

Comparison of the Metabolic Effects of Sterofundin and Plasmalyte-A in Adult Patients Undergoing Elective Craniotomies for Supratentorial Brain Tumor Resection

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Abstract:

Background: Now a days, balanced solutions are commonly used in neurosurgery but among these balanced crystalloids, the crystalloid with most favourable metabolic effects in neurosurgical patients remains unclear. The current study aimed to find a superior balanced solution among Sterofundin and Plasmalyte-A by comparing their metabolic effects and their impact on renal function in patients undergoing elective craniotomy for supratentorial brain tumor resection.

Methods: 60 patients (n=30) aged 18- 60 years of either sex posted for elective craniotomies for supratentorial brain tumor resection were randomly divided into two groups: Patients of Group A were administered with Sterofundin and that of Group B with Plasmalyte-A. Arterial blood gas parameters and serum electrolytes as primary objectives, and serum creatinine and BUN as secondary objectives were compared between these two groups.

Result: As compared to group B, group A showed statistically significant difference of pH, HCO₃⁻, base excess and lactate at 3 h after induction of anesthesia and at 1, 6 and 24 h after extubation; significantly higher level of PaCO₂ levels and anion gap at 6 and 24 h after extubation; significantly higher serum sodium, potassium and calcium levels. Difference of serum creatinine and BUN were statistically insignificant between these groups. Although the two groups showed significant difference in the ABG parameters and serum electrolytes, these parameters lie within the physiological range in both groups.

Conclusion: Both Sterofundin and Plasmalyte-A have comparable metabolic effects with no superiority of one over another and can be used safely with equally efficacy in adults undergoing elective craniotomies supratentorial brain tumor resection.

Keywords: Sterofundin, Plasmalyte-A, Supratentorial Brain Tumor.

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Introduction

Patients with brain tumors usually present with metabolic disturbances during the course of the disease due to various reasons. Poor oral intake, repeated vomiting, anti-edema measures (steroids, hyperosmolar agents, and/or diuretics) and sometimes, iatrogenic injury to hypothalamus during surgery can lead to dyselectrolytemia and dehydration in these patients.^[1-6] In addition, disturbances in sodium homeostasis as a result of syndromes like Diabetes Insipidus (DI), Cerebral Salt Wasting (CSW) or Syndrome of Inappropriate Secretion of Anti-Diuretic Hormone (SIADH) are very commonly seen in brain tumors, especially with supratentorial tumors.^[1] Prolonged duration of craniotomies also result in larger fluid shifts.

Therefore, choice of intravenous fluid plays a key role in these patients during the perioperative period. Ideally, isotonic crystalloids should be used as maintenance fluid therapy,^[7] and glucose-containing or hypo-osmolar solutions should be avoided.^[8-10] Normal saline (NS) is the most commonly administered intravenous fluid in neurosurgery,^[7,11] but it possess risk of hyperchloremic metabolic acidosis,^[12,13] and can cause acute kidney injury.^[14,15] Ringer lactate (RL) is hypo-osmolar, and lactate present in it is metabolized to glucose (Cori's cycle), and therefore avoided in neurosurgical patients.^[16] Now a days, trend is moving towards usage of balanced solutions (Plasma-Lyte or Sterofundin) in neurosurgery to avoid adverse

effects associated with normal saline and ringer lactate. Their composition is similar to plasma and therefore maintain better metabolic profile. Unlike other crystalloids, they have lower chloride concentration and are associated with lower risk of acute kidney injury.^[17-19] Several RCTs have been done previously which prove the superiority of these balanced solutions over NS and RL in maintaining better metabolic profile of neurosurgical patients. One such study was performed by Hassan et.al. who compared the changes in electrolytes and acid-base between NS (normal saline) and Sterofundin in adults with severe traumatic brain injury (TBI) requiring emergency craniotomy or craniectomy during 24 hours perioperative period, and found that Sterofundin showed better metabolic effects and reduced incidence of hyperchloremic metabolic acidosis than the NS therapy in these patients.^[20] Hafizah et.al. compared changes in acid-base and serum electrolytes with the use of Sterofundin and Normal Saline intraoperatively in 30 adults (n=15) undergoing elective neurosurgery and found that similar results with Sterofundin and NS during elective neurosurgery.^[21]

