**Perinatal hypoxic ischemic encephalopathy (HIE)** is associated with approximately one-quarter of global neonatal deaths. Dysregulated cerebral blood flow may be a key component for secondary neurologic injury in HIE. The load of fluids to increase intravascular volume is the point of care in infants because the cerebral blood flow in neonatal period depends mainly on the cardiac output but the choice of fluids is still debatable.

**Objective.** To determine the impact of 6% hydroxyethyl starch (HES) 130/0.42 in a balanced crystalloid solution on brain perfusion in term neonates with severe hypoxic-ischemic encephalopathy.

**Materials and methods.** Single-center, prospective, simple, randomized controlled study was performed in 205 full-term infants with hypoxic-ischemic encephalopathy grade II and grade III by Sarnat score in the period of 2012-2016. Depending on fluids for volume resuscitation, all infants were randomly divided into HES and control groups. In HES group 45 term infants with moderate to severe hypoxic-ischemic encephalopathy were treated at the 1st DOL with 6% hydroxyethyl starch (HES) 130/0.42 in a balanced crystalloid solution at a dose of 10 ml/kg. The control group included 160 term neonates with hypoxic-ischemic encephalopathy undergoing routine intensive care with normal saline at a dose of 20 ml/kg as the loading volume if needed. To assess the impact of 6% HES on systemic and cerebral hemodynamics, such criteria as mean blood pressure (MBP) and transfontanel Doppler indices RI, PI and CPP were obtained at the 1st, 2nd and 3rd DOL.

**Results.** Using of 6% HES 130/0.42 at the dose of 10 ml/kg of body weight for volume replacement in neonates with moderate to severe HIE at the 1st DOL led to increasing of Resistive Index (RI) in front cerebral artery 2nd DOL (p = 0.025) and 3rd DOL (p = 0.023).

**Conclusion.** Administration of 6% HES 130/0.42 in a balanced crystalloid solution in term newborns with severe hypoxic-ischemic encephalopathy for volume resuscitation results in significant improvement of cerebral blood flow, specifically increasing of Doppler Resistive Index in front cerebral arteries.

**Keywords:** neonates; hypoxia; encephalopathy; colloids; crystalloids; hemodynamics.

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**Introduction.** Perinatal hypoxic ischemic encephalopathy (HIE) is associated with approximately one-quarter of global neonatal deaths. In 2010, there were estimated 1.15 million cases of neonatal encephalopathy, of which 96% of were from low- and middle-income countries [23]. More than a million children who survive birth asphyxia develop problems such as cerebral palsy, mental retardation, learning difficulties, and other disabilities [25]. The main strategies of intensive care remain: mild therapeutic hypothermia of 33-35˚C for 72 hours; positive-pressure ventilation; volume resuscitation; cardiac output support; glucose control; anticonvulsant therapy [26].

Dysregulated cerebral blood flow may be a key component for secondary neurologic injury in HIE. Cerebrovascular autoregulation maintains relatively constant cerebral blood flow across changes in perfusion pressure. Cerebral vasoreactivity describes the vasodilatory and vasoconstrictive responses to changes in blood pressure that mediate cerebral blood flow autoregulation [2, 3]. The load of fluids to increase intravascular volume is the point of care in infants because the cerebral blood flow in neonates depends mainly on the cardiac output but blood pressure [11] but the choice of fluids is still debatable. However, the safety of HES 6% in newborns seems quite proven [16, 22], its efficacy as a fluid for volume replacement in the acute period of severe hypoxic-ischemic encephalopathy remains discussible.

**Objective**

The objective of the study was to determine the impact of 6% hydroxyethylstarch (HES) 130/0.42 in a balanced crystalloid solution on brain perfusion in term neonates with severe hypoxic-ischemic encephalopathy.

