A novel isotonic balanced electrolyte solution with 1% glucose for perioperative fluid management in children- an animal experimental pre- authorisation study

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A novel isotonic balanced electrolyte solution with 1% glucose for perioperative
fluid management in children- an animal experimental pre- authorisation study

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Running title: A novel balanced electrolyte solution

Abstract

Background: The recommendations for perioperative maintenance fluid in children have been adapted from hypotonic to isotonic electrolyte solutions with lower glucose concentrations (1-2.5% instead of 5%) in order to avoid hyponatraemia or hyperglycaemia.

Objective: The objective of this prospective animal study was to determine the margin of safety of a novel isotonic balanced electrolyte solution with 1% glucose (BS-G1) in comparison to normal saline with 1% glucose (NS-G1) in case of accidental hyperhydration with a focus on acid- base- electrolyte balance, glucose concentration, osmolality and intracranial pressure in piglets.

Methods: Ten piglets (bodyweight $11.8 \pm 1.8\text{kg}$) were randomly assigned to receive either 100 ml·kg⁻¹ of BS-G1 or NS-G1 within one hour. Before, during and after fluid administration electrolytes, lactate, haemoglobin, haematocrit, glucose, osmolality and acid-base parameters were measured.

Results: Unlike BS-G1, administration of NS-G1 produced mild hyperchloraemic acidosis (base excess BS-G1 vs. NS-G1, baseline 1.9 ± 1.7 vs. 2.9 ± 0.9 mmol·l⁻¹, study end 0.2 ± 1.7 vs. -2.7 ± 0.5 mmol·l⁻¹, $p < 0.05$, chloride BS-G1 vs. NS-G1 baseline 102.4 ± 3.4 vs. 102.0 ± 0.7 mmol·l⁻¹, study end 103.4 ± 1.8 vs. 109.0 ± 1.4 mmol·l⁻¹ $p < 0.05$).

The addition of 1% glucose led to moderate hyperglycaemia ($p < 0.05$) with a concomitant increase in serum osmolality in both groups ($p < 0.05$).

Conclusion: Both solutions showed a wide margin of safety in the case of accidental hyperhydration with less acid-base-electrolyte changes when using BS-G1. This novel solution could therefore enhance patient's safety within the scope of perioperative volume management.

Keywords: balanced electrolyte solution, normal saline, children, margin of safety, acid-base, fluid management

Introduction

Maintenance fluid therapy in children has been based for half a century on Holiday and Segar’s recommendations suggesting the use of hypotonic fluids with 5% glucose added (1). After several reports of serious hyponatraemia or hyperglycaemia (2, 3), guidelines of several associations of paediatric anaesthesiologists now recommend the perioperative use of isotonic electrolyte solutions, i.e. normal saline or balanced electrolyte solutions with or without 1-2.5% glucose in order to avoid perioperative electrolyte and glucose imbalances (4, 5). Unfortunately these solutions were not commercially available on the German market (6, 7). Therefore in 2005, the association of German paediatric anaesthesiologists filed an application for approval of a balanced electrolyte solution with 1% glucose (BS-G1) with the German regulatory agency. In October 2009, this solution achieved a national approval and was introduced on the German market. In order to determine the margin of safety of BS-G1 in comparison to normal saline with 1% glucose (NS-G1) in case of accidental hyperhydration, we conducted a prospective animal experimental pre-authorisation study with focus on acid- base- electrolyte balance, glucose concentrations, serum osmolality and intracranial pressure.

We formulated the hypothesis that BS-G1 has less influence on the acid- base- electrolyte balance, when compared to NS-G1, while the other outcome parameters will not differ significantly between the groups.

Material and Methods

After approval of the study by the local animal experimentation committee, ten female German landrace piglets, four weeks of age, were included in the study. After a water- only overnight fast, they received intramuscular premedication with azaperone and atropine. The piglets were then anaesthetised with intravenous propofol and fentanyl, orotracheally intubated and mechanically ventilated with 1.5% isoflurane in oxygen/air ($F_i O_2$ 0.5). The tidal volume was adjusted to maintain an end-tidal carbon dioxide tension of 40mmHg. All

