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British Journal of Anaesthesia **117** (1): 7–12 (2016) Advance Access publication 10 May 2016 · doi:10.1093/bja/aew067

In support of 'usual' perioperative care

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Compelling evidence from three recent large randomized controlled clinical trials (RCTs) [Protocolised Care for Early Septic Shock (ProCESS),¹ Australasian Resuscitation in Sepsis Evaluation (ARISE),² and Protocolised Management in Sepsis (ProMISe)³] led the Surviving Sepsis Campaign to update its guidelines for the initial management of patients with confirmed or suspected severe sepsis.⁴ Guidelines now recognize 'usual' non-protocolized care delivered by licensed independent practitioners as equivalent to the algorithmic early goal-directed therapy (EGDT) protocol during severe sepsis.⁴ Clinicians caring for patients around the time of major surgery may find a review of EGDT, including its initial success, current equipoise vs usual care, and potential physiological explanations for this equipoise, informative when considering whether goal-directed fluid therapy (GDFT) algorithms represent a similar paradigm with regard to perioperative haemodynamic optimization. We provide a framework in which to consider whether GDFT should be implemented routinely in perioperative settings vs usual non-protocolized care administered at the discretion of treating clinicians.

Early goal-directed therapy for severe sepsis Initial success

Early goal-directed therapy gained prominence after an influential, albeit small, RCT conducted by **Rivers** and colleagues⁵ from 1997 to 2000 at a single urban, tertiary care hospital in the USA between 1997 and 2000 that enrolled patients with suspected or confirmed severe sepsis. In this study, all subjects received arterial and central venous catheterization, critical care consultation, and emergency admission for inpatient care, with relevant specimens obtained for culture before the administration of antibiotics in the emergency department. Subjects were randomized to either a protocolized approach to resuscitation (EGDT) or to usual care. The EGDT algorithm involved titration of i.v. fluids, vasopressors, red blood cell (RBC) transfusions, or inotropes targeted toward achieving specific goals: a central venous pressure (CVP) between 8 and 12 mmHg in spontaneously breathing patients (between 12 and 15 mmHg in mechanically ventilated patients) and a central venous oximetry (Scv_{0_2}) value of >70%. In the EGDT arm, when Scv_{O2} values remained below threshold despite initial aggressive fluid therapy, clinicians were directed to transfuse RBCs (when the haematocrit was <30%), administer inotropes, or both. Results were dramatic, with EGDT improving 28 and 60 day survival by 16 and 13%, respectively, when compared with usual care.⁵ Benefit was confirmed in subsequent multicentre trials in Zhejiang, China⁶ and other low- and middle-income settings in Asia.⁷ With a low number needed to treat (one life saved for every five to six patients treated with EGDT rather than usual care), large-scale deployment of EGDT was promoted by the Surviving Sepsis Campaign.

Current equipoise

Nearly a decade later, the ProCESS, ARISE, and ProMISe trials¹⁻³ compared EGDT with non-protocolized usual care delivered during the first 6 h of treatment for suspected severe sepsis (the '6-hour bundle') by clinicians across more than 100 sites worldwide. The trials reported no difference in rates of surviva,l and this equipoise might be attributable to an increased penetration of EGDT into routine clinical practice such that usual care has started to resemble EGDT. However, the overall decline in patient fatality rates, by <u>~1% yr⁻¹ over the past decade</u>, began <mark>before</mark> widespread adoption of EGDT, suggesting that usual care was changing even before formal attempts to implement EGDT.⁸ In addition, current rates of various interventions in usual clinical practice, such as rates of RBC transfusions, central venous catheter insertion, and administration of inotropes or large volumes of i.v. crystalloids, are all significantly lower compared with EGDT (Tables 1 and 2). Consistently across time, patients receive more central venous catheters, larger i.v. fluid volumes, and more RBC transfusions¹⁻³ with EGDT compared with usual care. Meanwhile, only rates of vasopressor use have increased significantly in usual practice compared with a historical control, the 2001 usual care group in the original study by Rivers and colleagues.⁵ Based on these data (Tables 1 and 2), we can conclude that the improvement in survival with usual care has occurred with fewer RBC transfusions and central venous catheter insertions and with reductions in the administration of large volumes of crystalloids and inotropes. Potentially, care may have been escalated qualitatively (prompt antibiotics) over time rather than quantitatively (more interventions). Other explanations for improved survival rates over time have not been explored in detail but may include general improvements in the delivery of care before hospitalization and changing patterns of discharge disposition (i.e. increased rates of discharge to locations such as inpatient rehabilitation or skilled nursing facilities where death might occur after the 90 day window). Notably, the decrease in sepsis mortality over time appears significant regardless of whether the EGDT or usual care group in study by Rivers and colleagues⁵ is used as the baseline comparator.

