CON: Perioperative Goal-Directed Fluid Therapy Is an Essential Element of an Enhanced Recovery Protocol?

Girish P. Joshi, MBBS, MD, FFARCSI,* and Henrik Kehlet, MD, PhD†

Perioperative fluid therapy is one of the major factors that influences postoperative outcome after major abdominal surgery.[1–3] Undetected (i.e., subclinical) hypovolemia and hypervolemia are associated with increased perioperative complications and prolonged hospital stay.[1–3] Fluid therapy remains one of the most controversial aspects of perioperative care. There is continuing debate with regard to the quantity and the type of fluid resuscitation during elective major surgery. Recent evidence suggests that judicious perioperative fluid therapy improves outcomes after major elective gastrointestinal surgery.[1–3]

Goal-directed fluid therapy (GDFT), assessed by an optimized cardiac stroke volume, has been proposed as the "gold standard" for perioperative fluid therapy. GDFT has been shown to reduce perioperative complications and shorten length of hospital stay.[1–3] In fact, GDFT is considered an essential element of enhanced recovery after surgery (ERAS) protocols.[4] However, we question whether GDFT is a uniformly essential element of the ERAS protocol. As we will explain below, the systematic reviews and meta-analyses that have concluded that it improves postoperative outcome including morbidity and hospital length of stay are fraught with flaws.[5] Furthermore, most of the evidence suggesting the benefits of GDFT comes from studies without the implementation of ERAS programs. Extrapolating evidence from one setting (i.e., non-ERAS) to another (i.e., ERAS program) can be misleading and result in inappropriate patient care.

CURRENT CONTROVERSIES REGARDING GDFT

The randomized controlled trials included in several systematic reviews and meta-analyses suggesting the benefits of GDFT have significant heterogeneity.[5,6] For example, the definitions of "standard" fluid therapy and GDFT varied considerably, as did the triggers for fluid bolus administration. Although most studies evaluating GDFT have used stroke volume to optimize intravascular volume, other goals included dynamic hemodynamic variables (e.g., cardiac output, cardiac index, and oxygen delivery index) and static hemodynamic variables (e.g., mean arterial blood pressure and urine output). Several of these studies, particularly the older ones, did not include individual optimization of hemodynamic goals such as fluid administration based on fluid responsiveness but used prefixed goals such as achieving a predetermined amount of oxygen delivery or a predetermined cardiac output, which may not be applicable to all patients.[5] Some studies used only fluid administration, whereas others used combinations of fluids and vasoactive drugs (e.g., dobutamine and dopexamine).

The studies also varied in the fluid bolus volume and the type of fluids administered.[7] A recent study reported wide variability in crystalloid administration within and between individual providers.[8] The authors conclude that the use of specific protocols (i.e., GDFT) may reduce variation among providers. However, even the studies evaluating GDFT have reported a wide variation in the amount of fluids administered.[8] Several studies reported a larger amount of fluids administered in the GDFT group compared with the standard of care group.[9]

The other area of variability includes the monitors used to guide fluid therapy. These include esophageal Doppler monitoring, calibrated pulse contour analyses monitor, and bioreactance-based noninvasive cardiac output monitor. Because there is poor agreement among monitors,[10,11] they are not interchangeable with regard to hemodynamic optimization within a GDFT protocol.[11]

The definitions of postoperative complications among the studies included in systematic reviews and meta-analyses vary significantly. Many studies have used composite morbidity as the primary end point although the combinations of complications including the definition of morbidity vary significantly. Most importantly, the types of complications assessed in many studies were not always the consequences of perioperative fluid management, but rather the measures of competent patient care.[5]

Some studies included variable approaches to abdominal surgery (i.e., open and laparoscopic approaches). Pain management protocols varied, and the most consequential of which being the variability in the use of epidural

From the *Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center, Dallas, Texas; and †Section for Surgical Pathophysiology, Rigshospitalet Copenhagen University, Copenhagen, Denmark.

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Address correspondence to Girish P. Joshi, MBBS, MD, FFARCSI, Department of Anesthesiology and Pain Management, University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390. Address e-mail to girish.joshi@utsouthwestern.edu.

