

Fluid Therapy in Perioperative Setting in Children

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Abstract

Introduction: The composition of the ideal fluid for children is not standardized and there is a wide variation in clinical practice. We intended to study the safety and impact of routinely used fluids in the electrolyte and acid-base balance.

Methods: We conducted an exploratory, prospective, randomized, and controlled trial of children between 28 days and 17 years old undergoing elective surgery in a tertiary care university affiliated hospital in Portugal, between October 2017 and April 2019. Children received either 0.45% saline solution, 0.9% saline solution, or Plasma-Lyte (Baxter). Blood samples were obtained at three different times: baseline, at the end of the surgery, and in the morning after surgery. The main outcome was to evaluate the safety and efficacy of Plasma-Lyte.

Results: We studied 65 children with a median age of 10 years and a predominance of the male gender (78%). In the third sample, the 0.45% saline group presented lower sodium values ($p = 0.004$) and 0.9% saline group more negative base excess values ($p = 0.035$). In the 0.9% saline group, the chloride values increased over time ($p = 0.003$) and the median base excess in the second sample was within the acidosis range: -2.5 (-3.8, -0.2) mmol/L. In the Plasma-Lyte group, there were no clinically significant changes over time. There were very few electrolyte and acid-base disorders and none were of clinical significance.

Discussion: Plasma-Lyte was a safe and efficient solution in the perioperative setting. The differences between the groups were small and without important electrolyte disorders. In short and not complex surgeries, all three solutions can be used, depending on the costs, availability, and local policy.

Keywords: Acid-Base Equilibrium/drug effects; Adolescent; Child; Child, Preschool; Fluid Therapy/

methods; Hypotonic Solutions/therapeutic use; Infant; Isotonic Solutions/therapeutic use; Treatment Outcome; Saline Solution/therapeutic use

Introduction

Fluid administration is very common among hospitalized children and in the perioperative setting.¹⁻³ Although widely used, it may be associated with electrolyte and acid-base disorders⁴ that can increase morbidity as well as cause neurological damage and death.⁵ In addition, recommendations for intravenous fluid therapy are poorly standardized,^{2,6-9} and studies show a wide variation of the used practices.^{8,10,11}

The prescription of fluids requires an understanding of fluid homeostasis and should be tailored according to the individual, disease, and intended therapeutic goal.⁵ The fluid composition for children in the perioperative setting has not been established yet and it is common practice to use solutions designed for adults, such as 0.9% saline solution, Ringer's lactate, or Plasma-Lyte 148 (Baxter).¹² In general, fluids can be described as being hypotonic, isotonic, or hypertonic regarding the ability to exert an osmotic force across a cell membrane.^{2,3,13} Since glucose is rapidly absorbed by cells, it does not significantly contribute to the osmotic force across the cell membrane.^{2,3,13}

In the past, hypotonic fluids (as 0.45% saline solution) were considered the ideal maintenance fluids for hospitalized children based on the child's daily water and electrolyte requirements proposed by Holliday and Segar.^{2,8,14-16}

Several studies have demonstrated the association between hypotonic fluids and hyponatremia (sodium concentration less than 135 mmol/L), with the potential risk of severe neurological damage or death due to the increased intracranial pressure promoted by

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cerebral edema.^{2,3,8,12,13,15,17-23} Several situations, namely stress, vomiting, pain, infection, several diseases, and postsurgical patients, especially craniofacial or spinal surgery, are at an even higher risk of hyponatremia due to non-osmotic stimuli for antidiuretic hormone release.^{1,2,13,15,23} In these patients, the administration of hypotonic fluids at rates recommended for healthy children increases the risk of hyponatremia and its potential consequences.^{13,15,23}

Therefore, in recent years, the use of isotonic fluids, namely 0.9% saline solution, became more common in children.^{2,6,14}

However, 0.9% saline solution contains a supraphysiologic chloride concentration (154 mmol/L *versus* 98-106 mmol/L of plasma chloride) and can induce hyperchloremic metabolic acidosis and eventually acute kidney injury.^{3,6,10,24}

In order to overcome this, the use of balanced solutions became a frequent choice in adults.^{6,10,24} These solutions have physiochemical properties similar to the plasma, with a significantly lower concentration of sodium and chloride compared to 0.9% saline solution and they seem superior in maintaining the electrolyte and acid-base balance compared to the fluids traditionally used.^{6,18,25,26}

Since 0.9% saline solution has a relatively safe profile and balanced solutions are less available and more expensive, questions remain regarding which fluid is the best in the perioperative setting of elective surgeries.¹²

For the present study, we designed a randomized controlled trial to compare the perioperative use of 0.45% saline solution, 0.9% saline solution, and Plasma-Lyte 148, and the impact on the electrolyte and acid-base balance.