Potential physiological explanations

The CVP and Scvo₂, along with the lactate concentration, are key surrogate measures of circulatory adequacy in the EGDT algorithm.⁵ However, CVP values *per se* have been shown to be neither sensitive nor specific in the ability to distinguish between

patients who will and will not improve perfusion with additional fluid therapy (i.e. fluid responders vs non-responders).⁹ Fluid therapy guided by a CVP value may thus be physiologically flawed. Likewise, the use of Scv₀₂ as a surrogate for adequate global oxygen delivery is <u>conditional</u> on <u>accurate location</u> of the central venous catheter in the right atrium rather than in the superior vena cava.^{10 11} Ironically, instructions for use specifically recommend against locating the tip of oximetric central venous catheters in the right atrium (Edwards Lifesciences, Irvine, CA. USA). In the absence of these quantitative proxies of global tissue perfusion, repeated focused clinical evaluation and intervention by experienced clinicians appear to be as effective. Another important physiological basis for improved survival is the early administration of antibiotics.¹² Timely antibiotic therapy with the receipt of crystalloid therapy of ~30 ml kg⁻¹ i.v. within 6 h appears to suffice physiologically.

Generalizability

Once usual care includes routine early antibiotic therapy and resuscitation with ~2 litres of i.v. crystalloids, is EGDT necessary? Based on the results of the ProCESS, ARISE, and ProMISe studies, the answer appears to be 'no'.¹⁻³ For sites with higher mortality rates at baseline or where usual care does not include timely assessment by experienced clinicians, however, it is unclear whether the added risk and expense of protocolized EGDT (oximetric central venous catheters with RBC transfusions, inotrope administration, etc.) is justified. Sites with limited resources need to consider whether care during severe sepsis would be improved by more education and training to increase the numbers of licensed independent practitioners capable of identifying and responding to tissue hypoperfusion vs investing in the dissemination of EGDT. In countries such as the USA, where computer-based decision-support tools are diffusing into practice accelerated by 'meaningful use' mandates (and the 'Health Information Technology for Economic and Clinical Health' Act), the lag between initial clinical suspicion of sepsis and treatments may be decreasing, thereby making EGDT interventions unnecessary from a cost-effectiveness perspective.13

<u>Goal-directed fluid</u> therapy for perioperative haemodynamic optimization

Initial success

Perioperative GDFT algorithms—promoting an individualized titration of i.v. fluids, typically colloid solutions, to maximize cardiac output as measured by different types of devices—proved superior to usual care in several single-centre trials.^{14–17} At the time when initial success was encountered, usual perioperative care consisted of the 'liberal' use of crystalloids (deemed necessary during major surgery to replace 'third space losses', restore blood loss, and compensate for prolonged preoperative starvation).^{18 19} In contrast to this pattern of usual care, GDFT standardized perioperative resuscitation towards reducing 'liberal' use of crystalloids among fluid non-responders and increasing the use of colloids in fluid responders.^{18 19} A variety of devices, including pulmonary artery catheters, oesophageal Dopplers, arterial waveform-based, and non-invasive transthoracic Bioreactance®-based cardiac output estimating devices have been used to guide GDFT in multiple subsequent trials using changes in stroke volume (or pulse pressure variation or other surrogates) in response to fluid boluses to guide fluid management.^{14–23}

