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Stroke volume-directed administration of hydroxyethyl starch or Ringer's acetate in sitting position during craniotomy

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Background: To determine the volumes required for stable haemodynamics and possible effects on the coagulation, we studied stroke volume (SV)-directed administration of hydroxyethyl starch (HES 130 kDa/0.4) and Ringer's acetate (RAC) in neurosurgical patients operated on in a sitting position.
Methods: Thirty craniotomy patients were randomised to receive either HES or RAC. Before positioning, SV, measured by arterial pressure waveform analysis, was maximised by boluses of fluid until SV did not increase more than 10%. SV was maintained by repeated administration of fluid. RAC 3 ml/kg/h was infused in both groups during surgery.
Results: Comparable haemodynamics were achieved with the mean [standard deviation (SD)] cumulative doses of HES or RAC 271 (47) or 264 (50) ml ($P = 0.699$) before the sitting position. Mean (SD) doses of HES or RAC at 30 min after the positioning were 343 (94) or 450 (156) ml ($P = 0.036$), and at the end of surgery 464 (284) or 707 (425) ml, respectively ($P = 0.087$). The intraoperative fluid balance was more positive in the RAC than in the HES group [$P = 0.044$, 95% confidence interval (CI) –978 to –14]. Cardiac and stroke volume indexes [CI and stroke volume index (SVI)] increased in the HES group ($P < 0.05$) but not in the RAC group [non significant (N.S.)]. Neither coagulation profile nor blood loss differed between the groups.
Conclusion: Fluid filling with HES boluses resulted in a positive response in CI and SVI during the sitting position. The 34% smaller volume of HES than crystalloid and less positive fluid balance in the HES group might be important in craniotomy patients with decreased brain compliance.

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Anaesthesia in the sitting position is associated with significant risk of haemodynamical alterations. A decrease in arterial pressure[1–3] or cardiac index (CI)[4] jeopardises cerebral perfusion, especially in patients with disturbed cerebral blood flow (CBF) autoregulation. During craniotomy in the sitting position, pooling of venous blood in lower extremities,[5] venous air embolism (VAE),[6] or cranial nerve manipulation[7] further aggravates haemodynamic instability.

Colloid pre-loading (10 ml/kg) prevents the decrease in blood pressure in the sitting position in anaesthetised patients.[8] Reports of intraoperative fluid challenge in craniotomy patients are scarce.[9,10] Generally, the sitting position decreases the intracranial pressure and provides a clean surgical field by gravitational drainage of fluids,[11] but the options to maintain adequate circulating blood volume are unclear.

The perioperative fluid therapy is suggested to include goal-directed administration of fluids.[12] Hydroxyethyl starches (HES) are effective plasma expanders but carry a risk for coagulation disturbances[13] and may therefore not be suitable in neurosurgical patients. However, the HES-induced coagulation disturbance is dose dependent,[14] and small volumes of HES are not expected to disturb coagulation. On the other hand, with the goal-directed principle, patients may receive larger amounts of fluids perioperatively.[15] In craniotomy patients, the fluid strategy requires careful consideration as small intracranial fluid shifts between various compartments may be clinically significant.

Part of the results was presented as a poster at the Euroanaesthesia 2012 Congress in Paris, France.

In the current study, we examined the stroke volume (SV)-directed administration of fluids in the sitting position during neurosurgery. Possible effects on coagulation were studied with thromboelastometry. The hypothesis was that smaller volumes of HES than Ringer's acetate (RAC) are needed to achieve stable haemodynamics in the sitting position.