**Materials and methods.** Single-center, prospective, simple, randomized controlled study was performed in 205 full-term infants with hypoxic-ischemic encephalopathy treated in NICU of Dnipro Regional Children’s Hospital (Ukraine) in the period of 2012-2016. Inclusion criteria: gestational age 37 to 42 weeks, term infants with the present at admission signs and symptoms of hypoxic-ischemic encephalopathy grade II and grade III by Sarnat score during the first 72 hours of life [9, 15]. Exclusion criteria: gestational age less than 37 weeks, infants aged over 72 hours of life, trauma at birth, congenital malformations, early onset neonatal sepsis.

All the babies were treated using mild therapeutic hypothermia 33-35 °C for 72 hours, assisted positive-pressure ventilation under routine control of acid-base balance, monitoring of SpO2 and etCO2, control of systemic hemodynamics (heart rate, mean blood pressure (MBP), cardiac output), the estimation of consciousness by modified GCS [10], cerebral hemodynamic evaluation by non-invasive method based on conventional ultrasound Doppler transfontanel measurement of blood flow in the front cerebral artery (Arteria Cerebri Anterior, ACA) with estimation of systolic (Vs), diastolic (Vd), mean velocity (Vm) and calculation of Pourcelot
Resistive Index (RI), Gosling Pulsatility Index (PI) and cerebral perfusion pressure (CPP) by the formula of Aaslid R. (1986) [1].

Basing on cerebral perfusion Doppler indices and systemic circulation the hemodynamic support included volume resuscitation and control of blood pressure and cardiac output with the following inotropic and vasopressor administration if needed. Dobutamine and/or dopamine were administered in routinely recommended dosage. The intensive therapy was focused on normovolemia, support of mean blood pressure above 35-40 mm Hg and adequate cardiac output [26].

Dependent on fluids for volume resuscitation, all infants were randomly divided into HES and control groups. In HES group 45 term infants with moderate to severe hypoxic-ischemic encephalopathy were treated at the 1st DOL with 6% hydroxyethylstarch (HES) 130/0.42 in a balanced crystalloid solution at a dose of 10 ml/kg. The control group included 160 term neonates with hypoxic-ischemic encephalopathy undergoing routine intensive care with normal saline at a dose of 20 ml/kg as the loading volume if needed. The issues of safety of HES 6% 130/0.42 in newborns we considered in a previous publication [22]. To assess the efficacy of 6% HES we selected such criteria as mean blood pressure (MBP) and transfontanel Doppler indices RI, PI and CPP [1].

Statistical analysis was performed with JASP 0.9.0.1 software (Amsterdam, The Netherlands, 2018) in accordance with generally accepted standards for mathematical statistics. Before the statistical processing, all data were checked for normal distribution using the Shapiro-Wilk’s W-test. For non-parametric data primary statistical analysis included the calculation of the median, 25th and 75th percentiles. The Mann-Whitney U-test was used for statistical comparison of the studied groups.

Kendall’s Tau and Spearman’s rank correlation coefficient used to measure the strength of the relationship between variables. The unidirectional analysis of variance (ANOVA test) performed to determine the significant influence of each factor on subject effects in the dynamics. A p-value less than 0.05 was considered as significant in all of the tests.

**Results and discussion**

Analysis of the data for 205 term newborns has conducted. The average gestational age was 39.6±1.4 (37-42) weeks, the birth weight was 3573±549 (2440-5300) grams. 128 babies (62.4%) were males and 77 (37.6%) were females. 47 babies (22.9%) were admitted to the NICU in the first 6 hours of life, 136 (66.3%) in the 6-24 hours of life, 19 (9.3%) in 24-72 hours of life and 3 infants (1.5%) were admitted over 72 hours of life. Mortality ratio was 3 of 205 babies (1.46%) at the 28th day of treatment.

At the first step, we figured out benchmarks for the HES 6% efficacy evaluation. Depending on short-term end-point as cerebral leukomalacia rate, we conducted comparative analysis between central and cerebral hemodynamics indices and leukomalacia diagnosed by US/MRI criteria (Tab. 1).