Table 1 Randomized controlled trials of early goal-directed therapy. APACHE II, Acute Physiology and Chronic Health Evaluation II; CVC, central venous catheter; EGDT, early goal-directed therapy; PBST, protocol-based standard therapy; RBC, red blood cell

| Trial (calendar yr) | Rivers and colleagues (1997–2000) ⁵ | | ProCESS (2008–2013) ¹ | | | ARISE (2008–2013) ² | | ProMISe (2011–2013) ³ | |
|--|---|------------|---|------------|------------|--|------------|---|------------|
| Number of patients | 263 | | 1341 | | | 1600 | | 1260 | |
| Setting | Henry Ford Hospital, Detroit, MI, USA | | 31 academic hospitals in USA | | | 51 hospitals, majority in Australia and New Zealand | | 56 hospitals in England | |
| Treatment arms | EGDT | Usual care | EGDT | PBST | Usual care | EGDT | Usual care | EGDT | Usual care |
| APACHE II score | 20.4 (7.4) | 21.4 (6.9) | 20.8 (8.1) | 20.6 (7.4) | 20.7 (7.5) | 15.4 (6.5) | 15.8 (6.5) | 20 (6.9) | 19 (7.1) |
| CVC placement (%) | Standard | Standard | 93 | 57 | 58 | 90 | 62 | 92.10 | 50.90 |
| I.V. fluids administered (litres) | 5 | 3.5 | 2.8 | 3.3 | 2.3 | 2 | 1.7 | 2 | 1.8 |
| Vasopressor use (%) | 27 | 30 | 55 | 52 | 44 | 58 | 66 | 53.30 | 46.60 |
| RBC transfusion (%) | 64 | 19 | 14 | 8 | 8 | 13 | 7 | 8.80 | 3.80 |
| Inotrope use (%) | 14 | 1 | 8 | 1 | 1 | 15 | 3 | 18.10 | 3.80 |
| Primary outcome | In-hospital mortality 31 vs 47% (P=0.009) | | In-hospital death by 60 days 21 vs 18 vs 19% (P=0.31–0.89) | | | Death by 90 days 19 vs 19% (P=0.9) | | Death by 90 days 29.5 vs 29.2% (P=0.9) | |
| Secondary outcome | 60 day mortality 44 vs 57% (P=0.03) | | Death by 90 days 32 vs 31 vs 34% (P=0.66) | | | Death by 60 days 15 vs 16% (P=0.53) | | In-hospital mortality 25.5 vs 24.6% | |
| Statistical power (expected mortality) | 80% to detect 15% absolute risk reduction | | 80% to detect 6–7% absolute risk reduction (30–46% at 60 days) | | | 85–90% to detect 7.6% absolute risk reduction (38% at 90 days) | | 80% to detect 8% absolute risk reduction (40% at 90 days) | |

Table 2 Perioperative goal-directed fluid therapy. *Median volume infused in the operating room and initial 24 h in the intensive care unit. *Median volume infused during surgery and the 6 h after surgery. *Mean volume infused from enrolment until transfer to the operating room for organ procurement. CI, confidence interval; GDFT, goal-directed fluid therapy; LOS, length of stay; NA, not available

| Trial (calendar yr) | <mark>POEMAS</mark> 2014 (: | 2011–2012) ²¹ | OPTIMISE 2014 (2010–2012) ²² | | <mark>MONITOR</mark> (2009–2013) ²³ | | |
|---|---|--------------------------|--|-------------------|---|-------------------------|--|
| Number of patients | 142 | | 734 | 734 | | 556 | |
| Setting | Six tertiary hos and Israel (I undergoing abdominal s | batients major | 17 acute care hospitals in the UK (patients undergoing major abdominal | | Eight organ procurement organizations | | |
| | 0.0.0 | | surge | | ~~~~ | | |
| Perioperative interventions | GDFT | Usual care | GDFT | Usual care | GDFT | Usual care | |
| Total fluids (ml) | 5900* | 5625* | 4190 [†] | 4024 [†] | 1229 [‡] | 986 [‡] | |
| Crystalloids | NA | NA | 1506 | 2600 | NA | NA | |
| Colloids | 600 (450) | 325 (350) | 1750 | 500 | NA | NA | |
| Blood (units or ml) | 0.6 units (1.3) | 0.2 units (0.6) | 221 ml | 105 ml | NA | NA | |
| Vasopressor/inotropes (%) | NA | NA | 82.2 | 74.8 | 49.8 | 50.1 | |
| Dobutamine during operation (%) | 25 | 1.4 | NA | NA | NA | NA | |
| Dobutamine on first postoperative day (%) | 19.4 | 0 | NA | NA | NA | NA | |
| Primary outcome(s) | Overall complications 40 vs 41% (P=0.397) Hospital LOS 11.5 vs 10.5 days (P=0.874) | | Composite 30 day moderate or major complications and mortality 36.6 vs 43.4% [95% CI 0.71–1.01] | | Number of organs transplanted per donor 3.39 vs 3.29 organs per donor (P=0.56) | | |
| Secondary outcome(s) | Hospital mortal | itv | | All-cause 30 day | | 12 month survival in | |
| | 4.2 vs 5.7% (| 5 | | mortality | | transplant | |
| | | | 3.3 vs 3.0% (P> <mark>0.99</mark>) | | recipients | | |
| | | | Hospital LOS | | 7.8 vs 7.9% death | | |
| | | | | (median) | | (P= <mark>0.86</mark>) | |
| | | | • | 11 days | \- - | | |
| | | (P=0.5 | | | | | |

