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EDITORIAL

Perioperative goal directed therapy: Evidence and compliance are two sides of the same coin

Tratamiento perioperatorio enfocado hacia los objetivos: las pruebas y el cumplimiento son las dos caras de una misma moneda

A. Joosten a,b, J. Rinehart a, M. Cannesson a,*

a Department of Anesthesiology and Perioperative Care, University of California Irvine, 101 South City Drive, Orange, CA 92868, USA
b Department of Anesthesiology and Perioperative Care, Erasme University Hospital, Free University of Brussels, 808 Route de Lennick, 1070 Brussels, Belgium

Goal directed therapy (GDT) based on the optimization of cardiac output (CO) or dynamic parameters of fluid responsiveness have been shown to improve clinical outcome and to decrease the overall cost related to major surgery.1-6 This concept has recently been recommended by professional societies in the UK,7 in France,8 and in Europe.9 The most significant implementation has been made in the UK where the National Institute of Health and Clinical Excellence has endorsed the use of CO monitoring and optimization for high-risk surgical patients and financial incentives have even been created by the National Health Service to ensure that hospitals are adopting this strategy as standard of care for at least 80% of eligible patients.10

Despite the overwhelming support for its use, there remains significant variability in practice with a low adoption of GDT protocols among clinicians.11,12 One possible reason may be that protocols are time- and attention-consuming; even under optimal study conditions, “complete” adherence to protocol is often not greater than 50%.13-15 Another explanation may be the learning curve which is expected for applying such protocols correctly in clinical practice. This learning curve and the difficulty to adhere consistently to the protocol may thus be one of the major weaknesses of this approach, a fact highlighted by the "OPTIMISE" trial.5 This large multicenter trial reported the results of high-risk patients undergoing gastrointestinal surgery who were randomized to receive usual care or GDT. The results of this study showed no difference in the primary outcome between the two groups; however, when the results were adjusted for protocol adherence, the results became significant with GDT leading to fewer postoperative complications than the control group. Because the first 10 patients of each center were excluded after this adjustment, one can presume that a large learning curve exists and that the protocols are not necessarily easy to follow in an operating room already saturated with monitors, tasks, and distractions. A last potential reason may be explained by the fact that GDT strategies have never been well standardized. Studies of GDT have used several different techniques and devices to measure and achieve goals that have also varied. Over the past few years, anesthesiologists have witnessed a virtual explosion of new mini-and non-invasive hemodynamic monitors currently available to perform protocolized GDT strategies leading to confusion about how and when to correctly use them.

Moreover, most GDT studies showing an improvement in clinical outcome were single center trials6 with a small number of included patients. The two largest multi-center randomized controlled trials have recently questioned this strategy because they suggested that GDT is not bringing benefit to surgical care,5,16 adding to existing studies showing no benefit.17-19 Even if we accept that positive papers

* Corresponding author.
E-mail address: mcanness@uci.edu (M. Cannesson).

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and results are more likely to be published than negative ones, these controversies have caused and will certainly continue to cause much ink to flow. Interest on this topic will continue to grow and stimulate the creation of many more trials in the forthcoming years.

So, now the question becomes: How do we bridge the gap between evidence-based, international recommendations, and daily clinical practice? Anesthesiologists are somewhat unique among physicians in that they routinely use technology and new medical devices in their daily activities. However, with the development of increasingly sophisticated monitoring devices, they are confronted with an ever-increasing range of hemodynamic parameters and patient data and may feel overwhelmed, especially if a GDT protocol has to be followed. A natural extension in the engineering world would be to automate the aspects of fluid administration that are amenable to machine-control based on predefined algorithm, and closed-loop hemodynamic management offers an elegant and suitable way to integrate these different data streams.

Briefly, a closed-loop system is a system wherein a controller monitors one or multiple variables and adjusts one or more interventions using a feedback process. By way of example, our group has developed an automated closed-loop fluid administration system which is designed to assist anesthesiologists by making the implementation of goal directed fluid therapy (GDFT) protocols easier and more compliant. The closed-loop system uses flow-based parameters (stroke volume, cardiac output) and/or dynamic parameters of fluid responsiveness (pulse pressure variation, stroke volume variation) from a minimally or non-invasive CO monitoring device to automatically control fluid boluses in order to apply GDT protocols consistently and with minimal provider workload. The closed-loop can easily track each bolus that has been given and from accumulated data can project the anticipated benefit of another bolus in advance. This approach has been extensively tested in simulation, engineering and in animal studies before being tested in clinical practice.

What advantages and benefits – if any – could this system bring in the operating room? Firstly, the automated closed-loop system has been shown to maintain steadier hemodynamic parameters more consistently than trained anesthesiologists in simulated as well as animal hemorrhage models. This may be explained by the timing of fluid administration: the data suggest that the closed-loop administers fluid and optimizes stroke volume earlier than anesthesiologists acting alone would otherwise do. Secondly, the closed-loop can minimize individual operator variability in titration of fluids and thus help standardize GDT delivery across providers and even institutions. Reducing variability has been shown to be a key factor in improving medical quality and patient safety. Lastly, the system can facilitate the implementation of high-quality GDFT protocols with a high adherence to the protocol compared to standard practice. By accomplishing repetitive tasks, particularly those that should be performed for hours, closed-loop applications will reduce overall provider workload, allowing more time for the anesthesiologist to focus on higher level medical decisions.

Following the bench and animal testing, we designed two clinical studies assessing the feasibility of the closed-loop system to provide high-compliance GDFT while using a minimally invasive and even a completely non-invasive CO monitoring system in patients undergoing high-risk and moderate-risk surgeries, respectively. These studies found that the closed-loop system is successful in keeping patients in a preload-independent state (defined as a pulse pressure variation <13% and/or a cardiac index >2.5 liter/min/m²) for more than 85% of the surgery time. A more recent study comparing closed loop assisted versus manual GDT management during major abdominal surgery showed that closed-loop assistance also resulted in a greater portion of case time spent in a preload-independent state when compared to manual delivery of GDT without any difference in total fluid volumes administered to patients. Further trials are still needed to examine the benefits of this closed-loop system on clinical outcomes.

Perhaps no other medical specialty has benefited more from recent technological advances than anesthesiology. With improved technologies, evidence-based GDFT, dynamic predictors of fluid responsiveness and mini-/non-invasive monitors, the time for bringing long-established engineering practices into clinical care may have finally arrived. Since GDFT approaches have recently been integrated into both the Enhanced Recovery After Surgery programs in Europe and the Perioperative Surgical Home model in the United States, the main question will be: ‘What impact could automation have on clinical practice and may this technology one day change the way GDFT is performed?’ Only time will tell, but this is undeniably both an exciting and challenging future direction. Anesthesiologists will always remain the navigator, guiding patients through the perioperative process. But, under supervision of a skilled clinician, closed-loop technology may help ensure that our chosen strategies are consistently applied, bringing to the bedside a higher level of standardization and a safer fluid administration.

References


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