However, the current literature remains limited identifying which of these newer balanced crystalloids confer superior metabolic effects in neurosurgical patients. Although their composition of these solutions resembles human plasma, they may still exert different metabolic influences which could be relevant in this patient population. Therefore, the present study was conducted aiming to compare the metabolic effects of Sterofundin and Plasmalyte-A and their impact on renal function in patients undergoing elective craniotomy for supratentorial brain tumor resection. Primary objectives were to compare arterial blood gas analysis (pH, PaCO₂, PaO₂, HCO₃⁻, base excess, lactate, anion gap) and serum electrolytes (Na/K/Cl/Ca) between these two groups during perioperative period. Our secondary objective was to compare serum creatinine and blood urea nitrogen (BUN) between these two groups during perioperative period.

Methodology

After obtaining approval from Institutional Ethics Committee (IEC) and Scientific Research Committee (SRC), this prospective, randomized, non-blinded, observational study was conducted in the Department of Neuroanaesthesiology, Indraprastha Apollo Hospitals, New Delhi for a duration of one year.

Based on a study conducted by Mohamad Hasyizan Hassan et al.^[20], a sample size of 47 patients per group was estimated to provide 90% power to detect a statistically significant difference at a two-sided alpha level of 0.05. However, due to the limited duration of the study, a minimum of 30 patients were

included in each group. After obtaining informed written consent, 60 adult patients of age 18- 60 years of either sex and ASA grade I and II (inclusion criteria), posted for elective craniotomies for supratentorial brain tumor resection, were randomized (using a computer-generated random numbers) into two groups of 30 patients each. Even numbered patient was categorized to 'Group A' and odd numbered patient to 'Group B'.

Group A (n=30) – Sterofundin was given as maintenance fluid.

Group B (n=30) – Plasmalyte-A was given as maintenance fluid.

Patients aged <18 years and > 60 years, patients with cardiopulmonary disease, pre-existing acid-base (pH < 7.30) and electrolyte disturbances, ongoing mannitol therapy, coagulopathy (INR > 1.8, aPTT > 60 s), liver dysfunction (ALT/AST > 200 IU/L, total bilirubin > 5 mg/dl), severe anemia, diabetes mellitus, renal dysfunction (serum creatinine > 1.5 mg/dl), a history of allergy to the study solution and patients not willing to participate in the study were excluded from the study.

Preoperative medications including anticonvulsants and steroids were continued until the morning of the surgery. On the day of the surgery, patients were taken in operation theatre and standard ASA monitors (electrocardiography, non-invasive blood pressure (NIBP), capnography, temperature and pulse oximetry) were attached. Two 18G intravenous peripheral cannulae and an arterial cannula (under local anaesthesia) were secured. Baseline ABG (done on ABL800 BASIC analyzer), serum electrolytes, BUN and serum creatinine were recorded. Patients were excluded from the study if any metabolic derangement was found in baseline ABG analysis. Induction of anaesthesia was done with intravenous fentanyl 2 mcg/kg, thiopentone 5 mg/kg and atracurium 0.75 mg/kg, and trachea was intubated with appropriate size endotracheal tube. Anaesthesia was maintained with oxygen (35%), nitrous oxide (65%), propofol and atracurium infusion. Intraoperative analgesia was managed with intermittent intravenous boluses of injection Fentanyl @1mcg/kg. Central venous cannulation and urinary catheterization were done. Patient was positioned according to surgical approach for craniotomy. Target ETCO₂ levels were maintained in the range of 30-35 mmHg. According to the assigned group, patient was infused with either Plasmalyte-A or Sterofundin as maintenance intravenous fluid @ 2ml/kg/hour. At the beginning of skin incision, patients were given 20% mannitol 0.5-1g/kg intravenously over 20 minutes. Blood products were transfused (if required) as per ASA guidelines. Total amount of intraoperative fluid intake, blood loss, blood transfusion (if any) and urine output were recorded. ABG and serum

electrolytes were monitored and recorded at 1–2 hours intervals during the surgery. At the time of dural closure, injection Paracetamol 15mg/kg and injection Ondansetron 4 mg were given intravenously. After completion of the surgery, neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01mg/kg and patients were extubated.