The main goal of the study was to evaluate the safety and efficacy of a balanced solution (Plasma-Lyte 148) and compare it with the solutions used routinely in children (0.45% saline solution and 0.9% saline solution).

Methods

We designed an exploratory, prospective, single-center, randomized, controlled, and blinded to the investigator trial of children undergoing an elective surgery in the pediatrics department of a Portuguese tertiary care university affiliated hospital.

Approval for this study was provided by the Ethic Committee of our hospital (number 102/17) and written informed consent was obtained from parents and the patient, if older than 14 years.

The study population included children > 28 days to < 18 years of age, which were eligible for enrollment if they were undergoing an elective surgery and needed intravenous fluids until the morning of the day after the

surgery, and it was conducted between October 2017 and April 2019. Another condition was the ability to understand the Portuguese language.

Exclusion criteria included signs or symptoms of intracranial hypertension, renal failure requiring dialysis, renal pathology with excess renal sodium excretion, therapy with ion exchange resins or bicarbonate supplements, patients with life support techniques, such as extracorporeal membrane oxygenation, the need for intravenous hydration before surgery, and significant electrolyte changes at baseline (sodium < 130 or > 150 mmol/L, chloride < 95 or > 110 mmol/L, base excess < -7 or > 7 mmol/L).

The children were randomly distributed in three study groups that determined the fluids administered:

- 0.45% saline group: 0.9% saline solution as replacement and 0.45% saline solution with 5% dextrose as maintenance;

- 0.9% saline group: 0.9% saline solution as replacement and 0.9% saline solution with 5% dextrose as maintenance;

- Plasma-Lyte group: Plasma-Lyte 148 as replacement and Plasma-Lyte 148 with dextrose as maintenance.

Randomization was performed using the online randomization program Sealed EnvelopTM and used block randomization with a block size of nine children.

According to our department recommendations, infants were allowed breast milk/formula up to three hours before surgery and older children fasted for eight hours. Fluid therapy was started in the operating room. The anesthesiologist, according to the clinical needs, defined the volume and rhythm. In the postoperative period, the maintenance fluid was adjusted to two thirds of the child's daily needs, calculated according to their weight, in conformity with the Holliday-Segar formula and maintained until the morning of the day after the surgery. The anesthesiologist was not blinded to the fluids administered.

Blood products and diuretics could be administered, if necessary.

The children were submitted to blood tests in three samples:

1. Baseline: before starting fluids and surgery;
2. Second sample: at the end of the surgery;
3. Third sample: on the morning of the day after surgery.

In all the samples, laboratory assessments were made for sodium, potassium, chloride, phosphate, urea, creatinine, albumin, pH, and base excess (the last two from blood gas sample). Demographic variables (sex, age, and weight), type of surgery, surgical time, and type and volume of fluids used were also recorded. The study participants' privacy and anonymity were guaranteed,

through protected databases and the patients' personal data were not included.

Hyponatremia and hypernatremia were defined as sodium values < 135 mmol/L and > 145 mmol/L, respectively. Hypochloremia and hyperchloremia were defined as chloride values < 98 mmol/L and > 106 mmol/L, respectively. Hypokalemia and hyperkalemia were defined as potassium values < 3.5 mmol/L and > 5.0 mmol/L, respectively. Base excess values < -2 mmol/L were used as the cutoff for metabolic acidosis assumption and > 2 mmol/L for metabolic alkalosis.

The primary endpoint was to evaluate the safety and efficacy of Plasma-Lyte. The secondary purposes were the comparison of the study solutions impact on electrolyte and acid-base balance according to the above-mentioned definitions.

We estimated a sample of 100 children to guarantee at least 30 children in each group.

Statistical analysis was performed using the IBM SPSS Statistics™, software version 21.0. Descriptive statistics were performed. Categorical variables were presented in terms of absolute (n) and relative (%) frequencies and percentages. Continuous variables were characterized by mean and standard deviation, if normally distributed, or median and interquartile range (IQR 25,75), if no verification of normal distribution. A normality evaluation was performed by the Shapiro-Wilk test.

