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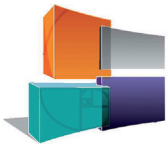

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Original article

First closed-loop goal directed fluid therapy during surgery: A pilot study

Première description de l'application du concept d'optimisation du remplissage vasculaire peropératoitre en boucle fermée : une étude pilote

J. Rinehart [a], Y. Le Manach [b,c], H. Douiri [b], C. Lee [a], M. Lilot [a], K. Le [a], C. Canales [a], M. Cannesson [a,*]

[a] *Department of anesthesiology and perioperative care, university of California Irvine, 101 S City Drive, Orange, CA 92868 Irvine, CA, USA*
[b] *Department of anesthesiology and critical Care medicine, CHU Pitié-Salpêtrière, Paris, France*
[c] *Departments of anesthesia and clinical epidemiology and biostatistics, faculty of health sciences, McMaster university and population health research institute, perioperative medicine and surgical research Unit, Hamilton, ON, Canada*

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ABSTRACT

Objective. – Intraoperative haemodynamic optimization based on fluid management and stroke volume optimization (Goal Directed Fluid Therapy [GDFT]) can improve patients' postoperative outcome. We have described a closed-loop fluid management system based on stroke volume variation and stroke volume monitoring. The goal of this system is to apply GDFT protocols automatically. After conducting simulation, engineering, and animal studies the present report describes the first use of this system in the clinical setting.
Study design. – Prospective pilot study.
Patients. – Patients undergoing major surgery.
Methods. – Twelve patients at two institutions had intraoperative GDFT delivered by closed-loop controller under the direction of an anaesthesiologist. Compliance with GDFT management was defined as acceptable when a patient spent more than 85% of the surgery time in a preload independent state (defined as stroke volume variation $< 13\%$), or when average cardiac index during the case was superior or equal to 2.5 l/min/m^2.
Results. – Closed-loop GDFT was completed in 12 patients. Median surgery time was 447 [309–483] min and blood loss was 200 [100–1000] ml. Average cardiac index was 3.2 ± 0.8 l/min/m^2 and on average patients spent 91% (76 to 100%) of the surgery time in a preload independent state. Twelve of 12 patients met the criteria for compliance with intraoperative GDFT management.
Conclusion. – Intraoperative GDFT delivered by closed-loop system under anaesthesiologist guidance allowed to obtain targeted objectives in 91% of surgery time. This approach may provide a way to ensure consistent high-quality delivery of fluid administration and compliance with perioperative goal directed therapy.

Mots clés :
Remplissage
Réponse au remplissage
Hémodynamique
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RÉSUMÉ

Objectif. – L'optimisation hémodynamique peropératoire basée sur l'optimisation du remplissage vasculaire permet d'améliorer la morbi-mortalité postopératoire au cours d'une chirurgie majeure. Nous avons décrit un système permettant d'appliquer ce concept en boucle fermée et sur la base de l'optimisation du volume d'éjection systolique et d'indices de précharge dépendance. Cette étude présente la première utilisation de ce système en clinique.
Type d'étude. – Étude pilote prospective.
Patients. – Douze patients au cours d'une chirurgie majeure.

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

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Méthodes. – L'administration du remplissage vasculaire était automatisée, basée sur l'optimisation de l'index cardiaque (IC) et d'indices de précharge dépendance (variation du volume d'éjection systolique [VVE] < 13 %) et sous la surveillance de l'anesthésiste en charge du patient. L'objectif d'optimisation était jugé atteint si le patient passait plus de 85 % du temps de la chirurgie en condition de précharge indépendance (VVE < 13 %) ou quand l'IC moyen au cours de la chirurgie était supérieur à 2,5 L/min/m^2.
Résultats. – L'optimisation était atteinte en boucle fermée sans intervention de l'anesthésiste chez les 12 patients. La durée médiane de la chirurgie était de 447 [309–483] minutes et les pertes sanguines médianes étaient de 200 [100–1000] mL. L'index cardiaque moyen était de 3,2 ± 0,8 L/min/m^2 et en moyenne les patients passaient 91 % (76 à 100 %) du temps en condition de précharge indépendance.
Conclusion. – L'optimisation du remplissage vasculaire en boucle fermée et basée sur l'optimisation du débit cardiaque et des indices de précharge dépendance permet une obtention des objectifs hémodynamiques pendant en moyenne 91 % du temps chirurgical.

1. Introduction

Intraoperative fluid and haemodynamic management based on stroke volume (SV) monitoring and optimization is an essential part of Enhanced Recovery After Surgery (ERAS) programs [1], and is recommended by the National Institute for Clinical Excellence for the management of high-risk surgery patients [2,3] and by the Société française d'anesthésie et de reanimation (Sfar) [4]. Indeed, it has been shown to improve postoperative outcomes in this setting [5,6]. The goal of this approach is to titrate fluid administration until SV reaches the plateau of the Frank-Starling relationship and to maintain SV in this range throughout the duration of the case. Despite this evidence, SV optimization is rarely applied in clinical practice [3,7].