Methods

We enrolled adult patients scheduled for elective craniotomy in the sitting position at the Helsinki University Central Hospital. Ethical approval (number 396/E9/2007) was provided by the Ethics Committee for Surgery of the Hospital District of Helsinki and Uusimaa, Helsinki, Finland, and the National Agency of Medicines in Finland accepted the study protocol (EudraCT ref. no. 2007–007106-30). All patients gave their written, informed consent. Patients with the age < 18, body mass index (BMI) > 40 (kg/m^2), known open foramen ovale, congestive heart failure, other than sinus rhythm in electrocardiography (ECG), renal failure (P-creatinine > 120 micromol/l), hepatic failure, anaemia [Haemoglobin (Hb) < 100 g/l], thrombocytopenia (Pc < 100 $\cdot 10^9$/L), and an anticipated need for mannitol during the surgery were excluded.

Patients fasted 6 h before the surgery. Preoperative antihypertensive medication was administered on the morning of surgery, except for angiotensin-converting enzyme inhibitors and angiotensin II antagonists. Patients were premedicated with oral diazepam 5–20 mg. Before the induction of anaesthesia, a basal infusion of RAC with NaCl 40 mmol/l added was started at a rate of 3 ml/kg/h. All patients were given pre-operative vancomycin. Anaesthesia was induced with fentanyl 3–7 microg/kg and either thiopenthal 2–7 mg/kg or propofol 2–2.5 mg/kg. All patients received glycopyrrolate 0.2 mg. Rocuronium (0.5–0.9 mg/kg) was used for muscle relaxation. Anaesthesia was maintained with a continuous infusion of propofol (4–12 mg/kg/h) and remifentanil (0.05–0.45 microg/kg/h). An additional use of sevoflurane at low concentrations was allowed to treat severe hypertension. The patients were intubated and mechanically ventilated using volume-controlled ventilation with a tidal volume of 8–10 ml/kg body weight at a rate of 10–15/min for normoventilation [target arterial carbon dioxide tension ($PaCO_2$) 4.5–5.0 kPa] with 50–100% inspired oxygen. Positive end-expiratory pressure (PEEP) was not applied. During data recording, ventilatory settings were kept constant.

We routinely monitored non-invasive arterial pressure, ECG (lead II), arterial saturation of oxygen (SpO_2), and after intubation and the start of mechanical ventilation, nasopharyngeal temperature, side-stream spirometry (Side stream®, Datex-Ohmeda Inc, GE Healthcare, Madison, WI, USA) and end-tidal concentration of carbon dioxide ($ETCO_2$). After the induction of anaesthesia, an 20G arterial catheter (Becton Dickinson, Temse, Belgium) was inserted into the radial artery for invasive monitoring of arterial pressures and to obtain blood samples.

Two blood pressure transducer sets were connected to the radial arterial line. The first pressure transducer set was zeroed at the heart level (FloTrac®, Edwards Lifesciences, Irvine, CA, USA) and connected to the Vigileo® System (Edwards Lifesciences) with software v 3.02 for continuous monitoring of cardiac output (CO), CI, SV, stroke volume index (SVI), and stroke volume variation (SVV). The second set was zeroed at the level of foramen Monro for measuring systolic, diastolic, and mean arterial pressure (MAP).

In a random order (using closed envelopes drawn in sequential order by the primary investigators), the patients were allocated in blocks of three to receive one of the following study solutions:

1. 6% HES solution (Voluven®; 60 mg/ml, average molecular weight 130 kDa, molar substitution ratio 0.4, pH 4.0–5.5, contents Na^+ 154 mmol/l, Cl^- 154 mmol/l; Fresenius Kabi, Bad Homburg, Germany) (HES group, $n = 15$); and
2. Ringer's acetate solution (Ringer-acetate®, pH 6.0, contents Na^+ 131 mmol/l, Cl^- 112 mmol/l, K^+ 4 mmol/l, Ca^{++} 2 mmol/l, Mg^{++} 1 mmol/l, CH_3COO^- 30 mmol/l; Fresenius Kabi) (RAC group, $n = 15$).

