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Restrictive versus Liberal Fluid Therapy for Major Abdominal Surgery

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RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
fluidi in chirurgia.pdf ù	RCT	?? ?	+	+	?	+

Characteristics of studies

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Population	1. In a pragmatic, international trial, we randomly assigned 3000 patients who had an increased risk of complications while undergoing major abdominal surgery to receive a restrictive or liberal intravenous-fluid regimen during and up to 24 hours after surgery . 2. Key secondary outcomes were acute kidney injury at 30 days, renal-replacement therapy at 90 days, and a composite of septic complications, surgical-site infection, or death.
Intervention	1. In a pragmatic, international trial, we randomly assigned 3000 patients who had an increased risk of complications while undergoing major abdominal surgery to receive a restrictive or liberal intravenous-fluid regimen during and up to 24 hours after surgery . 2. RESULTS During and up to 24 hours after surgery, 1490 patients in the restrictive fluid group had a median intravenous-fluid intake of 3.7 liters (interquartile range, 2.9 to 4.9), as compared with 6.1 liters (interquartile range, 5.0 to 7.4) in 1493 patients in the liberal fluid group (P<0.001).

	3. A bolus of a balanced salt crystalloid solution was administered at a dose of 10 ml per kilogram of body weight during the induction of anesthesia, followed by a dose of 8 ml per kilogram per hour until the end of surgery .
Outcomes	1. The primary outcome was disability-free survival at 1 year. 2. Key secondary outcomes were acute kidney injury at 30 days, renal-replacement therapy at 90 days, and a composite of septic complications, surgical-site infection, or death. 3. The primary outcome was disability-free survival up to 1 year after surgery.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. The volumes of fluids that were administered to patients in each group are presented in Table 2, and in Tables S3 to S5 in the Supplementary Appendix . 2. There were no significant differences between the groups at baseline (Table 1, and Table S2in the Supplementary Appendix). 3. The distributions of baseline variables in female patients and residents of New Zealand are provided in Tables S8 and S9 in the Supplementary Appendix, re- spectively.
Allocation concealment	low	1. All research staff members who were responsible for the primary outcome assessment were not aware of group assignments. 2. A bolus of a balanced salt crystalloid solution was administered at a dose of 10 ml per kilogram of body weight during the induction of anesthesia, followed by a dose of 8 ml per kilogram per hour until the end of surgery . 3. An infusion of a balanced salt crystalloid solution at a dose of 5 ml per kilogram per hour was administered until the end of surgery.
Blinding of participants and personnel	high/unclear	1. Members of a clinical end-points committee who did not participate in the trial adjudicated all secondary outcome events in a blinded manner. 2. All research staff members who were responsible for the primary outcome assessment were not aware of group assignments. 3. The attending anesthesiologist and most medical and nursing staff members who were caring for patients on the ward had knowledge of the group assignments.
Blinding of outcome assessment	low	1. An independent data safety and monitoring committee monitored the trial for safety, which included a review of the results of a formal interim analysis that was performed after 1632 patients had undergone randomization. 2. Members of a clinical end-points committee who did not participate in the trial adjudicated all secondary outcome events in a blinded manner. 3. All research staff members who were responsible for the primary outcome assessment were not aware of group assignments.