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analgesia, which will influence fluid requirements. Even among the subjects receiving epidural analgesia, some had thoracic epidurals, whereas others had lumbar epidurals.[12]

Finally, the majority of the studies assessing GDFT did not include the ERAS principles as a part of the perioperative care.[13] Therefore, it is not surprising that the length of hospital stays in the studies do not reflect the length of stay in current ERAS clinical practice.[5]

The authors of several meta-analysis concluded that the large heterogeneity among current studies could only be resolved with large prospective clinical trials.[6] A recent large (n = 734) multicenter randomized trial in high-risk patients undergoing major gastrointestinal surgery reported that GDFT did not significantly reduce postoperative complications and 30-day mortality compared with standard care.[14] However, these authors supplemented their negative findings with previous data in a flawed meta-analysis[5] that supported the use of GDFT.[14] Another recent study also concluded that GDFT did not reduce overall postsurgical morbidity or length of stay after major abdominal surgery.[12]

GOAL-DIRECTED PERIOPERATIVE FLUID THERAPY IN THE ERAS SETTING

The ERAS or fast-track concept involves implementation of multimodal, multidisciplinary perioperative care pathways designed to reduce perioperative organ dysfunction and morbidity. These pathways foster early ambulation and reduce hospital length of stay.[15] Evidence suggests that implementation of the ERAS protocols improves perioperative outcomes and reduces health care costs.[16] The elements of an optimal ERAS program for major abdominal surgery include minimally invasive surgery (i.e., a laparoscopic approach); avoidance of mechanical bowel preparation; avoidance of overloading with fluids before administration of epidural analgesia (or preferably avoidance of epidural analgesia[17]); GDFT; aggressive postoperative nausea, vomiting, and pain prophylaxis; limitation of intraoperative and postoperative opioids by using nonopioid analgesics,[18] and avoidance of unnecessary drains and catheters.[19] Implementation of these practices reduces postoperative complications such as ileus, nausea, and vomiting; accelerates resumption of enteral feeding; and promotes early mobilization.[5]

Perioperative fluid requirements depend on multiple factors, including the patient's preoperative intravascular volume status, preoperative comorbidities, anesthetic technique, and nature of the surgery. The above-mentioned elements included in the ERAS protocol can also influence perioperative fluid balance. Fluid requirements and pathogenesis of morbidity are procedure specific. Minimal access or laparoscopic surgical approaches minimize physiological stress response and blood loss as well as reduce postoperative pain and opioid requirements. These reduce perioperative fluid shifts and fluid requirements[20] while also reducing postoperative complications. Similarly, avoidance of mechanical bowel preparation and adequate preoperative fluid intake during the fasting period including preoperative carbohydrate loading avoid preoperative dehydration. Thus, patients are less likely to be volume-depleted preoperatively.

Several ERAS recommendations should reduce intravascular volume overload and thus eliminate the need for GDFT. For example, ERAS protocols recommend elimination of fluid preload before epidural analgesia, which should limit intraoperative fluid administration without encountering intraoperative hemodynamic instability and thus avoid fluid overload.[21] Similarly, the avoidance of deep general anesthesia is recommended, which would reduce the need for higher fluid administration to maintain adequate hemodynamics and avoid fluid overload. Also, use of lung-protective ventilation with lower tidal volumes, which has become the standard of care,[22] further minimizes hemodynamic changes observed with the use of larger tidal volumes and thus limits intraoperative fluid administration.

Although epidural analgesia has been shown to provide excellent pain relief, reduce opioid requirements, and attenuate the surgical stress response, optimal multimodal analgesic techniques with nonopioid analgesics combined with regional analgesia such as surgical-site local anesthetic infiltration have been shown to provide adequate pain relief with similar postoperative outcomes.[17,18] Furthermore, epidural analgesia may induce orthostatic hypotension and limb weakness, which may delay ambulation. In fact, a recent analysis of the international, multicenter ERAS registry data found that epidural analgesia was associated with increased length of hospital stay.[23] Avoidance of epidural analgesia and associated sympathectomy may limit fluid administration and the potential for fluid overload. One of the important elements of the ERAS program is early resumption of enteral feeding and early mobilization as well as avoidance of tubes and drains, which should allow improved postoperative fluid and nutritional balance.

Given the above-mentioned considerations, fluid therapy in patients within the ERAS pathway should be different from those in the non-ERAS practice. Current evidence suggests that GDFT was more effective outside the ERAS program,[9,24] but less effective in an ERAS program, as demonstrated by double-blind randomized multicenter trials in patients undergoing elective colorectal surgery.[25,26] Another randomized controlled trial found that the use of GDFT to optimize stroke volume offered no significant benefit with respect to postoperative outcome over fluid therapy using a "zero balance" strategy (i.e., replace only the fluid that is lost during surgery) and maintaining postoperative normal body weight.[21] A carefully monitored perioperative zero balance approach may be adequate in the context of ERAS, obviating the need for GDFT.