The assigned intravenous fluid was continued during 24-hours post-operative period as well. ABG analysis were done at the intervals of 1,6 and 24 hours after extubation, and serum electrolytes (Na/K/Cl/Ca), BUN and serum creatinine measured at 24 hours after extubation.

Statistical analysis of the collected data was done using statistical software SPSS version 22. Continuous variables were compared across the groups using Mann-Whitney U test. Categorical variables were compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate. An alpha level of 5% (p value < 0.05) was considered 'significant'.

Results

Both the groups were comparable with respect to the demographic characteristics of the patients (Table 1). Inter-group difference of duration of the procedure, intraoperative total volume of intravenous fluid consumption, urine output and blood loss were statistically insignificant (Table 2A).

Inter-group difference of total intravenous fluid consumption and urine output in 24hours postoperative period was statistically insignificant (Table 2B).

As shown in Table 3, a statistically significant inter-group difference of pH, HCO₃ and lactate was found at 3 hours after induction (p 0.019), 1 hour after extubation ($p < 0.001$), 6 hours after extubation ($p < 0.001$) and 24 hours after extubation (p 0.002). Inter-group difference of pCO₂ was statistically significant at 6 hours (p 0.018) and 24 hours (p 0.002) after extubation. Inter-group difference of base excess was found to be statistically significant at 1 hour (p 0.001), 6hours (p 0.037) and 24hours (p) after extubation. Inter-group difference of anion gap (AG) was significant at 1hour (p 0.044) and 24hours (p 0.003) after extubation (Table 3)

Inter-group difference of serum sodium, potassium and calcium was statistically significant at 3hours after induction and 1 hour, 6hours and 24hours after extubation. Intergroup difference of serum chloride (Table 3), BUN and serum creatinine (Table 4) was found be statistically insignificant during intraoperative and 24hours postoperative period.

Despite of statistically significant inter-group difference of ABG parameters and serum electrolytes, all these parameters were within normal physiological range.

Discussion

The present study was conducted aiming to find a superior balanced solution among Sterofundin and Plasmalyte-A in terms of their metabolic profile in patients with supratentorial brain tumors. The two groups of this study showed comparable demographic parameters, total intra-operative and post-operative fluid intake and urine output, intra-operative blood loss and total duration of the procedure.

A statistically significant difference of pH, pCO₂, HCO₃⁻, lactate, anion gap and base excess was found between the two groups, with their higher values in Sterofundin group as compared to Plasmalyte-A group. Although both the groups showed statistically significant difference of these parameters, all these parameters were within the physiological range at all the time points in both the groups. However, this finding was in contrary to a systematic review and meta-analysis done by Jeffrey D. Curran et.al.^[22] who analysed 24 randomized controlled trials comparing Plasmalyte, Ringer's Lactate, Ringerfundin, Hartmann's solution, Ringer's Bicarbonate, Sterofundin, Kabilyte and Normosol and found no significant difference of pH, base excess and lactate when Plasmalyte was compared with Sterofundin. Similarly, Radovan Uvizl et.al.^[23] compared the effects of Plasmalyte in 5% glucose infusion and Ringerfundin infusion on acid base homeostasis of adult patients undergoing abdominal and thoracic procedures, during their intensive care unit stay in the post operative period and found no significant differences in pH, base excess and bicarbonate values between the two groups. However, none of the studies in the past comparing Plasmalyte and Sterofundin mentioned about inter-group comparison of post-infusion anion gap. The results of acid base parameters of our study were different from the systematic review and meta-analysis done by Jeffrey D. Curran et.al.^[22] because of the following points:

- Firstly, the systematic review and meta-analysis showed similar pH, base excess and lactate levels in both the groups of Plasmalyte and Sterofundin, but the certainty of these findings was found to be low as the studies included heterogeneous populations (some studies conducted in perioperative setting, some in intensive care units and few in emergency department) leading to issues with inconsistency for some outcomes and risk-of-bias (ROB) among the included studies. While our study was restricted to only one set of population i.e. adults of only ASA grade I and

II with supratentorial brain tumors; therefore, chances of uncertainty of our findings are likely to be lower.

