



# The intraoperative therapeutic equivalence of balanced vs saline-based 6% hydroxyethyl starch 130/0.4 and their influence on perioperative acid-base status and renal functions<sup>☆,☆☆</sup>

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## Abstract

**Study objective:** This study was designed to evaluate the therapeutic equivalence of balanced 6% hydroxyethyl starch (HES) 130/0.4 (Tetraspan) vs saline-based 6% HES 130/0.4 (Voluven) regarding the volume effect and the effect on acid-base status and renal functions in patients undergoing major urologic procedures.

**Design:** Randomized comparative trial.

**Setting:** Operating room and ward.

**Patients:** Forty patients, American Society of Anesthesiologists statuses 1 and 2.

**Intervention:** Patients were randomly allocated to receive either Voluven (n = 20) or Tetraspan (n = 20).

**Measurements:** Hemodynamic variables. Laboratory variables in the form of arterial blood gases, serum chloride and sodium levels, hemoglobin level, international normalized ratio, and kidney and liver functions were measured after induction of anesthesia (T<sub>1</sub>), at the end of surgery (T<sub>2</sub>), and on the first postoperative day (T<sub>3</sub>).

**Main results:** Both groups were comparable regarding the total amount of study drugs and crystalloid consumption. No significant difference in hemoglobin levels between both groups, but there were significant differences between T<sub>1</sub> and T<sub>2</sub> hemoglobin within both groups and T<sub>3</sub> hemoglobin in the Tetraspan group. Both groups were comparable regarding the renal functions, but there was a significant difference between T<sub>1</sub> and T<sub>2</sub> creatinine within both groups. No significant differences between both groups in liver functions and coagulation profile, but there were significant differences between values at T<sub>1</sub>, T<sub>2</sub> and T<sub>3</sub> within each group. Relative to baseline, both pH and bicarbonate decrease significantly in both groups. In the Voluven group, bicarbonate decreased significantly at the end of surgery relative to the Tetraspan group. Serum electrolytes did not vary between both groups.

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**Conclusion:** Both balanced 6% HES 130/0.4 (Tetraspan) and saline-based 6% HES 130/0.4 (Voluven) were equally effective for hemodynamic stabilization of patients undergoing major urologic procedures without any significant impact on acid-base status or renal functions.

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## 1. Introduction

Optimal perioperative fluid management continues to be highly challenging, especially in patients undergoing major elective surgical procedures [1]. Although there is a long-standing debate about the relative merits of crystalloid and colloid solutions, colloids have a smaller volume of distribution, and therefore, less amounts of fluid and time are needed to replenish the intravascular volume deficit [2].

Among the artificial colloids, hydroxyethyl starch (HES) solutions have the least anaphylactic reactions [3] and are the most commonly used in Europe [4]. HES solutions are modified natural polysaccharides derived from the highly branched starch amylopectin found in waxy maize or potato. The pharmacologic properties of HES types depend on its mean molecular weight, molar substitution (MS), and the C2/C6 ratio [5]. MS is the number of hydroxyethyl residues per mole of glucose, whereas C2/C6 ratio is a pattern of hydroxylation at C2 and C6 carbon position within the glucose molecule. MS with a high C2/C6 ratio inhibits plasma  $\alpha$ -amylase enzyme and therefore increases the intravascular half-life of the HES solutions [6].

Two types of carrier solutions are, in current use, normal saline and “balanced” solutions. The composition of what is called balanced solutions varies, but it aims to mimic the biochemical composition of human plasma with fewer sodium and chloride load than normal saline [6].

Conventional HES solutions consist of normal saline (NaCl 0.9%) containing around 154 mmol/L of sodium and chloride ions, and this high chloride load might be associated with the development of hyperchloremic metabolic acidosis [7]. The clinical consequences of hyperchloremic acidosis are still not fully elucidated; some authors proposed that infusion-related hyperchloremic acidosis is benign [8,9]. There is increased evidence that this type of acid-base alteration might be associated with dose-dependent increased mortality [10–12].

The postoperative acid-base status might be improved by using colloid solutions with balanced carrier. The equivalence of 2 HES solutions and the influence on chloride levels and acid-base status by selectively changing the carrier of rapidly degradable modern 6% HES 130/0.4 showed lower serum chloride load and less metabolic acidosis when balanced carrier solution was used during cardiac surgery [13]. Also, a plasma-adapted HES preparation in addition to a balanced crystalloid resulted in significantly less decline in base excess, less increase in concentration of kidney-specific proteins, less inflammatory response, and less endothelial damage in patients undergoing cardiac surgery [14].

This prospective randomized study was designed to prove the therapeutic equivalence of both HES formulations regarding the volume effect within a predefined interval and to evaluate the effects of 0.9% saline-based and balanced 6% tetrastarch (6% HES 130/0.4) solutions on acid-base status and renal functions in patients undergoing radical prostatectomy or cystectomy with bladder replacement. The primary outcome was the volume of the study drug in milliliters that was needed for hemodynamic stabilization until the end of surgery (ie, the cumulative volume of the study drug in milliliters administered up to this time point). The secondary outcomes were the differences in the plasma creatinine concentrations and in acid-base homeostasis (pH, PaO<sub>2</sub>, PaCO<sub>2</sub>, HCO<sub>3</sub>) among the study groups.

## 2. Materials and methods

This study has been conducted in the Department of Anesthesia, Urosurgery Operating Theater, Cairo University hospitals, through the period from February 2013 to February 2014 after being approved by the Departmental Research and Ethics Committee at January 2013, and after obtaining informed consents from all patients. Forty patients older than 18 years with American Society of Anesthesiologists physical status I and II, both men and women, who underwent radical cystectomy with bladder replacement and men who underwent radical prostatectomy were included in the study. Patients known to have allergy to HES and patients with renal insufficiency (serum creatinine of >2.5 mg/dL), significant hepatic disease (liver function tests >3 times the upper limit of normal), or coagulation disorders (international normalized ratio [INR] >1.5) were excluded from the study.

Combined general epidural anesthesia was performed in all patients. On arrival to the operating room, an intravenous access was cited and epidural catheter was inserted between L3 and L4 and activated with 13 mL bupivacaine 0.25% and 2 mL fentanyl (100  $\mu$ g) followed by continuous epidural infusion of bupivacaine 0.25% at a rate of 5 mL/h till the end of surgery. General anesthesia then was induced with intravenous propofol (2 mg/kg), fentanyl (2  $\mu$ g/kg), and atracurium besylate (0.5 mg/kg). Anesthesia was maintained with isoflurane adjusted between 1% and 1.5% in 100% oxygen and atracurium besylate infusion at 0.5 mg kg<sup>-1</sup> h<sup>-1</sup>. Mechanical ventilation was provided by a Dräger anesthesia machine (Dräger Fabius Plus, Germany) using a tidal volume of 8 to 10 mL/kg with the respiratory rate adjusted to

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