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Effect of Hydroxyethyl Starch vs Saline for Volume Replacement Therapy on Death or Postoperative Complications Among High-Risk Patients Undergoing Major Abdominal Surgery: The FLASH Randomized Clinical Trial.

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Abstract

IMPORTANCE: It is not known if use of colloid solutions containing hydroxyethyl starch (HES) to correct for intravascular deficits in high-risk surgical patients is either effective or safe.

OBJECTIVE: To evaluate the effect of HES 130/0.4 compared with 0.9% saline for intravascular volume expansion on mortality and postoperative complications after major abdominal surgery.

DESIGN, SETTING, AND PARTICIPANTS: Multicenter, double-blind, parallel-group, randomized clinical trial of 775 adult patients at increased risk of postoperative kidney injury undergoing major abdominal surgery at 20 university hospitals in France from February 2016 to July 2018; final follow-up was in October 2018.

INTERVENTIONS: Patients were randomized to receive fluid containing either 6% HES 130/0.4 diluted in 0.9% saline (n = 389) or 0.9% saline alone (n = 386) in 250-mL boluses using an individualized hemodynamic algorithm during surgery and for up to 24 hours on the first postoperative day, defined as ending at 7:59 am the following day.

MAIN OUTCOMES AND MEASURES: The primary outcome was a composite of death or major postoperative complications at 14 days after surgery. Secondary outcomes included predefined postoperative complications within 14 days after surgery, durations of intensive care unit and hospital stays, and all-cause mortality at postoperative days 28 and 90.

RESULTS: Among 826 patients enrolled (mean age, 68 [SD, 7] years; 91 women [12%]), 775 (94%) completed the trial. The primary outcome occurred in 139 of 389 patients (36%) in the HES group and 125 of 386 patients (32%) in the saline group (difference, 3.3% [95% CI, -3.3% to 10.0%]; relative risk, 1.10 [95% CI, 0.91-1.34]; P = .33). Among 12 prespecified secondary outcomes reported, 11 showed no significant difference, but a statistically significant difference was found in median volume of study fluid administered on day 1: 1250 mL (interquartile range, 750-2000 mL) in the HES group and 1500 mL (interquartile range, 750-2150 mL) in the saline group (median difference, 250 mL [95% CI, 83-417 mL]; P = .006). At 28 days after surgery, 4.1% and 2.3% of patients had died in the HES and saline groups, respectively (difference, 1.8% [95% CI, -0.7% to 4.3%]; relative risk, 1.76 [95% CI, 0.79-3.94]; P = .17).

CONCLUSIONS AND RELEVANCE: Among patients at risk of postoperative kidney injury undergoing major abdominal surgery, use of HES for volume replacement therapy compared with 0.9% saline resulted in no significant difference in a composite outcome of death or major postoperative complications within 14 days after surgery. These findings do not support the use of HES for volume replacement therapy in such patients.