- Secondly, each patient of our study population was administered steroids and mannitol (and sometimes, diuretics like furosemide) during peri-operative period, which may not be true for every patient of the RCTs analysed in the above systematic review and meta-analysis. These drugs can cause disturbances in acid base homeostasis, and thereby, must have contributed to our acid base findings being different from those of the systematic review and meta-analysis by Jeffrey D. Curran et.al.^[22]

Additionally, Sterofundin contains acetate and maleate which are metabolized to bicarbonate in liver. As observed in our study, lactate levels were comparatively higher in Sterofundin group and it also gets metabolized into bicarbonate in liver. So, the metabolism of acetate, maleate and lactate might have contributed to higher bicarbonate levels and thereby metabolic alkalosis in Sterofundin group of our study. Hence, this overall inter-group significant difference of pH, bicarbonate, lactate, base excess

and anion gap can be attributable to the composition of administered fluids, administration of steroids, hyperosmolar agents and diuretics at different doses (depending upon the site and size of tumor, degree of peritumoral edema and degree of required brain relaxation during the surgery), variable amount of blood loss and blood transfusion (wherever required), and variable incidence of perioperative complications such as diabetes insipidus (DI), cerebral salt wasting (CSW) or syndrome of inappropriate anti-diuretic hormone (SIADH) in these patients.

The present study also observed that despite of observing statistically significant inter-group difference of partial pressure of carbon dioxide (pCO₂) at 6 hours and 24 hours after extubation (p 0.018 and p 0.002 respectively), with slightly higher pCO₂ values in Sterofundin group in comparison to Plasmalyte-A group, all values ranged within normal physiological limits. This perioperative rising trend of pCO₂ paralleled the rising trend of pH, bicarbonate, base excess, lactate in Sterofundin group suggesting an ongoing compensatory respiratory mechanism in response to metabolic alkalosis in these patients.

Table 1: Demographic characteristics of patients in both the groups

Parameters	Group A (mean ± SD)	Group B (mean ± SD)	p-value
Age (years)	42.97 ± 14.71	49.47 ± 12.65	0.093
Sex (Male:Female)	19:11	20:10	0.787
Weight (kg)	65.70 ± 12.59	71.65 ± 13.6	0.089

Table 2: Inter-group comparison of total duration of surgery, perioperative intake/output and blood loss

Table 2A: Intraoperative parameters of patients in both the groups			
Parameters	Group A (mean ± SD)	Group B (mean ± SD)	p-value
Duration of procedure (minutes)	203.17 ± 32.31	201.83 ± 37.66	0.486
Total volume of intravenous fluid used (ml)	1110 ± 286.6	1106.67 ± 265.14	0.947
Total urine output (ml)	1143.33 ± 359.77	1143.33 ± 359.77	0.859
Total blood loss (ml)	163.33 ± 50.36	136 ± 55.37	0.711
Table 2B: Postoperative parameters of patients in both the groups			
Parameters	Group A (mean ± SD)	Group B (mean ± SD)	p-value
Total intravenous fluid in 24hours post-operative period (ml)	1380 ± 230.29	1356.67 ± 228.46	0.788
Total urine output in 24hours post-operative period (ml)	1697.33 ± 371.86	1631.67 ± 324.43	0.411