Statistically significant differences in continuous variables between the three groups were tested using analysis of variance (ANOVA) and the correspondent non-parametric test, Kruskal-Wallis, to variables without normal distribution. Quantitative paired data were evaluated by the Friedman test.

A comparison of the categorical variables was made by the chi-square test or Fisher's exact test whenever expected frequencies were less than five.

We evaluated the possible association between age, weight, and the volume of the fluids administered, and the presence of hyperchloremia in the third sample and metabolic acidosis in the second and third sample with a multivariate logistic regression model.

All *p* values were two-tailed, with a *p* value of 0.05 indicating statistical significance.

Results

The study included 70 children undergoing elective surgery. The study was stopped before achieving the predictable number of patients due to slow recruitment after 70 patients. Of these, 65 were analyzed and five excluded (Fig. 1).

The children included in the study had a median and IQR age of 10.0 (4.0-15.0) years and there was a predominance of male gender (78%). Table 1 summarizes the baseline characteristics of the population included in the study.

The demographics between the three groups were balanced for age, gender, and weight. The baseline sample, duration of surgery, and volume of fluids administered were also balanced between the three groups (Table 2).

Regarding the type of surgery, the most frequent interventions were urologic (n = 29, 44.6%), sacral region (n = 11, 16.9%), abdominal (n = 8, 12.3%), and orthopedic (n = 8, 12.3%).

No adverse effects were reported from fluid administration.

There were no significant differences between the groups in the variables tested at the baseline and second sample.

On the third sample, there was a statistical difference between the three groups regarding sodium (*p* = 0.004), with the 0.45% saline group with lower sodium values compared to the 0.9% saline group and Plasma-Lyte group (*p* = 0.008 and *p* = 0.015, respectively).

There was also a statistical difference concerning base excess (*p* = 0.035) with the 0.9% saline group presenting lower values than the 0.45% group (adjusted *p* value 0.032).

The changes in the variables over time within each group was also analyzed (Table 3).

In the 0.45% saline group, there was a significant change in base excess over time (*p* = 0.007) with higher values in the third sample. There was no significant change in sodium and chloride over time.

In the 0.9% saline group, all of the variables had a significant variation over time with the exception of creatinine. Chloride values in the third sample were higher than in the first sample (*p* = 0.003) and the base excess values were lower in the second sample (*p* = 0.002), with a mean value in the acidosis range (mean base excess -2.5 mmol/L).

In the Plasma-Lyte group, all of the variables had a significant change over time, with the exception of chloride and pH, but all within the normal range and none with clinical relevance.

There was a significant reduction of potassium, phosphorus, urea, and albumin over time in the three groups.

Regarding electrolyte and acid-base disorders, there were not any cases of hypernatremia and there was only one case of hyponatremia in the second sample (0.9% saline group, sodium 134 mmol/L) and one in the third sample (0.45% saline group, sodium 134 mmol/L).

Hyperchloremia was found in six cases (9.5%) in the second sample and 13 cases (23.6%) in the third, with the majority (n = 8, 61.5%) in the 0.9% saline group. The highest prevalence of acidosis was found at the end of the surgery (n = 27, 44.3%), with the highest prevalence in the 0.9% saline group (n = 12, 18.5%). In the third sample, acidosis was found in 10 cases (17.9%), half in the 0.9% saline group (n = 5, 7.7%) and alkalosis was found in 12 cases (21.4%), with the majority in the

0.45% saline group (n = 7, 15.4%). Plasma-Lyte was the solution with fewer acid-base imbalances. We also evaluated the possible association between other factors, such as age, weight, and the volume of fluids administered, and the presence of hyperchloremia in the third sample and metabolic acidosis in the second, and the third sample with a multivariate logistic regression model. No predictable factors were identified.