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3 animals received $20\mu\text{g}\cdot\text{kg}^{-1}\cdot\text{h}^{-1}$ fentanyl and $0.5\text{mg}\cdot\text{kg}^{-1}\cdot\text{h}^{-1}$ rocuronium during the surgical
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5 interventions. Body temperature was maintained by using an infrared lamp (LP1, Lister,
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7 Germany) and a circulating water mattress (HICO Aquatherm 650, Hirtz, Cologne,
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9 Germany). Heart rate, body temperature, and end-tidal carbon dioxide were measured using a
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11 patient monitoring system (Cardiocap 5, Datex-Ohmeda, Freiburg, Germany). Using standard
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13 cut down techniques, 5 F percutaneous sheath introducer sets (Arrow, Reading, USA) were
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15 inserted in the right jugular vein and the right common carotid artery. Through the venous
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17 introducer set, a 4 F two-lumen central venous catheter (Arrow, Reading, USA) was placed in
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19 the superior vena cava for central venous pressure (CVP) recording. Additionally, a 20-G
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21 cannula was placed in the right saphenous vein for fluid administration. Arterial pressure and
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23 CVP were recorded from a calibrated pressure transducer. Thereafter all animals underwent
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25 burr hole craniotomy (9mm) 1cm paramedian to the sagittal suture over the right cortex in
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27 order to fix a 1.65mm precision pressure catheter (Neurovent P, Raumedic, Helmbrechts,
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29 Germany) for intracranial pressure (ICP) measurements. Continuous ICP was monitored by
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31 transduction of the cortex tissue with pressure lines set to zero at the external auditory
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33 meatus.
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37 After catheter placement and burr hole craniotomy, the first blood samples for blood gas
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39 analysis using a standard blood gas oximetry system (ABL 735, Radiometer, Copenhagen,
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41 Denmark) were collected into heparinised syringes. In each sample, pH, $p_a\text{O}_2$, $p_a\text{CO}_2$, actual
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43 base excess, actual bicarbonate, sodium, chloride, potassium, lactate, haemoglobin and
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45 haematocrit were measured. Additionally, a further blood sample was drawn to measure
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47 serum phosphate (PO_4), serum albumin and serum osmolality using standard laboratory
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49 techniques. The piglets were then randomly assigned to receive either $100\text{ml}\cdot\text{kg}^{-1}$ NS-G1
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51 (Table 1, Central Pharmacy Department, Hanover Medical School, Hanover, Germany) or
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53 $100\text{ml}\cdot\text{kg}^{-1}$ BS-G1 (Table 1, E148 G1 PÄD, Serumwerk Bernburg, Bernburg, Germany),
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55 within one hour. During fluid administration, blood samples were collected every 15 minutes.
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When the infusion was stopped, the last blood sample was collected and the piglets were euthanized by intravenous injection of pentobarbital.

For calculation of strong ion difference (SID), the sum of chloride and lactate concentrations was subtracted from the sum of sodium and potassium concentrations. The total of weak acids (A^-) was calculated using the equation of Fencil *et al.*(8)

$$[A^-] = [\text{albumin } [g\cdot l^{-1}] \cdot (0.123 \cdot pH - 0.631)] + [\text{phosphate } [mmol\cdot l^{-1}] \cdot (0.309 \cdot pH - 0.469)]$$

The power calculation was carried out using the nQuery Advisor software 6.0 (Statistical solutions, Cork, Ireland) with a power of 90% and a significance level (α) of 0.05. This showed that a sample size of 5 piglets per group would allow detection of a difference of 10% in the sodium, chloride and osmolality values in each infusion group. As all measured and calculated data described above were normally distributed (as tested by Kolmogorov-Smirnov tests), these are presented as mean values with standard deviations. For demographic data and measured values before and after fluid administration two-way ANOVA test were performed. Significance was accepted at $p < 0.05$. Recorded data were analysed using the SPSS 15.0 software for Windows (SPSS Software, Munich, Germany).

Results

All ten piglets used in the study received their intended treatment, completed the study protocol and were analysed as reported. The two groups were comparable for weight (BS-G1 group $11.7 \pm 2.0\text{kg}$, NS-G1 group $11.9 \pm 1.6\text{kg}$) and length (BS-G1 group $73.4 \pm 3.5\text{cm}$, NS-G1 group $73.5 \pm 3.5\text{cm}$). At baseline, there were no between-group differences in acid-base variables, concentrations of serum electrolytes, albumin and glucose, serum osmolality, haemoglobin, haematocrit, CVP or ICP (Tables 2 and 3). However, mean arterial pressure differed significantly between the groups at the start of the study, with the higher values in the NS-G1 group. During the experiment, haemoglobin, haematocrit, albumin and phosphate decreased and CVP increased significantly in both groups, while the mean arterial pressure remained almost stable, preserving the primarily significant between-group difference (Table