pH	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	7.40 ± 0.03	7.42 ± 0.03	7.43 ± 0.02	7.44 ± 0.02	7.45 ± 0.03
Group B	7.41 ± 0.03	7.41 ± 0.03	7.41 ± 0.03	7.41 ± 0.02	7.42 ± 0.03
p-value	0.426	0.019	<0.001	<0.001	0.002
pCO₂	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	39.66±0.96	35.01±1.35	36.27±4.46	40.77±3.48	42.06± 4.22
Group B	39.94±0.77	35.29±2.37	37.99±3.42	38.51±3.90	38.86± 4.26
p-value	0.952	0.676	0.061	0.018	0.002
Bicarbonate	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	23.83±1.17	23.90±1.97	24.58±2.49	25.20±1.98	25.81±1.52
Group B	24.09±1.08	22.77±1.44	22.94±1.65	24.30±1.60	24.56 ± 1.71
p-value	0.349	0.007	0.007	0.002	0.003
Base excess	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	0.11 ± 1.31	0.15 ± 1.27	0.44 ± 1.43	0.44 ± 1.41	1.49 ± 0.53
Group B	0.32 ± 1.29	0.13 ± 1.26	-0.28 ± 1.6	-0.01 ± 1.33	0.76 ± 0.93
p-value	0.134	0.507	0.001	0.037	<0.001
Lactate	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	1.20 ± 1.45	1.37 ± 0.64	1.56 ± 0.73	1.77 ± 0.69	1.88 ± 1.22
Group B	0.88 ± 0.31	0.77 ± 0.26	0.77 ± 0.34	0.80 ± .31	0.80 ± 0.25
p-value	0.675	<0.001	<0.001	<0.001	<0.001
Anion Gap (AG)	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	8.91±2.13	9.68±1.58	10.12±1.93	10.81±1.26	9.39±1.68
Group B	9.32±2.33	9.01±1.95	9.50±2.68	8.64±3.66	8.13±1.86
p-value	0.755	0.091	0.044	0.124	0.003
Serum Sodium	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	138.53±2.80	140.57±3.08	141.6±3.17	142.3±2.76	141.03±2.20
Group B	138.93±2.29	138.43±2.28	138.6±2.25	139.23±3.37	139.63±1.97
p-value	0.420	0.005	<0.001	<0.001	0.035
Serum potassium	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	3.84±0.25	4.19±0.30	4.00±0.30	4.08±0.30	4.26±0.24
Group B	3.89±0.20	3.88±0.27	3.77±0.28	3.86±0.26	4.07±0.36
p-value	0.411	<0.001	0.003	0.003	0.033
Serum calcium	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	1.07±0.22	1.13±0.03	1.13±0.05	1.15±0.03	1.14±0.07
Group B	1.11±0.18	1.18±0.34	1.15±0.36	1.14±0.35	1.27±0.48
p-value	0.159	0.032	0.007	<0.001	0.005
Serum chloride	Baseline	At 3hours after induction	At 1hour after extubation	At 6hours after extubation	At 24hours after extubation
Group A	105.1±4.89	106.6±3.14	108.6±2.59	107.9±1.73	106.77±1.99
Group B	105.53±3.71	106.47±3.20	106.23±4.92	107.07±4.18	106.77±2.87
p-value	0.794	0.858	0.116	0.485	0.736

	Baseline serum creatinine (mEq/L)	Serum creatinine (mEq/L) 24 hours after extubation	Baseline BUN (mEq/L)	BUN (mEq/L) 24 hours after extubation
Group A	0.74±0.20	0.74±0.17	33.60±8.64	33.63±4.34
Group B	0.80±0.21	0.78±0.13	34.49±8.41	35.83±7.85
p-value	0.268	0.468	0.573	0.230

On follow up of all the patients of both the groups beyond 24 hours postoperative period (though it was not the part of the study), we found that all the arterial blood gas parameters (including pH, bicarbonate, lactate, pCO₂) were normalized in the next 24 hours.