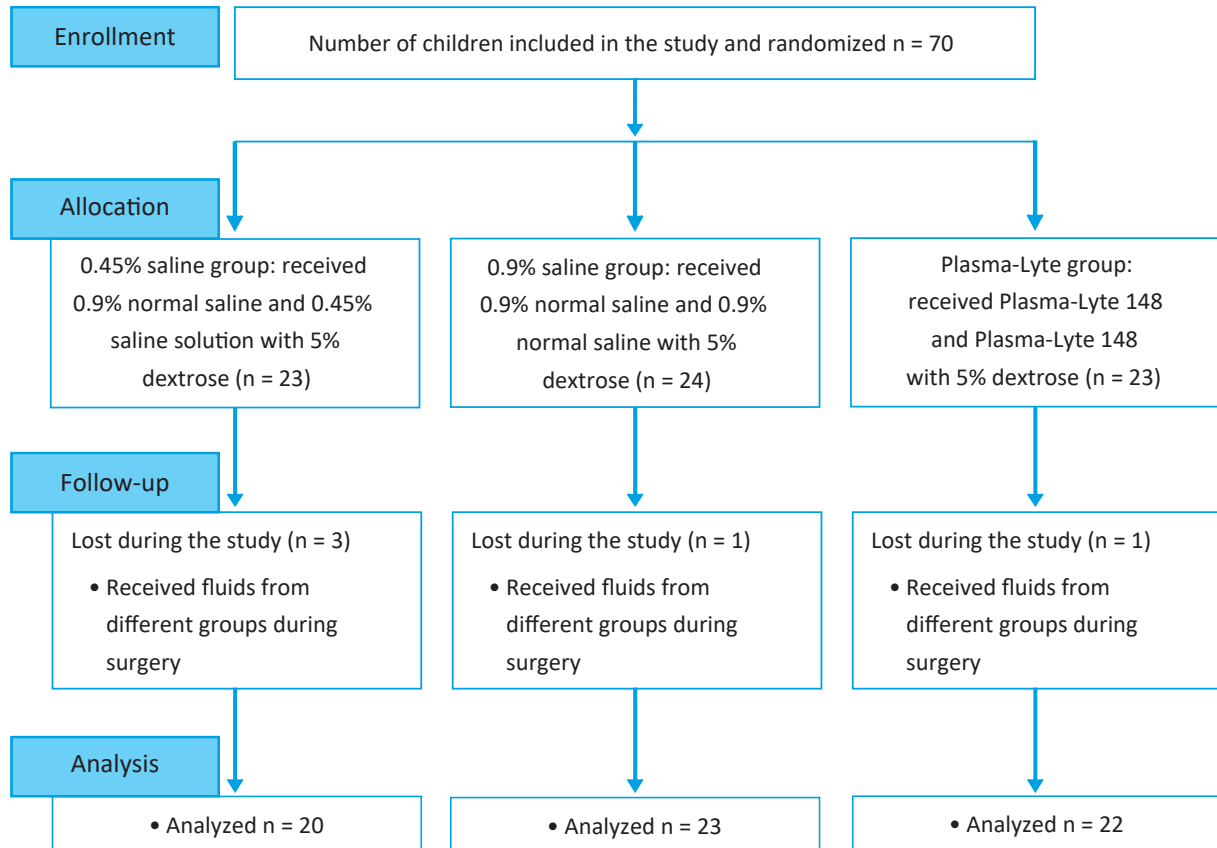


Figure 1. Participant flow diagram.

Variable	0.45% saline group (n = 20)	0.9% saline group (n = 23)	Plasma-Lyte group (n = 22)	Total
Male/female (n)	17/3	16/7	18/4	51/14
Age (years)	10.5 (7.5, 15.8)	9.0 (4.0, 15.0)	6.5 (1.0, 16.0)	10.0 (4.0, 15.0)
Weight (kg)	35.5 (23, 53)	40.0 (19, 55)	23.0 (13, 70)	37.0 (17, 63)
Duration of surgery (minutes)	92 (70, 125)	80 (58, 165)	101 (69, 132)	97 (67, 140)
Amount of fluids in the OR (mL)	265 (200, 403)	400 (240, 469)	200 (146, 465)	283 (176, 450)
Amount of fluids in the OR (mL/kg)	7.5 (4.4, 13.3)	10.5 (6.5, 17.0)	8.4 (3.3, 14.4)	9.3 (5.3, 14.5)
Amount of fluids after the surgery (mL)	1124 (896, 1396)	1094 (941, 1284)	869 (615, 1552)	1080 (745, 1372)
Amount of fluids after the surgery (mL/kg)	31.2 (20.1, 46.2)	26.3 (20.9, 51.6)	36.1 (22.6, 55.2)	30.4 (21.1, 47.4)
Total amount of fluids (mL)	1375 (1104, 1706)	1437 (1239, 1694)	1329 (735, 2056)	1403 (1045, 1716)
Total amount of fluids (mL/kg)	38.9 (25.1, 58.9)	37.1 (27.8, 65.3)	45.9 (28.5, 70.1)	38.5 (27.6, 64.3)

OR - operating room.

