte de anestezia spinală, parte a tehnicii CSE. Am comparat parametrii hemodinamici între cele două soluții și efectul acestora asupra trombelastometriei, nivelului hemoglobinei și a testelor funcționale hepatice și renale.

Rezultate. Nu au existat diferențe în privința parametrilor hemodinamici, precum valorile cele mai scăzute ale tensiunii arteriale sau utilizarea de vaso-presoare. Singura diferență care s-a găsit, indiferent de grupul studiat, a fost creșterea semnificativă a valorilor minime ale TA sistolice la parturientele la care anestezia spinală a fost efectuată în poziția șezând sau la cele la care operația cezariană a fost efectuată în cursul dimineții. Trombelastometria și concentrația de LDH au fost influențate în ambele grupuri mai semnificativ după administrarea de Voluven, dar fără diferențe semnificative între cele două soluții. Nivelul hemoglobinei a scăzut în ambele grupuri, dar semnificativ a scăzut numai în grupul Vo. Diferența dintre cele două soluții coloidale a fost semnificativă. Fosfataza alcalină, γ GT și bilirubina au avut o scădere similară după ambele soluții coloidale.

Concluzii. Nu au existat diferențe privind efectul hemodinamic între cele două soluții coloidale. Soluția Voluven® a influențat mai mult parametrii trombelastogramei și LDH-ul fără diferențe semnificative, în timp ce scăderea concentrației hemoglobinei a produs o diferență semnificativă comparativ cu soluția Venofundin®/Venohes®. Deși au fost măsurate modificări semnificative, valorile au rămas între limitele de referință normale, astfel încât nu este clar dacă extensia alterărilor a depășit sau s-a găsit în cadrul efectului de hemodiluție.

Cuvinte cheie: Anestezie: spinală, operație cezariană, coloizi, amidon, trombelostografie, trombelastometrie