Comparison of Albumin and Ringer's Solution for Optimization of the Plasma Volume and Hemodynamics During Laparoscopic Surgery

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Introduction

A quick intravenous infusion of a limited amount of fluid, called ”fluid challenge”, is a vital part of the general recommendations for fluid treatment during long-lasting surgery, especially for patients with an increased risk for complications. A long-lasting increase in circulating volume after a fluid challenge is a prerequisite to recommend the technique. Depending on the results, this study can either support or question the practice of fluid challenges. If the study shows that a similar plasma expansion is obtained with acetated Ringer’s as with colloids (albumin), crystalloids can be recommended, which would implicate significantly lower costs and an increased application of the technique.

Another issue is the challenge to reduce the total volume of administered intraoperative fluid. It is therefore of interest to investigate whether a similar volume effect can be obtained with hyperoncotic albumin requiring smaller volumes?

Surgery has evolved and is to a large extent performed with laparoscopic techniques. Intra-abdominal CO2-inflation may cause decreased preload. It is important to counteract this effect, by optimizing circulating volume with fluid therapy.

Primary Outcome Measure:

1. Does a fluid challenge increase plasma volume?
2. Does a bolus of acetated Ringer’s result in a similar volume and temporal effect as albumin solutions?

Secondary Outcome Measures:

1. Do changes in plasma volume correlate to circulatory changes.
2. Does a "fluid challenge" with acetated Ringer’s have any relevant clinical effect (on plasma volume and/or cardiac output) in a longer perspective?
3. Is it possible to achieve a similar effect with a smaller fluid volume using hyperoncotic albumin?
4. Does the choice of fluid used in the "fluid challenge" have a significant influence on total fluid balance during the day of surgery?
5. Are markers of kidney function and acid-base balance influenced by the choice of fluid when a "fluid challenge" is performed?

Inclusion criteria:

- Written consent to participate in the study
- For women: relevant contraceptive, menopausal or a negative pregnancy test.
- ASA category I to III
- Laparoscopic abdominal surgery, with an expected duration of at least 90 minutes.
- 18 to 80 years

Exclusion Criteria:

- Patients with known cardiac failure
- <18 or >80 years
- known allergy to albumin

- extracellular hyperhydration or hypervolemia
- kidney failure
- pregnancy or planned pregnancy

Study drugs:

acetated Ringer's, albumin 5 % and albumin 20 %

Primary variable:

Reduction of hemoglobin concentration during a fluid bolus. The reduction will mathematically be processed in a kinetic model.

When intravenous fluid is rapidly infused in healthy individuals, blood is diluted due to an increase in plasma volume. This dilution can be utilized to calculate the increase of the blood and plasma volume. The change is not static, since infused fluid will leave the circulation to the tissues or as urine. The effect of the bolus on blood and plasma volume can be described in a graph, with an initial increase of the plasma volume during the infusion followed by a steady decrease during which the volume returns to the pre-infusion level.

The primary variable is the change in blood hemoglobin, which will be transformed into the increase of the circulating volume during the fluid bolus, with follow up, up to an hour after the infusion.

The calculated plasma volume before the infusion, directly after the infusion and 30 minutes after the infusion will be used in the statistical calculations related to the primary hypothesis.

Secondary variables:

- Circulatory physiological measurements.

- Changes in P-albumin and P-creatinine, acid-base parameters, bioimpedance measurements and fluid balance preoperatively and one day later.

Short

A short bolus infusion of fluid, called "fluid challenge" is commonly recommended for fluid treatment during longer surgery. However, a prolonged increase in blood volume caused by the fluid challenge is a prerequisite to recommend the technique. The purpose of the study is to examine the plasma expanding effect of three different fluid challenge strategies (acetated Ringer's 4ml/kg bodyweight, albumin 5% 4 ml/kg bodyweight or albumin 20% 1 ml/kg bodyweight), using hemoglobin as a dilution indicator.

Detailed Description:

60 patients scheduled for laparoscopic abdominal surgery, with a planned duration exceeding 90 minutes will be included in the study. These are randomized to three different

groups (20 in each group): The first group of patients will receive boluses of acetated Ringer's 4 ml/kg body weight, the second albumin 4ml/kg body weight and the third albumin 20% 1 ml/kg body weight. The infusions will be performed during 10 minutes.

Hemoglobin, albumin and colloid osmotic pressure (COP) are sampled the day before surgery and in the morning directly prior to anesthesia. Bioimpedance measures, urine osmolality and urine-creatinine are also measured. After induction of anesthesia a CardioQ probe is inserted through the nose into the esophagus, for circulatory measurements. Initial/baseline blood samples are taken after insufflation of the abdomen with CO_2. Before every bolus of fluid and 5, (10), 15, 20, 30, 40, (50) and (60) minutes after end of the fluid bolus, new blood samples are taken for determination of hemoglobin, albumin and COP. Artery blood gases are sampled 15 minutes after every infusion or depending on the clinical need.

Circulatory parameters, i.e., blood pressure, pulse, stroke volume and cardiac output, will be registered as well at the same occasions.

If the first fluid bolus has a positive effect a second will be administered. The second fluid bolus will be monitored with the same parameters as the first. Other fluid infusions are avoided apart from compensation for insensible perspiration or for larger blood losses.

Based on the blood samples, increase of circulating volume will be calculated with both mass balance and volume kinetics. Mass balance is based on anthropometric assessed blood volume and the dilution of hemoglobin making it possible to estimate increases in circulating volume. Volume kinetics is based on pharmacokinetics and illustrates fluid flows between a central and a peripheral fluid compartment.

Diuretic effect of the fluids is registered as osmolality and creatinine measured from two urine samples, preoperative urine and from urine collected during the complete surgery.

Plasma-creatinine is measured prior to and the day after surgery to detect acute kidney injury (defined as > 50 % increase of plasma creatinine).