Our study recorded statistically significant inter-group difference of serum sodium, potassium and calcium concentration at 3 hours after induction ($p < 0.005$), and at 1 hour ($p < 0.001$), 6 hours ($p < 0.001$) and 24 hours ($p < 0.035$) after extubation, with comparatively higher concentration in Sterofundin group than in Plasmalyte-A group, although these electrolyte concentrations were within normal physiological range at all the times. This is in contrast to findings of some studies done in the past. Mohamad Hasyizan Hassan et.al. when compared the changes in ABG and electrolytes between normal saline and Sterofundin in adult patients with severe TBI, found no significant differences in serum sodium level between the groups but a significantly higher concentration of serum calcium and potassium in Sterofundin group at 24 hours of fluid therapy.^[20] Ankita Dey et.al. also noted no significant difference with reference to serum sodium concentration, when metabolic effects of normal saline were compared with Plasmalyte in adults with supratentorial brain tumors.^[24] The systematic review and analysis done by Jeffrey D. Curran et.al.^[22] found similar serum potassium concentrations in both the groups comparing Plasmalyte and Sterofundin.

Both Sterofundin and Plasmalyte can interact with corticosteroids, leading to sodium and water retention.^[25]

Variable degree interaction with corticosteroids along with perioperative use of mannitol and comparatively higher sodium concentration in Sterofundin (145mEq/L in Sterofundin Vs 140 mEq/L in Plasmalyte-A) might have contributed to our finding of higher serum sodium concentration in Sterofundin group (although it always stayed within normal physiological range).

Sterofundin contains calcium (2.5 mmol/L) while Plasmalyte-A does not, being the reason for comparatively high serum calcium concentration with Sterofundin infusion in our study. So, Sterofundin can be used in conditions of hypocalcemia, and should be avoided in

hypercalcaemia. It should not be coinfused with blood products through the same intravenous cannula.

Inter-group difference of serum chloride concentration was statistically insignificant at all the time intervals in our study. Although Sterofundin contains chloride in higher concentration (127 mmol/L in Sterofundin Vs 98 mmol/L in Plasmalyte-A), hyperchloremia was not seen in any of the patients of both the groups. This observation of our study was similar to the findings of the systematic review and meta-analysis performed by Jeffrey D. Curran et.al.^[22] and Zadák Z et.al.^[26] Inter-group difference of Blood urea nitrogen (BUN) and serum creatinine concentration were comparable (statistically insignificant) at baseline (day before surgery) and 24 hours after extubation, and neither of these solutions showed adverse effect on renal function. Matthew W. Semler et.al. conducted two trials comparing either lactated Ringer's solution or Plasma-Lyte A with normal saline in critically ill adult patients in ICU (SMART trial - 'Isotonic Solutions and Major Adverse Renal Events Trial')^[27] and noncritically ill adults treated in the emergency department before hospitalization outside the ICU (SALT-ED trial - 'Saline against Lactated Ringer's or Plasma-Lyte in the Emergency Department')^[28]; both these trials showed a lower incidence of major adverse kidney events in the group using either lactated Ringer's solution or Plasma-Lyte A, when compared to normal saline group.

The possible factors which would cause fluid and electrolyte imbalance in such surgeries and would bias the study result, are prolonged duration of craniotomies, massive blood loss and pituitary and/or hypothalamic tumors. None of such factors were present in our study as duration of all craniotomies in both the study groups ranged between 164.17min to 235.48 min (2.7hours - 3.9hours) with tolerable blood loss (80.63ml – 213.7ml), and patients with pituitary and/or hypothalamic tumors were not included in the study.

To summarize, our study showed that both Sterofundin and Plasmalyte have no superiority of one over another and can be used safely and with equal efficacy in patients with supratentorial brain tumors during perioperative period. Both the fluids share similar metabolic profile with no adverse impact renal function, being safe in these patients.

The present study had few limitations such as shorter duration of study, smaller sample size and study population restricted to only ASA grade I and II patients. Since chances of fluid shifts and metabolic disturbances are more likely in patients ASA grade III and above, future research should focus on addressing these aspects. To validate and expand the horizon of current findings, larger, long-term randomized controlled trials involving all sets of population encompassing various neurosurgical, neurotrauma, neurocritical care patients as well as patients with multiple comorbidities in perioperative setting are warranted.

Conclusion

Sterofundin and Plasmalyte-A do not show superiority of one over another. Both of them demonstrate comparable metabolic profile, and can be used safely and with equal efficacy in patients undergoing craniotomies for supratentorial brain tumor resection.

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