### Table 1

Comparative analysis of central and cerebral hemodynamics on Day 1 and Day 3 of the study in infants with cerebral leukomalacia / no leukomalacia as short-term follow up

| Variables       | No leukomalacia group (n=180) | Leukomalacia group (n=25) | p-value |
|-----------------|-------------------------------|----------------------------|---------|
|                 | Median (25%-75%)               | Median (25%-75%)            |         |
| **Day 1**       |                               |                            |         |
| MBP, mm Hg      | 55 (47-60)                    | 53 (42-63)                 | 0.842   |
| ACA Vs, cm/s    | 21 (16-28)                    | 21 (17.4-28.2)             | 0.671   |
| ACA Vm, cm/s    | 11.6 (8.1-15.6)               | 13 (10-17.5)               | 0.244   |
| RI              | 0.68 (0.59-0.75)              | 0.62 (0.55-0.69)           | 0.037   |
| PI              | 1.2 (0.99-1.5)                | 1.0 (0.84-1.22)            | 0.006   |
| CPP Aaslid      | 7.8 (4.2-11.5)                | 8.9 (5.75-13.85)           | 0.232   |
| MBP, mm Hg      | 60 (52-69.3)                  | 54 (50-58.8)               | 0.053   |
| ACA Vs, cm/s    | 26 (20.1-33)                  | 26 (18.8-34.5)             | 0.854   |
| ACA Vm, cm/s    | 14 (11-18)                    | 16.5 (10.8-19.8)           | 0.336   |
| RI              | 0.67 (0.61-0.73)              | 0.6 (0.5-0.76)             | 0.033   |
| PI              | 1.2 (1.0-1.4)                 | 1.0 (0.75-1.5)             | 0.042   |
| CPP Aaslid      | 10.4 (6.7-15.2)               | 12.5 (6.6-16.8)            | 0.418   |

**Note. HES – Hydroxyethyl starch, MBP – Mean Blood Pressure, RI – Resistive Index, PI – Pulsatile Index, CPP – Cerebral Perfusion Pressure**

The data presented in Table 1 shows that newborns, who subsequently were diagnosed with cerebral leukomalacia, had statistically lower RI and PI rates on the 1st and 3rd days of intensive care. The correlation between these variables is also confirmed by the correlation analysis of Kendall-Tau. The RI value on Day 1 negatively correlated with the development of leukomalacia (r = -0.12; p = 0.018), as well as RI on Day 3 (p = -0.13; p = 0.016). The weakness of the described correlation could be explained by the unpredictable state of autoregulation of cerebral blood flow in newborns with HIE during therapeutic hypothermia and the presence of ante-/-intranatal factors that influence the development of leukomalacia.

Understanding that hemodynamics and cerebral Doppler indices on Day 1 are mostly baseline characteristics, we used mean blood pressure, Pourcelot Resistive Index (RI) and Gosling Pulsatility Index (PI) on Day 3 as benchmarks for the HES 6% efficacy evaluation. Exactly the same, Day 3 RI predictable value coincides with data by Elstad M. et al. (2011) and Gerner G.J. et al. (2016) [5, 7].
Next step we conducted the comparative analysis between central and cerebral hemodynamics indices on Day 2 and Day 3 in neonates with HES 6% administration / no HES 6% on Day 1 (Tab. 2).

**Table 2**

Comparative analysis of central and cerebral hemodynamics on Day 2 and Day 3 of the study in infants with HES 6% administration / no HES 6% on Day 1

| Variables | No HES 6% group (n=160) | HES 6% group (n=45) | p-value |
|-----------|-------------------------|---------------------|---------|
|           | Median (25%-75%)         |                     |         |
| **Day 2** |                         |                     |         |
| MBP, mm Hg| 56 (48-65)              | 55 (49-65)          | 0.007   |
| RI        | 0.69 (0.64-0.76)        | 0.71 (0.59-0.79)    | 0.649   |
| PI        | 1.29 (1.12-1.55)        | 1.35 (0.98-1.76)    | 0.395   |
| **Day 3** |                         |                     |         |
| MBP, mm Hg| 57 (50-68)              | 61 (53-71)          | 0.115   |
| RI        | 0.66 (0.60-0.71)        | 0.68 (0.59-0.76)    | 0.879   |
| PI        | 1.2 (0.99-1.37)         | 1.24 (0.96-1.52)    | 0.667   |

Note. HES – Hydroxyethyl starch, MBP – Mean Blood Pressure, RI – Resistive Index, PI – Pulsatile Index

Evaluating data from Table 2, no statistically significant differences in RI and PI values on Days 2 and 3 between two groups found excepting slight but significant distinction in mean blood pressure (MBP).