In the supine position, after induction of anaesthesia, all patients received an initial 200 ml bolus of the study fluid over 2–4 min, and haemodynamic measurements were performed before and 3 min after the administration of study fluid. A new bolus of 100 ml over 2–4 min was given immediately after the haemodynamic measurements, until an increase of more than 10% in SV was not noted. The haemodynamic measurements were performed at 3 min after each bolus. Thereafter, the patients were dressed in an antigravity suit (pressurised at 40 mmHg) and placed in the sitting position with a head holder device (Mayfield; Integra Life Sciences, Plainsboro, NJ, USA).

In the sitting position, haemodynamic parameters were registered at 5 min intervals during surgery. Further study fluid boluses of 100 ml were given if SV decreased more than 10% from the value obtained in the supine position. The patient was considered to be a non-responder, and the volume expansion was stopped if the SV did not increase with three consecutive boluses of the study fluid during surgery. Haemodynamic measurements were also performed at the end of surgery in the sitting position and thereafter in the supine position. Post-operatively, a basal infusion of RAC 1 ml/kg/h with additional NaCl according to the Plasma sodium level was given until the following morning. Urine output and fluid balance were registered at pre-determined intervals.

The target for MAP was 60 mmHg or higher at the brain level. Boluses of phenylephrine (0.05–0.1 mg) or ephedrine (5–10 mg) were given if MAP was below 60 mmHg despite the study fluid administration. A phenylephrine infusion was started whenever MAP remained below 60 mmHg for more than 5 min.

The patient's upper body was elevated 50–100 degrees, and the patient's head was tilted 20–30 degrees forward with the patient sitting with knees slightly flexed on a pillow. A two-finger-breadth distance between the chin and sternum was mandatory. In the sitting position, the probe of pre-cordial Doppler (Versatone D8 Perioperative Doppler; MedSonics Inc, Mountain View, CA, USA) was placed to the right of the sternum over the fifth intercostals space.

Thromboelastometry

Modified thromboelastometry coagulation analysis (ROTEM®; Pentapharm GmbH, Munich, Germany) using InTEM®, ExTEM®, FibTEM®, and ApTEM® tests was performed according to the manufacturer's instructions after the induction of anaesthesia (pre), after the total amount of boluses of the study infusion given before positioning (post), and at the end of surgery (end).

Arterial blood samples were analysed for haemoglobin concentration (Hb, g/L), haematocrit (Hct, %), and platelet count (PC, 10^9/L) using Sysmex K-4500® (Sysmex Corporation, Kobe, Hyogo, Japan) at the same time intervals as thromboelastometry. Arterial blood gases and acid–base equilibrium were analysed using Radiometer ABL825® (Radiometer, Copenhagen, Denmark) after the positioning and in case of VAE.

Statistics

The study was designed to discover a threefold difference in the needed volume of study fluid (α-error = 5%) between the groups. Study power was 80%. On the basis of our previous study,[16] the number of subjects per group is also sufficient to detect a difference of 15% in maximum clot firmness (MCF) of the thromboelastometry. The results are reported as mean with standard deviation (SD) or standard error of the mean or 95% confidence interval. Skewed data are shown as medians with range. Kolmogorov–Smirnov was used for test of normality. Mann–Whitney *U*-test or Wilcoxon signed-rank test was applied for paired comparisons with Bonferroni correction between or within the groups, respectively. $P < 0.05$ was considered statistically significant. The statistical calculations were carried out using SPSS (version 17.0) or SigmaStat (version 2.03) for Windows software (SPSS Inc., Chicago, IL, USA).

Results

Between August 2008 and March 2011, a total of 37 patients were assessed for eligibility. Data from 28 patients were analysed (Fig. 1). One patient in the RAC group needed a mannitol bolus due to brain swelling. The data of this patient were analysed until the administration of mannitol, applying the intention-to-treat principle. Two patients in the HES group needed a bolus of hypertonic saline (100 ml Nail 7.6%), but otherwise no brain swelling was observed. The characteristics of the patients are presented in Table 1.