Table 2. Electrolyte and base excess values and the difference between the groups (median and interquartile range)

Variable	0.45% saline group	0.9% saline group	Plasma-Lyte group	p value
Baseline				
Sodium, mmol/L	138 (137, 141)	140 (130, 141)	139.5 (137.5, 141)	0.68
Potassium, mmol/L	4.3 (4.0, 4.6)	4.3 (4.1, 4.7)	4.4 (4.2, 4.7)	0.97
Chloride, mmol/L	103 (101, 104)	103 (102, 105)	103 (101, 104)	0.42
Base excess, mmol/L	-0.4 (-2.0, 0.8)	-1.6 (-2.6, 0.5)	-1.3 (-3.6, 0.8)	0.22
Second Sample				
Sodium, mmol/L	137.5 (137, 139)	139 (138, 140)	139 (137, 139.5)	0.18
Potassium, mmol/L	4.2 (4.0, 4.6)	4.4 (4.2, 4.7)	4.4 (4.3, 4.7)	0.19
Chloride, mmol/L	103 (101, 104)	103 (102, 105)	104 (101, 105)	0.72
Base excess, mmol/L	-1.7 (-2.9, -0.3)	-2.5 (-3.8, -0.2)	-1.8 (-4.0, -0.2)	0.70
Third Sample				
Sodium, mmol/L	138.5 (137, 140)	140 (139, 142)	140 (140, 141)	0.004
Potassium, mmol/L	3.9 (3.8, 4.2)	4.1 (3.9, 4.4)	4.0 (3.9, 4.2)	0.15
Chloride, mmol/L	104 (101, 105)	105 (103, 108)	105 (102, 106)	0.13
Base excess, mmol/L	1.7 (-0.8, 2.1)	-0.5 (-2.0, 0.8)	0.3 (-2.3, 1.8)	0.035

Table 3. Variation of the laboratory parameters over time grouped by the fluid type (median)

	0.45% saline group				0.9% saline group				Plasma-Lyte group			
	BS	2 nd	3 rd	p	BS	2 nd	3 rd	p	BS	2 nd	3 rd	p
Sodium, mol/L	138	137.5	138.5	NS	140	139	140	0.037	140	138	140	0.013
Chloride, mmol/L	103	103	103.5	NS	103	103	105	0.003	103	104	105	NS
Potassium, mmol/L	4.3	4.1	3.9	0.004	4.4	4.4	4.1	0.010	4.4	4.6	4.0	0.002
Base excess, mmol/L	-0.4	-1.7	1.7	0.007	-1.6	-2.5	-0.5	0.002	-1.3	-1.8	0.3	0.035
Phosphate, mg/dL	4.4	4.2	4.0	0.047	4.8	4.7	3.9	< 0.001	4.8	4.7	4.0	0.02
pH	7.38	7.38	7.39	NS	7.36	7.37	7.40	0.032	7.37	7.38	7.40	NS
Urea, mg/dL	26	27	19.5	< 0.001	27	27	21	< 0.001	27	27	18	0.006
Creatinine, mg/dL	0.50	0.51	0.52	NS	0.39	0.44	0.47	NS	0.52	0.58	0.55	0.006
Albumin, g/dL	4.3	4.1	4.0	0.013	4.4	3.9	4.0	0.001	4.4	3.9	4.0	0.001

BS - baseline, NS - not significant.

Discussion

The results from this prospective randomized trial demonstrated that 0.45% saline solution causes lower sodium values when used as a maintenance fluid. This result agrees with the other studies described in the literature, where 0.45% saline solution was associated with hyponatremia.^{2,12,13,17-22} However, this difference was only significant in the third sample, after more than 17 hours of fluids and only one patient had a very mild hyponatremia without any associated adverse effects. This trial also revealed that maintenance with 0.9% saline solution was associated with more negative base excess values and with an increase in chloride over time. The association with more negative base excess values is concordant with various studies^{6,10,24} where 0.9% saline solution is associated with metabolic acidosis. The increase in chloride reflects the supraphysiologic

chloride concentration and favors the association with hyperchloremic metabolic acidosis described in the literature.^{6,10,24}

None of the studied variables (age, weight, and volume of fluids) in the multivariate logistic regression model were predictors of hyperchloremia or metabolic acidosis. Plasma-Lyte was a safe solution with few variations in the electrolytic balance.

