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The effect of 0.9% saline versus plasmalyte on coagulation in patients undergoing lumbar spinal surgery; a randomized controlled trial☆

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HIGHLIGHTS

- Perioperative fluid resuscitation with 0.9% saline is associated with hyperchloremic metabolic acidosis even in amounts of 2–4 L.
- The changes on coagulation function assessed by rotation thromboelastometry are similar between 0.9% saline and plasmalyte.
- Perioperative administration of plasmalyte resulted in greater intraoperative urine output compared with 0.9% saline.

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ABSTRACT

Introduction: In multi-level lumbar spinal fusion surgery yielding a large amount of blood loss, choice of fluid for volume resuscitation is an important issue since it can influence acid-base status, coagulation, and patients' outcome. This study compared the effect of plasmalyte to 0.9% saline on coagulation assessed by rotation thromboelastometry (ROTEM) and acid-base balance in the aforementioned patients.

Methods: Fifty patients were randomly allocated to receive either 0.9% saline or plasmalyte during operation and until postoperative 12 h. ROTEM was performed at 10 min after anesthetic induction and end of surgery. Arterial blood gas analyses were serially performed from 10 min after anesthetic induction until postoperative 12 h. Fluid balance, blood loss, and transfusion requirement were assessed.

Results: ROTEM variables showed sporadic deterioration in both groups after surgery without intergroup differences. Intraoperatively, arterial pH, base excess, and bicarbonate concentrations were lower and serum chloride concentrations were higher in the 0.9% saline group compared with the plasmalyte group. The differences in base excess and bicarbonate concentrations persisted until postoperative 12 h. Fluid balance, blood loss, and transfusion requirement were similar between the groups while urine output was greater in the plasmalyte group compared with the 0.9% saline group (3.2 ± 1.6 ml/kg/h vs. 1.8 ± 1.1 ml/kg/h, $p = 0.001$).

Conclusion: In contrast to plasmalyte, fluid therapy with 0.9% saline resulted in transient hyperchloremic acidosis in patients undergoing multi-level lumbar spinal fusion, while coagulation assessed by ROTEM analysis and the amount of blood loss were similar between the groups.

1. Introduction

Multi-level spinal fusion surgeries frequently yield considerable amount of blood loss and appropriate intraoperative fluid resuscitation is essential for optimizing preload and consequently cardiac output to ensure adequate oxygen delivery to the tissues. On the other hand, large amount of fluid resuscitation inevitably results in various degrees of coagulopathy and metabolic derangement

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depending on the type of fluid used [1].

For over 50 years, 0.9% saline has been widely used for perioperative fluid therapy due to its simple composition and low cost. However, the electrolyte composition of 0.9% saline, sodium and chloride at 154 mmol/l each, is less physiologic compared with balanced salt solutions such as lactated Ringer's solution. Accordingly, fluid resuscitation using 0.9% saline has been reported to be associated with hyperchloremic metabolic acidosis, even at amounts of 2–3 L [2–4]. Of note, a number of experimental studies suggested that hyperchloremic metabolic acidosis may impair coagulation, as well as myocardial contractility, and renal function [5]. Disturbances in coagulatory function may be deleterious to patients undergoing major surgeries with significant blood loss and fluid shifts requiring large amount of fluid resuscitation. Indeed, 0.9% saline use on the day of major abdominal surgery was associated with more frequent blood transfusion and dialysis compared with balanced salt solution [6].

Large amount of fluid resuscitation alone causes coagulatory dysfunction as a result of hemodilution. Further deterioration in coagulatory function as a result of metabolic acidosis related to the specific type of crystalloid used would be especially detrimental to patients undergoing closed-space surgeries, which are frequently accompanied by large amount of blood loss as in multi-level spinal fusion. As yet, the influence of 0.9% saline on coagulatory function in relation to metabolic acidosis in this subset of patients had not been addressed heretofore.

Contrary to the assessment of hard clinical endpoints such as the amount of blood loss or transfusion requirement, comparison of coagulatory function using sophisticated measurements according to the type of resuscitation fluid is readily feasible and may impose clinical relevance. In that context, rotation thromboelastometry (ROTEM) enables monitoring of multiple parameters of coagulation as a point-of-care test by measuring clotting time and clot strength [7].

Plasmalyte is a balanced salt solution which has similar electrolyte composition and osmolarity to plasma, which has been shown to elicit less hyperchloremic metabolic acidosis compared with 0.9% saline [8]. This study investigated the effect of plasmalyte or 0.9% saline administration on acid-base balance and coagulation profile measured by ROTEM in patients undergoing multi-level lumbar spinal fusion expected to yield considerable amount of blood loss.