Compared with HES, the mean cumulative dose of RAC needed to optimise fluid filling at 30 and 60 min after the positioning was significantly higher ($P = 0.036$) (Table 2). At the end of the surgery, the mean (SD) cumulative doses of HES or RAC were 464 (284) or 707 (425) ml ($P = 0.087$, 95% confidence interval −524 to 38 ml). Two patients in the RAC group were classified as non-responders, and the volume expansion was stopped. Intraoperative blood loss ($P = 0.536$) and urine output ($P = 0.214$) were comparable in the groups. No diuretics were administered intraoperatively, besides the one patient receiving mannitol. The intraoperative fluid balance was more positive in the RAC than in the HES group ($P = 0.044$, 95% confidence interval −978 to −14).

During the entire study period, HR and MAP did not differ between the groups. CI and SVI increased in the HES group ($P < 0.05$) but not in the RAC group [non significant (N.S.)] during the surgery

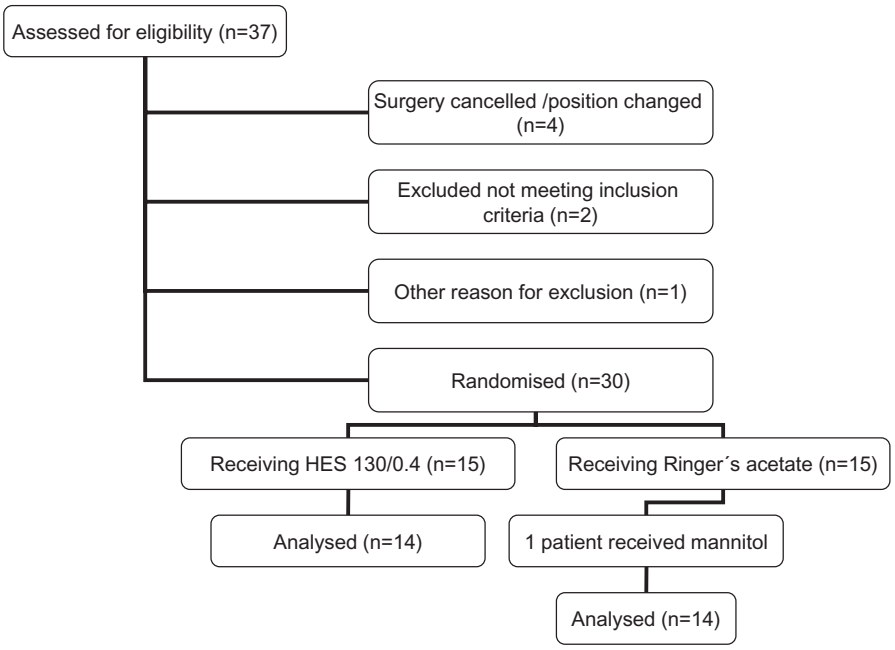

Fig. 1. Flow chart.

Table 1

Perioperative data.

	HES	RAC
	n = 14	*n* = 14
Gender (male/female)	2/12	6/8
Age (years)	40 ± 13	43 ± 17
Weight (kg)	76.0 ± 14.9	76.4 ± 14.1
Height (cm)	163 ± 7	171 ± 10
BSA (m^2)	1.8 ± 0.19	1.9 ± 0.22
ASA classification, III/IV	13/1	13/1
Duration of surgery (min)	145 ± 43	146 ± 63

Data are presented as numbers of patients (*n*) or mean ± standard deviation.
ASA, American Society of Anesthesiologists; BSA, body surface area; HES, hydroxyethylstarch 130/0.4; RAC, Ringer's acetate.

(Fig. 2A,B). There were no significant differences between the groups regarding the total amount of vasoactive drugs used ($P > 0.05$). Doses of the continuous infusion of propofol as well as the total dose of propofol were comparable between the groups ($P > 0.05$). Sevoflurane was used temporary in three patients in each group. The endtidal concentrations of sevoflurane did not differ between the groups ($P > 0.05$). There was no difference in the total dose of fentanyl, remifentanil, or local anaesthetics between the groups ($P > 0.05$).