Current equipoise

Three large recent RCTs (POEMAS, OPTIMISE, and MONITOR) compared various versions of GDFT with usual perioperative care and, as in the RCTs on patients with severe sepsis, found that GDFT led to more interventions (more colloids, transfusions, and inotropes; Tables 1 and 2) without improvement in outcome.²¹⁻²³ Usual care is now 'restrictive' in terms of the volumes of crystalloid used as a result of a combination of increasing knowledge about the dangers of perioperative fluid overload, replacement of routine 8 h 'NPO' orders with strategies that endorse oral hydration up to 2 h before major surgery, use of selective rather than routine 'bowel preparation' before gastrointestinal surgery, and a damage-control approach to the replacement of blood loss (where the balanced use of blood products is emphasized) rather than aggressive crystalloid therapy.²⁴ Therefore, given that patients are more likely to be euvolaemic before major elective surgery and that 'liberal' fluid therapy is no longer the usual approach to perioperative care,^{21–23} neither the aggressive resuscitation of hypovolaemic volume responders nor the restriction of fluids among volume nonresponders (otherwise likely to receive 'liberal' crystalloid therapy) is afforded with GDFT. Furthermore, as in the case of sepsis, rates of adverse perioperative outcomes have also decreased significantly over the past two decades, as seen in the rates of outcomes in historical^{14–19} vs current RCTs.^{21–23}

Potential physiological explanations

A key assumption underlying GDFT is that peak cardiac performance should be reached, using i.v. fluid therapy when feasible, with the explicit goal of avoiding occult oxygen debt, maximizing global delivery of oxygen to tissues, or both.²¹⁻²³ Accordingly, individuals with demonstrable volume responsiveness during surgery (those improving stroke volumes or reducing pulse pressure variation in response to fluid boluses) would receive i.v. fluids in a GDFT algorithm as long as cardiac performance improves. However, cardiovascular physiological responses to the induction of general anaesthesia (with and without pre-emptive epidural analgesia) and the cardiorespiratory responses to tracheal intubation with the initiation of positive pressure ventilation will predictably lead to volume responsiveness. A shift in blood volume away from central (stressed) blood volume compartments to unstressed compartments is expected with the vasodilatation that accompanies anaesthesia. Likewise, the decrease in venous return from increased intrathoracic pressure during positive pressure ventilation is also expected and will respond to volume loading. Thus algorithmic GDFT, based on an assessment of volume responsiveness, will result in fluid (typically colloid) loading rather than fluid restriction. This increase in fluid therapy with GDFT, however, does not necessarily correct inadequate perfusion because perfusion may already be adequate in spite of volume responsiveness. As such, fluid therapy may merely result in an excess of supply relative to demand. As shown in the Supplementary data, Fig. 1, GDFT oriented toward maximization of stroke volume can in theory lead to three possible supply-demand scenarios. Supply can exactly meet, exceed, or fall short of demand. The underlying philosophy implicit with a GDFT approach is that an excess of supply over demand in some patients is preferred to a possible deficiency of supply relative to demand

in any patient. With changes in usual perioperative care over time now favouring euvolaemia rather than hypovolaemia before induction, the scenario of excessive (rather than deficient) supply is more likely.