Obviously, patients with significant comorbidities may benefit from more intense hemodynamic monitoring, but such practice would be a component of optimal anesthesia care for all types of surgical procedures, and not limited to abdominal surgical procedures.

CONCLUSIONS

Despite the significant evidence demonstrating the benefits of GDFT, there is no clear consensus about the most effective goals or the most appropriate monitoring device for guiding therapy. Several confounding factors that hinder conclusive evidence for routine use of perioperative GDFT include ERAS programs not implemented, different technologies

used for GDFT, different goals for GDFT, different GDFT protocols (fluid volume), different procedures with different fluid pathophysiology, limited data on postoperative GDFT, and limited data in specific high-risk patients. This heterogeneity has led to confusion among practitioners about which GDFT algorithm and device should be used in clinical practice. Because an optimal ERAS protocol may reduce the risk of perioperative fluid imbalance, the value of GDFT may be less in ERAS programs than in programs that do not implement ERAS principles. We submit that the "routine" use of GDFT is not only questionable, but may also lead to increased costs, inappropriate patient care, and unintended consequences.

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Name: Henrik Kehlet, MD, PhD.
Contribution: This author helped write the manuscript.
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PRO: Perioperative Goal-Directed Fluid Therapy Is an Essential Element of an Enhanced Recovery Protocol

Maxime Cannesson, MD, PhD,* and Tong J. Gan, MD†

Perioperative fluid management influences patients' outcomes. The type of fluid, the volume of fluid, and how we administer fluid all affect outcome. However, there is considerable variability in fluid administration among specialists (anesthesiologists, surgeons, nurses, perioperative physicians, and intensivists) and even within individual specialties. The volume of fluid administered to a surgical or critical care patient depends to a large extent on the individual practitioner,[1] with large interprovider and intraprovider variability.[1] Most practitioners use clinical end points such as urine output, mean arterial blood pressure, or central venous pressure that have little to do with the hemodynamic goals of fluid administration.[2] The end result is closer to random chaos than either art or science.[3]

The basic problem is that we do not know the ideal fluid volume a patient should receive during surgery. Contrary to physics, physiology is an imperfect science. Anesthesia, intensive care, and perioperative medicine are medical disciplines where level 1A evidence is rare. But it seems likely that huge interprovider variability cannot be good for our patients or for population health. Variability is the enemy of quality. Perioperative fluid administration should be standardized based on the best evidence available and on the most rational physiologic end points. We believe that perioperative goal-directed therapy is the rational approach for moderate- to high-risk patients. Put another way, if you were to undergo high-risk surgery tomorrow, would you rather be in the control (wild) group or in the goal-directed therapy group? We (MC and TJG) would want to be in the goal-directed therapy group as long as the physiologic endpoint of the goal-directed therapy group was rational and the crystalloid administration limited. We have overwhelming data to support the benefits of goal-directed therapy in high-risk patients or patients undergoing major procedures.

From the *Department of Anesthesiology and Perioperative Care, David Geffen School of Medicine at UCLA, Los Angeles, California; and †Department of Anesthesiology, Stony Brook Medicine, Stony Brook, New York.

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Address correspondence to Maxime Cannesson, MD, PhD, Department of Anesthesiology and Perioperative Care, David Geffen School of Medicine at UCLA, Ronald Regan UCLA Medical Center, 757 Westwood Plaza, Suite 3325, Los Angeles, CA 90095. Address e-mail to mcannesson@mednet.ucla.edu.