Baseline values of Hb, Hct, and PC did not differ between the groups. After the initial boluses of study fluid, Hb ($P = 0.010$) and Hct ($P = 0.007$) values were slightly lower in the HES group. The thromboelastometry parameters were comparable in the groups during the whole study period. None of the patients received fresh frozen plasma, packed red blood cells, or platelet concentrates.

The post-operative course was uneventful and without complications for all patients. There were no group differences regarding length of respirator treatment ($P = 0.661$). The duration of Intensive Care Unit (ICU) stay in the HES and RAC groups were 24 (16–500) and 19 (7–101) hours ($P = 0.034$).

The incidence of minor VAE was 50% ($n = 14$ of 28), and there was no difference between the groups ($P = 0.458$). VAE was diagnosed by a 0.3 kPa or greater decrease in $ETCO_2$ or by pre-cordial Doppler. There was no cases of compressive peripheral neuropathy, quadriplegia or facial and tongue oedema. Glasgow Outcome Scale (GOS) at 3 months was comparable between the groups ($P = 0.645$).

Discussion

In the present study, we compared the volume of RAC and HES in patients undergoing craniotomy in the sitting position and found a crystalloid vs. colloid volume ratio of 1.0 before positioning and 1.5 at the end of surgery. Titration of fluid administration according to the stroke volume resulted in a relatively small amount of administered fluid despite the challenging position. According to our findings, most patients undergoing neurosurgery in the sitting position can be managed with an acceptable volume of RAC. The significant increase in CI

Table 2

Intraoperative fluid balance.

	HES	RAC	*P* between groups	95% confidence interval
Pre	271 ± 47	264 ± 50	0.699	–30 to 45
Dose (ml)	300 (200–300)	300 (200–300)		
30 min	343 ± 94	450 ± 156	0.036	–207 to –7
Dose (ml)	300 (200–500)	400 (300–800)		
60 min	371 ± 114	538 ± 257	0.036	–322 to –11.6
Dose (ml)	400 (200–600)	500 (300–1200)		
End	464 ± 284	707 ± 425	0.087	–524 to 38
Dose (ml)	400 (300–1400)	500 (300–1500)		
Total basal RAC	750 ± 202	767 ± 240	0.843	–189 to 155
Dose (ml)	812 (424–1014)	702 (462–1210)		
Intraoperative blood loss (ml)	106 ± 106	136 ± 145	0.536	–128 to 68
	65 (0–400)	75 (0–450)		
Intraoperative urine output (ml)	754 ± 671	488 ± 276	0.214	–163 to 695
	610 (150–2500)	478 (35–950)		
Intraoperative fluid balance (ml)	612 ± 650	1108 ± 520	0.044	–978 to –14
	758 (–1185–1309)	882 (459–2315)		

Cumulative amounts of the study fluids administered before the sitting position (Pre), 30 and 60 min thereafter (30 min and 60 min), and at the end of surgery (End). Values are mean ± standard deviation and median (range). *T*-test with 95% confidence interval for difference of the mean of the amounts of fluid.
HES, hydroxyethylstarch 130/0.4; RAC, Ringer's acetate.

and SVI within the HES group, however, might justify administration of HES (< 500 ml) according to the goal-directed principle without fear of coagulation disturbances when instant restoration of plasma volume is indicated.