We verified a higher prevalence of acidosis at the end of the surgery in the three groups that was corrected during the postoperative time. In the operating room, the rhythm of fluids used was higher than in the postoperative and the absence of a difference in the prevalence of acidosis in the three groups reflected the limitations of the study, namely the short duration and low complexity of the surgeries. The effects of general anesthesia and the operating room environment, namely the low temperature, could have also played a role in the development of acidosis.^{27,28}

The reduction of potassium values over time in the three groups validates the safety of using maintenance fluids that have a small amount of potassium, such as Plasma-Lyte 148 (5 mmol/L). There were no potassium values > 5.0 mmol/L. There were very few electrolyte and acid-base disorders across all the studied groups and none were of clinical significance.

Our study has a relatively small sample size. We had a lower than planned enrollment, which was explained by the fact that few elective surgeries fulfilled the study inclusion criteria, certain patients did not accept being included in the study, and anesthesiologists were reluctant to include patients with complex conditions or surgeries in the study. Not meeting the planned enrollment may have impaired our ability to detect differences between the groups.

The authors consider that the short duration of most surgeries could have precluded the occurrence of electrolyte or acid-basic disorders.

In conclusion, this trial demonstrated that Plasma-Lyte was safe and efficient in the perioperative setting. Concerning other solutions, 0.45% saline solution was associated with lower sodium and the 0.9% saline solution with more negative base excess. However, the differences between groups were small, and were without significant electrolyte disorders or adverse effects. This suggests that, during elective noncomplex surgeries, all three solutions can be used in children, depending on the costs, local policy, and availability in the hospital.

These results should be interpreted with caution because they probably reflect the limitations of the study, namely the sample size and volume of fluids administered. We consider that more studies with a larger sample size and including more complex surgeries are needed.

WHAT THIS STUDY ADDS

- Plasma-Lyte 148 was safe and efficient in the perioperative setting.
- 0.45% saline solution was associated with lower sodium and 0.9% saline solution with more negative base excess but without significant electrolyte disorders.
- All three solutions can be used in noncomplex surgeries in children without comorbidities, depending on the costs, availability, and local policy.

Conflicts of Interest

The authors declare that there were no conflicts of interest in conducting this work.

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Protection of human and animal subjects

The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Provenance and peer review

Not commissioned; externally peer reviewed

Confidentiality of data

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

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Awards and presentations

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The study was presented at 1ª Jornadas Digitais de Pediatria, October 2020.

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Fluidoterapia em Ambiente Perioperatório em Crianças

Resumo:

Introdução: A composição do soro ideal em idade pediátrica não está estabelecida e existe grande variabilidade na prática clínica. Pretendemos estudar a segurança e o impacto dos soros mais usados no equilíbrio eletrolítico e ácido-base.

Métodos: Estudo prospetivo, aleatorizado e controlado de crianças entre 28 dias e 17 anos submetidas a cirurgia eletiva num hospital universitário terciário, entre outubro 2017 e abril 2019. As crianças foram aleatorizadas em três grupos: cloreto de sódio 0,45%, cloreto de sódio 0,9% e Plasma-Lyte (Baxter). Foi realizada avaliação laboratorial em três momentos: basal, final da cirurgia e manhã seguinte. O resultado principal foi avaliar a segurança e eficácia do Plasma-Lyte.

Resultados: Foram estudadas 65 crianças, com mediana de idade de 10 anos e predomínio do sexo masculino (78%). Na terceira avaliação laboratorial, o grupo cloreto de sódio 0,45% teve valores de sódio inferiores ($p = 0,004$) e o grupo cloreto de sódio 0,9% mediana mais negativa de excesso de

bases ($p = 0,035$). No grupo cloreto de sódio 0,9% verificou-se aumento do cloro ao longo do tempo ($p = 0,003$), com acidose metabólica ligeira na segunda avaliação laboratorial: -2,5 (-3,8, -0,2) mmol/L. No grupo Plasma-Lyte não houve variações ao longo do tempo com significado clínico. As alterações hidro-eletrolíticas foram poucas e nenhuma teve significado clínico.

Discussão: Plasma-Lyte é um soro seguro e eficaz no peri-operatório. As diferenças entre os grupos foram ligeiras, sem distúrbios eletrolíticos significativos. Em crianças submetidas a cirurgias não complexas de curta duração os três soros podem ser usados, devendo a escolha ser baseada nos custos, disponibilidade e política local.

Palavras-Chave: Adolescente; Criança; Equilíbrio Ácido-Base/efeitos dos fármacos; Hidratação/métodos; Lactente; Pré-Escolar; Resultado do Tratamento; Solução Salina/uso terapêutico; Soluções Hipotónicas/uso terapêutico; Soluções Isotónicas/uso terapêutico