Effect of a perioperative, cardiac output-guided hemodynamic therapy algorithm on outcomes following major gastrointestinal surgery: a randomized clinical trial and systematic review

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IMPORTANCE: Small trials suggest that postoperative outcomes may be improved by the use of cardiac output monitoring to guide administration of intravenous fluid and inotropic drugs as part of a hemodynamic therapy algorithm.

OBJECTIVE: To evaluate the clinical effectiveness of a perioperative, cardiac output-guided hemodynamic therapy algorithm.

DESIGN, SETTING, AND PARTICIPANTS: OPTIMISE was a pragmatic, multicenter, randomized, observer-blinded trial of 734 high-risk patients aged 50 years or older undergoing major gastrointestinal surgery at 17 acute care hospitals in the United Kingdom. An updated systematic review and meta-analysis were also conducted including randomized trials published from 1966 to February 2014.

INTERVENTIONS: Patients were randomly assigned to a cardiac output-guided hemodynamic therapy algorithm for intravenous fluid and inotrope (dopexamine) infusion during and 6 hours following surgery (n=368) or to usual care (n=366).

MAIN OUTCOMES AND MEASURES: The primary outcome was a composite of predefined 30-day moderate or major complications and mortality. Secondary outcomes were morbidity on day 7; infection, critical care-free days, and all-cause mortality at 30 days; all-cause mortality at 180 days; and length of hospital stay.

RESULTS: Baseline patient characteristics, clinical care, and volumes of intravenous fluid were similar between groups. Care was nonadherent to the allocated treatment for less than 10% of patients in each group. The primary outcome occurred in 36.6% of intervention and 43.4% of usual care participants

(relative risk [RR], 0.84 [95% CI, 0.71-1.01]; absolute risk reduction, 6.8% [95% CI, -0.3% to 13.9%]; P = .07). There was no significant difference between groups for any secondary outcomes. Five intervention patients (1.4%) experienced cardiovascular serious adverse events within 24 hours compared with none in the usual care group. Findings of the meta-analysis of 38 trials, including data from this study, suggest that the intervention is associated with fewer complications (intervention, 488/1548 [31.5%] vs control, 614/1476 [41.6%]; RR, 0.77 [95% CI, 0.71-0.83]) and a nonsignificant reduction in hospital, 28-day, or 30-day mortality (intervention, 159/3215 deaths [4.9%] vs control, 206/3160 deaths [6.5%]; RR, 0.82 [95% CI, 0.67-1.01]) and mortality at longest follow-up (intervention, 267/3215 deaths [8.3%] vs control, 327/3160 deaths [10.3%]; RR, 0.86 [95% CI, 0.74-1.00]).

CONCLUSIONS AND RELEVANCE: In a randomized trial of high-risk patients undergoing major gastrointestinal surgery, use of a cardiac output-guided hemodynamic therapy algorithm compared with usual care did not reduce a composite outcome of complications and 30-day mortality. However, inclusion of these data in an updated meta-analysis indicates that the intervention was associated with a reduction in complication rates.