It is commonly reported that 2–3 times more crystalloid than colloid is needed to restore and maintain filling pressures in the treatment of hypovolaemia.[17] Recent studies show that the ratio is in fact more in a range between 1 and 2.[18] Our finding of a RAC and HES volume ratio of 1.0 and 1.5 is in accordance with these observations. The volume effect of 264 ml of RAC or 271 ml of HES before positioning resulted in comparable haemodynamic responses. In the sitting position, patients within the HES group had an increase in CI. It is notable that the volumes administered before positioning are much less than those of 10 ml/kg in the earlier study.[8]

It is highly possible that the main reason for the relatively low pre-operative and total fluid input in the current study is the stroke volume-directed fluid administration but also normovolaemia after overnight fasting,[19] the minimal blood loss, and the short time of surgery may have contributed. In a study of patients undergoing craniotomy in the supine position, the volumes of fluids are comparable with ours.[20]

The major aims during craniotomy in the sitting position are to minimise the risk of inadequate CBF and to maintain good neurosurgical conditions. CBF can be increased in normovolaemic patients, either by elevation of MAP or CO.[21] In the present study, MAP did not differ between the study groups, but CI increased in the HES group. This observation might suggest a more favourable effect on CBF by HES than RAC. Furthermore, some experimental studies show that a decrease in plasma colloid oncotic pressure, in addition to decreased plasma osmotic pressure, may aggravate cerebral oedema.[22] It is known that during liberal crystalloid fluid resuscitation, patients with disrupted blood brain barrier are particularly vulnerable to brain oedema.[23]

In neurosurgery, the use of HES solutions has been limited by their adverse effects on coagulation.[24] Also, the modern rapidly degradable HES solutions decrease the whole blood cloth strength, but the effect is dose dependent.[13] In the present study, an average dose of < 500 ml of 6% HES 130/0.4 did not impair whole blood coagulation in thromboelastometry, nor increase blood loss or blood volume in post-operative CT-scans, and should be considered safe. Moreover, colloid oncotic pressure reduction *per se* has the potential to contribute to the formation of post-traumatic cerebral oedema.[25]

According to the current guidelines, there is hardly any indication for colloids in critically ill patients.[26] In comparision with a crystalloid, HES increased mortality in severe sepsis.[27] These observations cannot directly be translated into patients undergoing surgery but indicate cautious attitude towards perioperative colloid administration. Our study highlights close monitoring of fluid adminis-