Generalizability

Based on results of the POEMAS, OPTIMISE, and MOnIToR studies, should perioperative clinicians abandon GDFT?²¹⁻²³ A recent meta-analysis on pre-emptive haemodynamic optimization¹⁹ and the systematic review accompanying OPTIMISE²² reported that GDFT was associated with a reduction in the rates of perioperative complications. However, the study accounting for the most weight in current analyses, OPTIMISE, reported no difference in primary outcomes.²² More importantly, as we discussed above, 'usual' perioperative care has changed over time, but neither meta-analysis^{19 22} accounts for this heterogeneity in the patterns of usual perioperative fluid management despite including studies conducted throughout a 25 yr period (from 1988 to 2014).^{19 22} When considering whether GDFT should be implemented routinely in perioperative settings or usual non-protocolized care, administered at the discretion of treating clinicians, should be preferred, clinicians may weigh the prevalent rate of complications against the cost-effectiveness of GDFT.²⁵ If the rates of complications are aligned with historical rather than contemporary cohorts, and if the prevailing patterns of perioperative practice favour patients presenting in a hypovolaemic state, clinicians might favour GDFT. On the contrary, in settings where usual perioperative care is highly variable, quality-improvement efforts may be need to focus on the implementation of strategies to decrease unwarranted variations in perioperative fluid management practices rather than promote GDFT.

Conclusion

In conclusion, a cognitive bias that economists term 'substitution' is worthy of careful consideration by clinicians caring for patients in perioperative settings. Substitution involves the replacement of a difficult question—is fluid necessary to meet impending demand?—with a simpler but unrelated question: is volume responsiveness present? An affirmative answer to the latter question does not imply that the answer to the former question is also affirmative. As such, routine GDFT based on volume responsiveness may not offer added value beyond the usual care delivered by licensed independent practitioners.

Supplementary material

Supplementary material is available at British Journal of Anaesthesia online.

Acknowledgements

We would like to acknowledge guidance received from Drs Richard Moon and Jonathan Mark, both of whom are Professors at the Department of Anesthesiology at Duke University Medical Center.

Declaration of interest

The authors are not supported by, nor maintain any financial interest in, any commercial activity that may be associated with the topic of this article.

Funding

Institutional and departmental funds.

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British Journal of Anaesthesia **117** (1): 12–16 (2016) Advance Access publication 4 May 2016 · doi:10.1093/bja/aew106

Value of knowing physical characteristics of the airway device before using it

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For many years, there was arguably little progress at the front line of airway management, because all we had was our hands, then a classic laryngoscope, and later, a classic laryngeal mask to control the airway. Since then, the airway armamentarium has progressed in quantum leaps, particularly with the introduction of videolaryngoscopy and a wide range of supraglottic airway devices (SADs).¹ At present, SADs have collectively enjoyed an unparalleled safety record and are very popular devices in everyday practice,² with broadening indications. Globally, of the ~250 million patients undergoing major surgery under general anaesthesia on an annual basis, some 60% receive such a device to maintain a patent airway.³⁻⁵ The vast majority of anaesthetics in patients undergoing elective surgery are performed using some form of SAD. Since the initial introduction of the LMA-Classic,⁶ the evolution in supraglottic airway designs has been a continuous process.⁷ Consequently, many new characteristics have been added in an attempt to combine efficacy with safety.8 9 Some of these changes were subtle, such as from re-usable to single-use disposable, or progression from classic to flexible SAD. Other changes genuinely added innovations in functions through design, such as facilitation of tracheal intubation or facilitation of stomach decompression via an oesophageal vent.

Anaesthetists are faced with a multitude of different SADs being introduced to their clinical practice, and the problem is that many lack the evidence of efficacy and safety to inform evidence-based decision-making regarding which devices to adopt. In order to introduce new devices into clinical practice or develop an appropriate clinical trial, detailed knowledge of the physical characteristics and potential application is essential. Only by careful analysis of the design of new devices, with appropriate preclinical research and development followed by preclinical testing, can specific hypotheses be generated that are amenable to clinical testing. We demonstrate this through the recently introduced LMA-ProtectorTM, for which limited clinical evidence exists.

Faced with the concern that an increasing number of airway management devices were being introduced into clinical practice with little or no previous evidence of their clinical efficacy or safety, the Airway Device Evaluation Project Team (ADEPT) was formed by the Difficult Airway Society (DAS) in the UK in 2011.¹⁰ The ADEPT strategy proposes 'procurement pathways'