2). ICP increased significantly in both groups, but remained within physiological ranges (Table 2). The increase in chloride concentrations was significantly higher in the NS-G1 group. Actual bicarbonate and actual base excess decreased in both groups and were significantly lower in the NS-G1 group at study end (Figure 1, Table 3). Regarding further acid-base variables, significant decreases in SID and A^- were found in both groups. Osmolality and glucose concentrations increased with both BS-G1 and NS-G1 infusion. Sodium levels in the NS-G1 group increased significantly, while the potassium and lactate concentrations decreased at the same time. The infusion of balanced electrolyte solution caused no significant changes in sodium, potassium and lactate levels.

Discussion

The objective of this prospective animal study was to determine the margin of safety of a novel isotonic balanced electrolyte solution (BS-G1) in comparison to the likewise recommended isotonic normal saline solution (NS-G1) both with 1% glucose. The experimental study design was chosen to illustrate an accidental hyperhydration. Key findings were mild hyperchloraemic acidosis after administration of NS-G1 and stable acid-base parameters after BS-G1 application. The development of moderate hyperglycaemia resulting in increased serum osmolality in both groups, while the intracranial pressures remained stable within the physiological range.

Intravenous fluid administration influences the composition of serum electrolytes, osmolality, acid-base balance and glucose concentration due to the composition of the administered fluid.

Incidents due to parenteral infusion in infants and children are mainly caused by changes in one of these parameters (3, 9-11). In case of a high volume load, these effects are more pronounced and may include fatal complications, as reported in several case reports (3).

A balanced volume replacement strategy is a well established concept for perioperative fluid management using plasma adapted isotonic crystalloid solutions with a physiological

electrolyte pattern and acetate as bicarbonate precursor in order to prevent iatrogenic acid-base imbalances (12, 13). Acetate may be preferable to lactate because it is metabolised significantly faster, more independently of hepatic function, with a lower increase in oxygen consumption and no interference with the diagnostic use of lactate as a marker of low tissue perfusion (14, 15). Rapid administration of high acetate doses (e.g. during haemodialysis) may lead to metabolic disturbances like a transient elevated blood glucose level or the release of cytokines (16) with a potential decrease in mean arterial pressure. However, in our study blood glucose levels increased comparable in both groups and mean arterial blood pressures and acid-base- electrolyte parameters were stable during hyperhydration with the acetate containing BS-G1 solution.

When compared to extracellular fluid or plasma normal saline contains unphysiological large amounts of sodium (154 mmol l^{-1}) and chloride (154 mmol l^{-1}). The potential acidifying effect of large volumes of normal saline solutions on plasma has been recognised in several controlled trials (17, 18), but controversy has surrounded the aetiology of this phenomenon. In traditional terms, according to Hendersson-Hasselbalch, acidosis from fluid administration implies that plasma expansion and the consecutive dilutional reduction of plasma bicarbonate are the underlying mechanisms (19). Based on these findings, we demonstrated a decrease in actual bicarbonate and mild hyperchloraemic acidosis with normal saline infusion and almost stable acid-base conditions after BS-G1 application.

In contrast to Hendersson-Hasselbalch, the Stewart approach, which is discussed in detail elsewhere (20), defines $p_a\text{CO}_2$, SID and the sum of all anionic charges of weak plasma acids (mainly albumin and phosphate) as independent pH-regulating variables, whereas pH and bicarbonate are dependent variables (21). Assuming a constant $p_a\text{CO}_2$, the Stewart approach provides an alternative to simple dilution as an explanation for acidosis and postulates that a decrease in SID or an increase in A^- will result in a decrease in pH, or vice versa an increase in SID or a fall in A^- will cause a pH increase (21). Morgan *et al.* (22) previously

demonstrated a linear relationship between crystalloid SID and post-dilutional metabolic acid-base status. They proved that a crystalloid infusion with a SID of 24 mmol l^{-1} preserves normal acid-base status (22). According to these findings, in the present study the change in SID was significantly lower in the group with the novel isotonic balanced electrolyte solution (chloride 118 mmol l^{-1} , SID 26 mmol l^{-1}) when compared to normal saline (chloride 154 mmol l^{-1} , SID 0 mmol l^{-1}). The simultaneous decreases in A^- , caused by the dilution of serum albumin, prevent severe metabolic acidosis (22). In other words, according to Stewart, the hyperchloraemic acidosis in both groups is completely (BS-G1 group) or mostly (NS-G1 group) neutralised by hypoalbuminaemic alkalosis.