We have recently described a novel closed-loop fluid administration and haemodynamic management system based on SV monitoring and optimization (Learning Intravenous Resuscitator: LIR) [8,9]. The goal of this system is to ease the implementation of goal directed fluid therapy (GDFT) protocols in the perioperative environment and increase the adoption of evidence-based haemodynamic strategies among clinicians [10]. The system is designed to titrate fluid administration until SV reaches the plateau of the Frank-Starling relationship and then maintain that plateau during management. To achieve this goal, the closed-loop system monitors SV, tracks volume expansion induced changes in SV, and uses pulse pressure variation (PPV) or stroke volume variation (SVV) to refine fluid responsiveness prediction [11,12]. Because closed-loop algorithms should be thoroughly evaluated before any use in the clinical setting [13–17], our system had been previously tested in simulation [8,9], engineering [18], and animal studies [19] with good results.

In the present report, we describe the first use of this system in a pilot study of 12 patients undergoing high-risk surgery. This pilot study was conducted in two institutions, each using one specific haemodynamic monitoring system in one specific type of high-risk surgery (major aortic vascular and hepatobiliary surgery respectively). The goal of this pilot study was to assess the ability of this automated system to provide acceptable GDFT. For the purpose of the present study, compliance with GDFT was defined as acceptable when a patient spent more than 85% of the case in a preload independent state (defined as a SVV < 13%), or when the average cardiac index (CI) during the case was superior or equal to 2.5 l/min/m^2.

2. Material and methods

This study was conducted between May 21st 2012 and May 25th 2012 in Paris, France and between October 20th 2012 and December 2nd 2012 in Irvine, California. Institutional Review Board approval was obtained in April 2012 for the pilot study in Paris. According to French law, research protocols that do not subject patients to a particular treatment or that require them to behave in a particular way, do not apply to the Medical Research Involving Human Subjects Act. As the closed-loop system used in this pilot study only provided evidence-based information to physicians, the institutional ethical review board (Comité de Protection des Personnes, Paris VI) waived the need for individual written consent and approved the study protocol. However, each patient was informed of the present study and could decline his or her participation. Institutional Review Board approval was obtained in September 2012 in Irvine (HS #2011–8554). All patients included in this pilot study in Irvine gave written informed consent.

Patients with arrhythmia, body mass index > 35 k/m^2, left ventricular ejection fraction < 40%, or right ventricular failure were excluded from this pilot study. All patients were equipped with a right or left radial arterial line and two peripheral IVs (18 and 14 G).

2.1. Anaesthesia protocol

In Paris, anaesthesia was induced and maintained with target-controlled infusion of propofol (2 to 4 μg.ml^{-1}) and remifentanil (1–2 ng.ml^{-1}) and all patients were paralyzed using atracurium and ventilated using volume controlled mode (tidal volume set between 6 and 8 ml/kg of ideal body weight, respiratory rate adjusted to achieve an end tidal CO_2 between 32 and 36 cmH_20, I:E ratio 1:2).

In Irvine, anaesthesia was induced with propofol (2 to 3 ml/kg) and fentanyl (2 μg/kg) and maintained with Sevorane (0.8 to 1.2 MAC) and fentanyl boluses (1 μg/kg every 30 to 45 minutes). All patients were paralyzed using cisatracurium and ventilated using volume controlled mode (tidal volume between 8 and 10 ml/kg of ideal body weight, respiratory rate adjusted to achieve an end tidal CO_2 between 32 and 36 cmH_2O, I:E ratio 1:2). Epidural anaesthesia was used for all patients and activated 30 to 45 minutes before tracheal extubation (6 to 10 ml of 0.25% bupivacaine).

2.2. Closed-loop system set-up

In Paris, a LiDCO *Rapid* monitor (LiDCO Ltd, London, UK) was connected to the Spacelabs anaesthesia monitoring system (Spacelabs Healthcare, Snoqualmie, USA and GE) through the LiDCO-supplied interface cable. The closed-loop LIR software was run on a Sony Vaio (Sony Corp, Tokyo, Japan) running Windows 7 (Microsoft Corp, Redmond, USA). The LIR system was connected with the LiDCO monitor with a USB-to-serial adapter connected to serial output port 1 on the LiDCO *Rapid*, and communication was managed with the LiDCO serial data transfer protocol (Version 1.00, dated October 16th 2009). The LiDCO *Rapid* device was set to the LiDCO Serial mode "Obs Interval Beat" so that each detected heartbeat was transferred over the serial cable (and thus no vitals