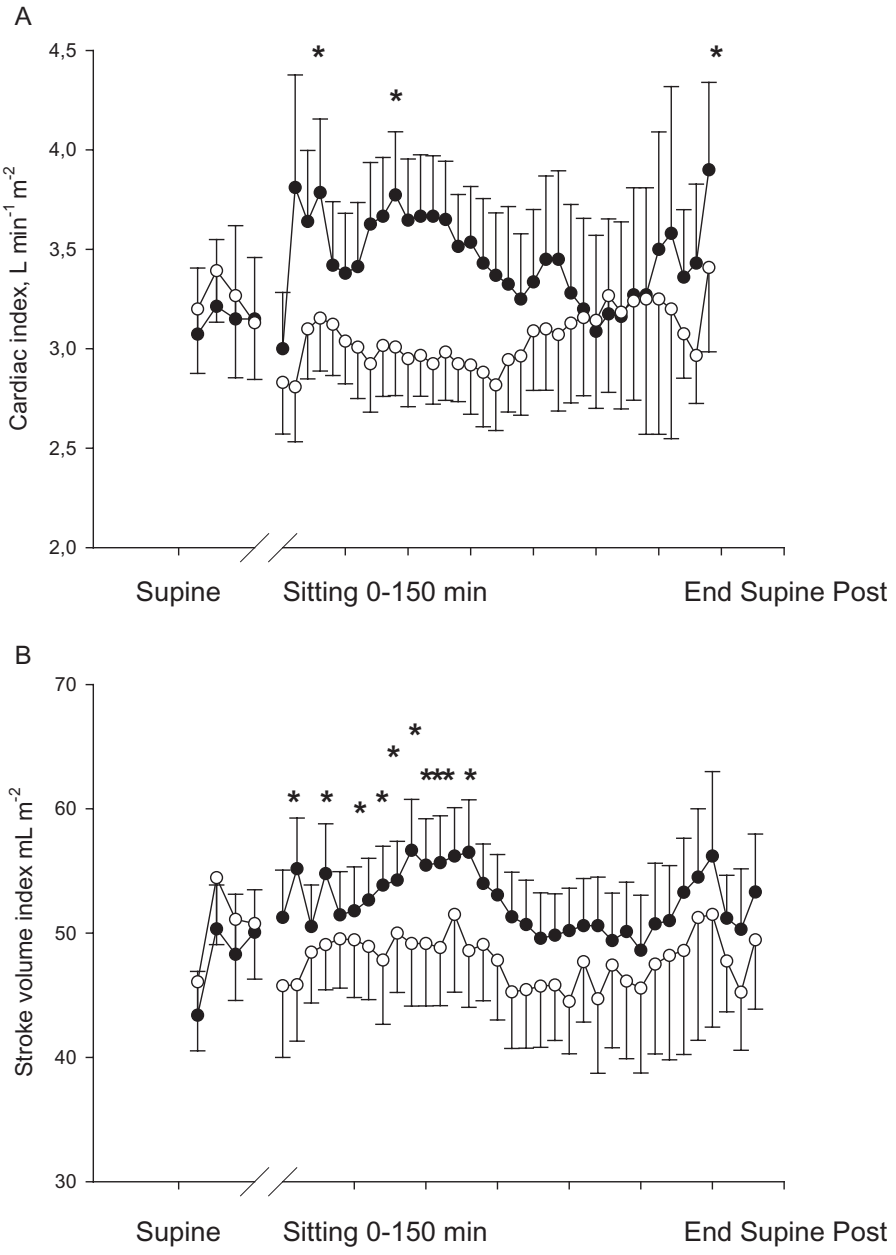

*Fig. 2. Mean (standard error) Cardiac index in supine (A) and Stroke volume index in supine (B) (before and after administration of 200 ml and 300 ml of the study solution, and after dressing of G-suit), sitting (0–150 min at 5-min intervals and at the end of surgery), and in supine postoperatively. ANOVA, pairwise comparisons with Bonferroni method. * P < 0.05 compared with before administration of study solution in supine position in the HES group. HES, hydroxyethyl starch; RAC, Ringer acetate.*

tration in terms of haemodynamics in order to optimise the fluid volumes during craniotomy in the sitting position. The effects of fluid administration, which are largely dependent on the combined effect of the degree of hypovolaemia, dosing regimen, and the type of the fluid, on outcome has to be investigated in larger studies.

There are limitations in this study. We were unable to blind the anaesthesiologists as to the treatment group. However, intraoperative fluid administration in both groups was guided by specific fluid administration protocols, which should minimise bias. The diagnostic value of SVV in predicting fluid responsiveness is good with an area under curve (AUC) of 0.84.[28] CBF was not monitored during surgery. Near-infrared spectroscopy may not be valid during craniotomy due to the possible air between the brain and the skull, the placement of the probe of transcranial Doppler may not be accurate enough for continuous monitoring during surgery, and the brain tissue oxygen monitoring ($pbrO_2$) would have required the invasive insertion of a catheter.

In summary, we conclude that to achieve comparable haemodynamic profiles in the study groups, the amount of RAC was 34% higher than the amount of HES, which is lower than previously

reported. With careful titration and monitoring of either RAC or HES volumes, such as SV-directed administration of fluids, it is possible to maintain a stable circulatory state in the sitting position during neurosurgery. Most of the patients undergoing neurosurgery in the sitting position can be managed with an acceptable volume of RAC. However, HES may be administered when fluid volume should be minimised and instant restoration of intravascular volume is indicated.

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Conflict of interest
Tomi Niemi has received lecturing-honoraria from Fresenius Kabi Ab and Bayer Health Care, Finland, and a grant from Leo Pharma, Finland. For the remaining authors none were declared.

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