Considering of the above, we provided the ANOVA test to decisively figure out if the administration of HES 6% 130/0.42 fluid on Day 1 for volume resuscitation affects cerebral blood flow patterns the nearest days after. Impact of HES 6% administration at Day 1 on RI dynamics on Day 1 and Day 2 presented in Table 3 and Figure 1.

**Table 3**

Effect of HES 6% administration at Day 1 on RI dynamics on Day 1 and Day 2

| Variables | Sum of Squares | df | Mean Square | F      | p-value |
|-----------|----------------|----|-------------|--------|---------|
| RI dynamics | 0.069          | 1  | 0.069       | 5.568  | 0.020   |
| RI dynamics • Day 1 HES 6% (0-no, 1-yes) | 0.008          | 1  | 0.008       | 0.659  | 0.418   |
| Residual   | 1.839          | 148| 0.012       |        |         |

Note. HES – Hydroxyethyl starch, RI – Resistive Index

The results from ANOVA test in the Table 4 show, that there is a significant difference between RI measured on the Day 1 and Day 2 (p=0.020) inside the groups of patients who received and did not receive HES 6% at Day 1. However, administration of HES 6% at Day 1 resulted in similar changes in RI level on both Day 1 and Day 2 of treatment (p=0.418), exactly RI increased in both days. RI level was significantly higher in patients who received HES 6% comparing to no-HES 6% group (p=0.025).

The graph on Figure 1 represents the dynamics confirming that administration of HES 6% resulted in significant improvement of RI level on Day 1 and Day 2 (p=0.025).

Impact of HES 6% administration at Day 1 on RI dynamics on Day 2 and Day 3 presented in Table 4 and Figure 2.

The results from ANOVA test in the Table 4 show, that there is a significant difference between RI measured on the Day 2 and Day 3 (p=0.019) inside the groups of patients received and did not receive HES 6% at Day 1. However, administration of HES 6% on Day 1 resulted in similar changes in RI values on both Day 2 and Day 3 of treatment (p=0.330), exactly RI increased in both days. RI level was significantly higher in infants who received HES 6% comparing to no-HES 6% group (p=0.023).
The graph on Figure 2 represents the dynamics confirming that administration of HES 6% resulted in significant improvement of RI level on Day 2 and Day 3 (p=0.023).

The ideal fluid for neonates should have a composition as similar as possible to the extracellular fluid, to support cellular metabolism and avoid organ dysfunction, and should increase intravascular volume and persist over time, to optimize cardiac output. Unfortunately, no ideal fluid exists, and the available fluid options are roughly divided in three groups: crystalloids, colloids, and blood products. Crystalloid and colloid solutions are discussed, emphasizing advantages and disadvantages of each [18].

Crystalloids are the fluids most commonly used in neonates as well as in pediatric and adult population [6]. Comparing to colloids crystalloids are low-cost, thenoted side effect such as tissue edema can develop when large volumes are used. However, the volume-replacement ratio for crystalloids is quite low and crystalloids only have a short-lived effect on the systemic perfusion. According to Starling's "Three-compartment model", four-times more crystalloids have the same volume effect as colloids [12].

Colloids are composed of large molecules designed to remain in the intravascular space for several hours, increasing plasma osmotic pressure and reducing the need for further fluids. The use of albumin is associated with improved mean arterial pressure and cardiac output with an infusion of a lower volume, but the increased blood–brain barrier permeability restricts it’s using in neonates with severe HIE because of the relative risk of brain edema [4].