The choice of glucose concentration in perioperative solutions in paediatric anaesthesia is a compromise between avoiding hypoglycaemia and hyperglycaemia (23). Several clinical trials comparing the perioperative use of infusion solutions containing no glucose, 1% glucose or 5% glucose showed that the use of 1% glucose prevents hypoglycaemia and lipid mobilisation and is associated with blood glucose concentrations in the normal range (24, 25). The present study showed that in the case of accidental hyperhydration 1% glucose concentration may lead to moderate hyperglycaemia (study end: BS-G1 $12.6 \pm 1.8 \text{ mmol l}^{-1}$, NS-G1 $13.0 \pm 2.0 \text{ mmol l}^{-1}$) but the plasma glucose concentrations did not reach levels where severe health threatening events were likely. Actually, in a recent study of de Ferranti *et al.* (26), evaluating long-term neurological development of neonates and infants after correction of transposition of the great arteries, patients who presented low blood glucose concentrations had an increased risk of electroencephalic seizures whereas high glucose concentrations were not associated with worse neurodevelopmental outcomes.

However, rapid infusion with normal saline and balanced electrolyte solution with 1% glucose leads to a significant increase of serum osmolality. Serum osmolality is primarily determined by sodium, glucose and urea concentrations. Urea concentrations were not measured in this study setting, but hyperhydration with urea-free solutions makes stable to decreased urea

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concentrations likely. The simultaneous decrease (BS-G1 group) or only modest increase in sodium concentrations (NS-G1 group) suggests that the increase in glucose concentrations is the main reason for the rise in serum osmolality in both groups. In any case, serum osmolality remained within the physiological range; therefore, severe effects on the osmotic balance did not occur. The significant increase of central venous pressure (CVP) in both groups, was most likely due to the volume load and may contribute to the likewise moderate increase in ICP. Nevertheless, although the increases in CVP and ICP were statistically significant, the values remained in physiological ranges, so that the clinical impact is negligible.

In conclusion, both solutions showed a wide margin of safety in the case of accidental hyperhydration with less acid-base-electrolyte changes when using the novel isotonic balanced electrolyte solution. The addition of 1% glucose led to moderate hyperglycaemia with a concomitant increase in serum osmolality in both groups, while CVP and ICP remained in physiological ranges. Therefore, this novel solution can be regarded, even in the case of accidental hyperhydration, as being almost `foolproofed` (6) and should enhance patients safety.

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Table 1

	Serum at baseline (n=10)	BS-G1	NS-G1
Sodium (mmol·l ⁻¹)	136.6 ± 3.1	140.0	154.0
Potassium (mmol·l ⁻¹)	3.7 ± 0.3	4.0	-
Calcium (mmol·l ⁻¹)	1.4 ± 0.1	2.0	-
Chloride (mmol·l ⁻¹)	102.2 ± 2.3	118.0	154.0
Actual bicarbonate (mmol·l ⁻¹)	26.5 ± 1.3	-	-
Acetate (mmol·l ⁻¹)	-	30.0	-
Lactate (mmol·l ⁻¹)	1.1 ± 0.4	-	-
Glucose (mmol·l ⁻¹)	3.4 ± 0.9	55.0	55.0

Table 2

Variable	Baseline		¹ p	Study end		² p
	BS-G1	NS-G1		BS-G1	NS-G1	
Haemoglobin (g·dl ⁻¹)	8.7 ± 0.3	9.2 ± 0.7	ns	6.6 ± 0.1*	7.0 ± 0.7*	ns
Haematocrit (%)	27.2 ± 0.8	28.4 ± 2.0	ns	20.7 ± 0.4*	22.0 ± 2.0*	ns
Mean arterial pressure (mmHg)	71.8 ± 3.3	88.2 ± 7.5	<0.05	75.6 ± 1.1	94.0 ± 13.7	<0.05
Central venous pressure (mmHg)	4.2 ± 2.1	5.0 ± 2.2	ns	12.4 ± 2.0*	10.4 ± 3.1*	ns
Intracranial pressure (mmHg)	4.2 ± 1.8	5.4 ± 6.1	ns	8.0 ± 2.0*	8.8 ± 6.3*	ns