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Over the past 10 years, several meta-analyses studying the impact of goal-directed therapy versus standard of care in patients undergoing moderate and major surgeries have been conducted and published in major journals.[4–8] These meta-analyses have consistently shown that goal-directed therapy improves outcome compared with standard of care. However, some may argue that studies included in these meta-analyses are highly heterogeneous. These studies use different protocols, different physiologic end points, and different technologies to measure stroke volume and cardiac output, and these studies show that even patients in the goal-directed therapy groups received highly variable volumes of fluids. This is all true. However, we believe that this emphasizes the strength of the intervention. First, it is clear from these studies that a protocol of care is better than no protocol of care when it comes to fluid management and hemodynamic optimization. We do not know what the best end point is, but a rational physiologic goal seems better than no goal at all. Second, goal-directed therapy is not supposed to eliminate variability. No clinical pathway, protocol, or standard of care is meant to eliminate all forms of variability. Clinical care is fundamentally variable. It is expected that clinical care is variable because each patient is different. What is not desirable is variability of care related to the practitioners or the system. The whole philosophy of goal-directed therapy is that if one wants to improve hemodynamics, then give fluid whenever the patient is a responder to fluid. When the patient is not a responder to fluid and if the arterial blood pressure is still low, consider vasopressors instead. It is simple, straightforward, and rational. To apply this approach, we need to assess fluid responsiveness and/or monitor stroke volume or cardiac output. Negative studies are underpowered and conducted in relatively healthy patients with minimal blood loss.

Admittedly, there are some negative studies for goal-directed therapy, including a 2014 publication in *Anesthesia & Analgesia*.[9] This was a well-conducted multicenter study that showed no difference in outcome. In addition, Pearse et al.[5] reported the results of a multicentered randomized study showing "no improvement" in outcome in patients undergoing major surgery. However, the study by Pearse et al. is interesting in the sense that the sample size was calculated based on an expected 30-day complication incidence of 50% (yes, 50%) in the control group and a 37.5% incidence in the goal-directed group. When the study was conducted (in the United Kingdom, where enhanced recovery after surgery [ERAS] is widely popular and consistently applied nationwide for abdominal surgery), the incidence

of complications was only 43.4% in the control group and 36.6% in the goal-directed therapy group ($P = 0.07$). Thus, the initial sample size calculation was based on a much higher incidence of postoperative complications than expected, and hence, the study was underpowered to show a difference. Instead of continuing the study (which would have required more funding), the authors chose to include their results in an updated meta-analysis. In this manner, the authors demonstrated that the treatment effect was still positive. In addition, according to the authors of this study, "In the prespecified adherence-adjusted analysis conducted using established methods, the observed treatment effect was strengthened when the 65 patients whose care was non adherent were assumed to experience the same outcome as if they had been allocated to the alternative group (RR, 0.80; 95% CI, 0.61–0.99; P = 0.04)." In other words, when the goal-directed therapy protocol was consistently applied, the treatment effect was strengthened. Finally, there was no risk associated with the goal-directed therapy protocol (specifically, no increased cardiac morbidity). Several countries including the United Kingdom and France have chosen to apply this approach consistently to patients undergoing major surgery and have made it part of their national expert recommendations.[10–12]

We agree that some questions related to goal-directed fluid therapy remain incompletely answered. What is the ideal end point? What is the best technology? What should be the baseline crystalloid administration rate? What is the ideal patient population? Should goal-directed therapy protocols include inotropic support? Even though the answers to these questions are not clear, having a hemodynamic goal is better than having no goals at all. Should we wait for these questions to be answered before we adopt goal-directed therapy? Institutions and departments have protocols and standardized pathways for pain management, despite the absence of level 1A evidence. This is done to reduce variability of care and improve quality. In our view, we should do the same for hemodynamic and fluid management. We should encourage institutions that do not have an ERAS program in place to apply goal-directed therapeutic strategies, because the current evidence supports patient benefit.

We believe that goal-directed therapy has the potential to reduce length of stay in the hospital and decrease postoperative complications in patients undergoing major and high-risk surgery. In fact, recent studies using goal-directed therapy in an ERAS setting have demonstrated a reduction in length of stay and complications.[13,14]

Goal-directed therapy can rely on pulse pressure variation minimization alone, which permits use in the absence of a cardiac output monitor and in clinical settings where more advanced monitoring is not available. As a result, there is almost no incremental cost with implementing goal-directed therapy. Goal-directed therapy can improve outcome in settings where ERAS protocols are not implemented. Thus, neither the presence nor the absence of ERAS protocols should limit the application of goal-directed therapy.

One of the cornerstones of modern medicine is to increase quality of care. Variability is the enemy of quality. Standardization of fluid administration could be achieved using basic crystalloid restriction strategies in low- to moderate-risk surgery. However, for moderate- to high-risk surgeries, it is foolish to believe that crystalloid restriction alone can achieve this goal. For complex surgeries, clinicians need to follow basic physiologic end points to make fluid administration rational, consistent, and standardized. That is the main goal of perioperative goal-directed therapy. ■

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Name: Tong J. Gan, MD.
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