2. Material and methods

2.1. Study population

This study was approved by the Institutional Ethics Committee, and registered with clinicaltrial.gov (unique identifier: NCT01855542). Fifty patients between 20 and 65 years of age with ASA physical status I or II and undergoing multi-level posterior lumbar spinal fusion were enrolled and written informed consent was obtained from all patients. Patients were excluded if they had preexisting acid-base disturbance, electrolyte abnormalities (plasma sodium concentration >145 mmol/l or <135 mmol/l, plasma potassium concentration >5.5 mmol/l or <3.5 mmol/l), anemia (preoperative hematocrit <27%), coagulation abnormalities, renal insufficiency, pulmonary disease, psychiatric disease, pregnancy, drug or alcohol abuse, or were taking diuretics preoperatively. A written informed consent was secured from all of the enrolled patients.

2.2. Study design

Patients were randomly allocated to either the 0.9% saline or plasmalyte group with a block size of two according to a computer-generated random number sequence. The group assignment was concealed by opaque envelopes until anesthetic induction. Intraoperative anesthetic management was conducted by anesthesiologists who were not involved in the study, and investigators including outcome assessors were blinded to the group assignment. Anesthesia was induced by intravenous bolus of propofol 1.5 mg/kg and remifentanil 1 μg/kg. Neuromuscular blockade was facilitated with rocuronium 0.8 mg/kg. Anesthesia was maintained with inhaled sevoflurane in 40% oxygen and continuous infusion of remifentanil at 0.1–0.2 μg/kg/min. Body temperature was maintained above 36 °C using forced-air warming blankets and intravenous fluid warmers. Each group received 0.9% saline or plasmalyte during surgery and until postoperative 12 h. Intraoperative crystalloid solutions were administered at a rate of 6 ml/kg/h, and increased at the discretion of the attending anesthesiologists according to the estimated blood loss. In case of estimated blood loss greater than 500 ml, a colloid solution (6% hydroxyethyl starch 130/0.4 in 0.9% saline) was administered to replace blood loss. Allogeneic packed red blood cell (pRBC) was transfused when the hematocrit value was decreased below 24%.

2.3. Data collection

After anesthetic induction, a radial arterial catheter was placed for continuous monitoring of arterial blood pressure and sampling of blood. ROTEM was performed 10 min after anesthetic induction and at the end of surgery by an anesthesiologist who was blinded to the group assignment. Three ROTEM assays including INTEM, EXTEM and FibTEM were performed according to the standard protocols by the manufacturer. The INTEM, EXTEM and FibTEM assays represent the intrinsic and extrinsic coagulation pathways, and fibrinogen activity, respectively. Ellagic acid and tissue factor activation were used to trigger coagulation pathways in INTEM and EXTEM assays, respectively. In FibTEM assay, coagulation was triggered by tissue factor following inhibition of platelets by Cytochalasin D. Assessed ROTEM variables include clotting time (CT) which represents the onset of coagulation, clot formation time (CFT) and α angle which represent the initial fibrin polymerization rate, and maximum clot firmness (MCF) which measures the strength of the clot. Arterial blood gas analyses were serially performed at following time points; 10 min, 1 h, 2 h, 3 h and 4 h after anesthetic induction, at the end of surgery, and postoperative 12 h. Hemodynamic variables including arterial blood pressure and heart rate were also recorded at the same time. The amounts of crystalloid and colloid administered, pRBC transfusion, urine output and blood loss during surgery were recorded. Blood urea nitrogen (BUN) and serum creatinine (Cr) concentrations were measured at postoperative 24 h.

2.4. Statistical analysis

It was assumed that difference of CT of EXTEM between the 0.9% saline and plasmalyte group would be 10 s with a within group standard deviation of 10 s (mean difference of 1 standard deviation derived from preliminary institutional data). Twenty two patients for each group were needed to have a power of 90% at an α level of 0.05. The size of each group was set to 25 patients considering a possible 10% drop-out rate. Data were expressed as mean ± SD or median [interquartile range], or number of patients (percentage). Continuous data were analyzed by independent t-test. Transfusion requirements and length of hospital stay were analyzed by Mann–Whitney U test. Categorical data were analyzed by $\chi 2$ test or Fisher's exact test as appropriate. Repeatedly measured data including ROTEM and arterial blood gas analysis were analyzed by