Table 3

Variable	Baseline			Study end		
	BS-G1	NS-G1	¹ p	BS-G1	NS-G1	² p
pH	7.42 ± 0.0	7.43 ± 0.0	ns	7.38 ± 0.0	7.34 ± 0.0*	<0.05
p _a CO ₂ (mmHg)	41.6 ± 5.0	41.6 ± 4.0	ns	42.6 ± 2.6	42.9 ± 3.9	ns
Actual base excess (mmol·l ⁻¹)	1.9 ± 1.7	2.9 ± 0.9	ns	0.2 ± 1.7*	-2.7 ± 0.5*	<0.05
Osmolality (mosmol·kg ⁻¹)	289.4 ± 5.4	291.6 ± 3.7	ns	299.2 ± 4.9*	303.2 ± 6.2*	ns
Glucose (mmol·l ⁻¹)	3.4 ± 1.3	3.4 ± 0.5	ns	12.6 ± 1.8*	13.0 ± 2.0*	ns
Sodium (mmol·l ⁻¹)	136.8 ± 4.2	136.4 ± 2.1	ns	135.4 ± 2.8	138.8 ± 2.1*	ns
Potassium (mmol·l ⁻¹)	3.7 ± 0.3	3.8 ± 0.4	ns	3.4 ± 0.2	3.1 ± 0.3*	ns
Chloride (mmol·l ⁻¹)	102.4 ± 3.4	102.0 ± 0.7	ns	103.4 ± 1.8	109.0 ± 1.4*	<0.05
Actual bicarbonate (mmol·l ⁻¹)	26.1 ± 1.7	26.9 ± 0.7	ns	24.7 ± 1.7*	22.3 ± 0.9*	<0.05
Lactate (mmol·l ⁻¹)	1.1 ± 0.5	1.0 ± 0.2	ns	1.3 ± 0.2	0.8 ± 0.2*	<0.05
Phosphate (mmol·l ⁻¹)	2.5 ± 0.6	2.4 ± 0.7	ns	2.0 ± 0.5*	1.98 ± 0.46*	ns
Albumin (g·l ⁻¹)	27.3 ± 2.8	28.0 ± 0.9	ns	19.1 ± 2.4*	19.2 ± 0.8*	ns
Strong ion difference (mmol·l ⁻¹)	37.0 ± 3.0	37.1 ± 1.9	ns	34.1 ± 2.5*	32.1 ± 1.6*	ns
Weak acids (mmol·l ⁻¹)	12.3 ± 1.8	12.3 ± 1.5	ns	8.9 ± 2.0*	8.7 ± 1.0*	ns

Figure 1

Table 1 Composition of piglets' serum at baseline (expressed as means $\pm$ SD), balanced electrolyte solution with 1% glucose (BS-G1) and normal saline with 1% glucose (NS-G1).

Table 2 Comparison of haemoglobin, haematocrit, mean arterial pressure, central venous pressure and intracranial pressure at baseline and at the end of the study after infusion of 100 ml·kg⁻¹ of either balanced electrolyte solution with 1% glucose (BS-G1) or normal saline with 1% glucose (NS-G1), within one hour.

Data are expressed as means $\pm$ SD, ¹p value at baseline, BS-G1 vs. NS-G1, ²p value at end of study, BS-G1 vs. NS-G1, * p<0.05, end of study vs. baseline

Table 3 Comparison of acid-base, electrolyte parameters, osmolality, glucose and albumin at baseline and at the end of the study after infusion of 100 ml·kg⁻¹ of either balanced electrolyte solution with 1% glucose (BS-G1) or normal saline with 1% glucose (NS-G1), within one hour.

Data are expressed as means $\pm$ SD, ¹p value at baseline, BS-G1 vs. NS-G1, ²p value at end of study, BS-G1 vs. NS-G1, * p<0.05, end of study vs. baseline

Figure 1 Changes in pH, bicarbonate, base excess and chloride concentrations after infusion of 100ml·kg⁻¹ of either balanced electrolyte solution with 1% glucose (BS-G1) or normal saline with 1% glucose (NS-G1), within one hour.

Data are expressed as means $\pm$ SD, * p<0.05, BS-G1 vs. NS-G1

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For Peer Review