Systematic reviews regarding use of stanches in children have shown that there are not enough evidence as to influence on the risk of death using crystalloid vs colloid in pediatric intensive care [20, 21]. Applying of 6% hydroxyethylstarch (HES) 130/0.42 in a balanced crystalloid solution approved for use in the neonatal period, but there is limited data on its benefit/risk ratio in hypoxic-ischemic encephalopathyof newborns [8].

Unlike adult population [13, 14], there are no strict evidences in neonatal patients regarding serious adverse events as coagulopathy or renal impairment related to administration of HES 6% 130/0.42 in routine dosage 10 ml/kg IV [8, 17, 19] as well as in children [24]. Considering that fluid restriction is typically recommended for infants with HIE [26], 6% HES 130/0.42could be used for volume replacement in this group of patients in standard dosage not exceeding 10-15 ml/kg of body weight to avoid potential side effects.

**Conclusion**

Administration of 6% HES 130/0.42 in a balanced crystalloid solution at the dose of 10 ml/kg of body weight in term newborns with severe hypoxic-ischemic encephalopathy isan effective tool for volume resuscitation resulting in improvement of cerebral blood flow, specifically increasing of Doppler Resistive Index in front cerebral arteries. Having regard toits influence on central and cerebral hemodynamics, preventing of secondary post-ischemic brain injury is quite feasible, but additional data needs to be collected before any further conclusions can be drawn.

**The perspectives of future studies**

**Compliance with Ethical Standards.** The study was approved by Biomedical Ethical Commission of the Regional Children's Hospital, Dnipro, Ukraine. Protocol #5, 2011 Feb 21.

**Disclosure**

The author has no conflict of interest to declare. Acknowledgements. No external funding source.
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Відновлення 6% гідроксіetyлкравмалю 130/0,42 у збалансований кристаллоїдний розчин для волемічної ресусцитації у новонароджених з важкою гіпоксично-ішемичною енцефалопатією

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Резюме

Вступ. Перинатальну гіпоксично-ішемічну енцефалопатію (ГІЕ) пов’язують приблизно з ¼ усіх випадків неонаATALНОї смертельності у світі. Порушення регуляції церебрального кровотоку може бути ключовим моментом щодо розвитку вторинного пошкодження головного мозку при ГІЕ. Волемічне навантаження для забезпечення адекватного внутрішньосудинного об’єму крові розглядається як терапія вибору у немовлят, оскільки мозкова перфузія протягом неонаタルного періоду залежить в основному від серцевого викиду, але вибір розчинів для інфузії залишається дискусійним.

Мета дослідження. З’ясувати вплив 6% гідроксиетилкрахмалю (ГЕК) 130/0,42 у збалансованому кристаллоїдному розчині на стан мозкової перфузії у доношенних новонароджених з важкою ГІЕ.

Матеріали і методи дослідження. Одноценове, просте, рандомізоване контрольоване дослідження було проведено у 205 доношенних новонароджених з ГІЕ II та III ступенів визначення за шкалою Sarnat протягом 2012-2016 років. У залежності від обраного розчину для полемічного повітрання всі немовлята були рандомізовано розподілені на групу з інтенсивною терапією (ГЕК) та контрольну групу. Група з ГЕК 45 малюків із середньою вагою 2,82 ± 0,64 кг, контрольна група 160 доношенних новонароджених з ГІЕ 2,81 ± 0,52 кг.

Результати дослідження. Використання 6% ГЕК 130/0,42 у дозі 10 мл/кг маси тіла для відновлення об’єму цируючої крові у доношенних малюків з середньою або важкою ГІЕ з’ясувало у відповідності до встановленої гіпоксично-ішемичної енцефалопатії важливі показники. Мета дослідження була досягнута на 2й день дослідження (р = 0,025). Суттєвий збільшення показники церебрального кровотоку зазначений на 3й день дослідження.

Висновки. Застосування 6% ГЕК 130/0,42 у збалансованому кристаллоїдному розчині при волемічній ресусцитації збільшує показники церебрального кровотоку, зокрема підвищення допплерівського індексу резистентності передніх мозкових артерій. Ключові слова: новонароджений; гіпоксія; енцефалопатія; колоїди; критична енцефалопатія; гемодинаміка.
