



Hemodynamic optimization through Perioperative Goal-Directed Therapy

Protocol summary



Edwards

BLANK PAGE

INSIDE FRONT COVER



Evidence-based Perioperative Goal-Directed Therapy (PGDT) protocols

This protocol summary is designed to help inform clinicians of key published protocols used to guide hemodynamic monitoring in moderate-to high-risk surgery.

It is not intended to recommend a specific protocol, but to guide hemodynamic optimization through perioperative goal-directed therapy protocols that have been shown to reduce the number of peri- and postoperative complications, and improve patient outcomes.¹⁻³

Since every case is different, physicians must weigh the risks and benefits of initiating any specific protocol.

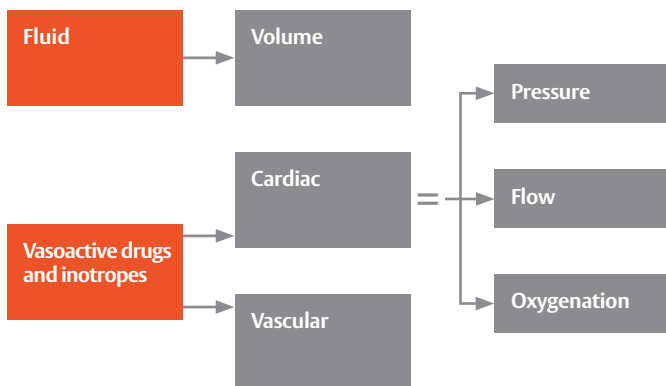
Please refer to [edwards.com/clinicaleducation](https://www.edwards.com/clinicaleducation) for updates and additional information. Issue Date: December 2018

The physiologic principles of fluid support

"A patient's physiologic status in general and hemodynamic stability in particular define the need for cardiovascular support, including fluid therapy and use of vasoactive drugs (vasopressors, vasodilators) and inotropes. Specific hemodynamic goals include maintaining adequate blood volume and sustaining perfusion pressure so as to maintain cardiac output, tissue blood flow, and adequate oxygen delivery. Fluid therapy is often the first line of hemodynamic support because decreased effective circulating blood volume often accompanies induction of anesthesia and surgical trauma. However, fluid therapy only indirectly impacts cardiac and vascular function. Optimizing oxygen delivery and assuring the removal of metabolic bioproducts may require a combination of individualized fluid therapy, pharmacotherapy, and occasionally mechanical cardiovascular support."

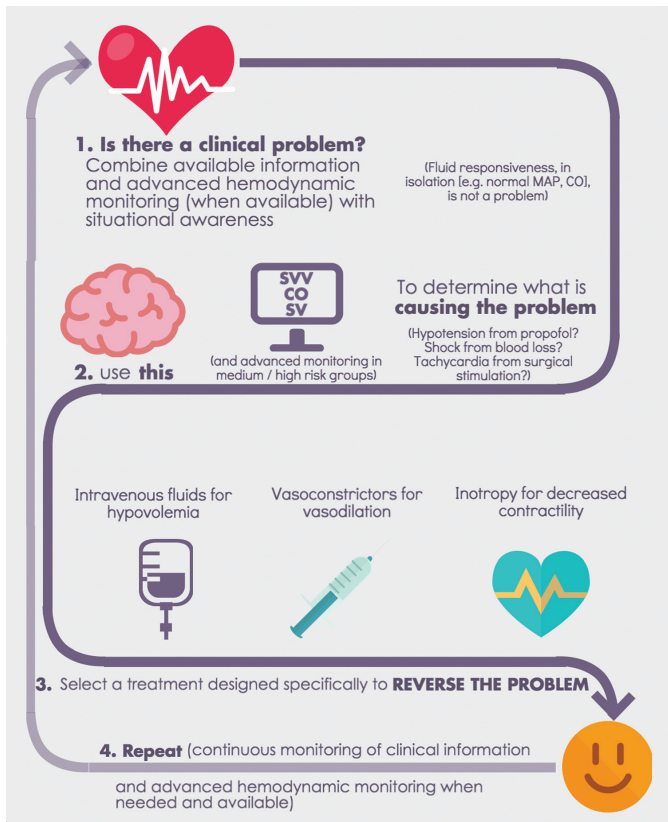
Perioperative fluid therapy: a statement from the international Fluid Optimization Group

Lais Helena Camacho Navarro, corresponding author Joshua A Bloomstone, Jose Otavio Costa Auler, Jr, Maxime Cannesson, Giorgio Della Rocca, Tong J Gan, Michael Kinsky, Sheldon Magder, Timothy E Miller, Monty Mythen, Azriel Perel, Daniel A Reuter, Michael R Pinsky, and George C Kramer



Hemodynamics Framework

by the POQI Fluids Subgroup
a rational, step-wise approach



American Society for Enhanced Recovery (ASER) and Perioperative Quality Initiative (POQI) joint consensus statement on perioperative fluid management within an enhanced recovery pathway for colorectal surgery

Robert H. Thiele¹, Karthik Raghunathan², C. S. Brudney³, Dileep N. Lobo⁴, Daniel Martin⁵, Anthony Senagore⁷, Maxime Cannesson⁸, Tong Joo Gan⁹, Michael Monty G. Mythen¹⁰, Andrew D. Shaw¹¹, Timothy E. Miller^{12*} and For the Perioperative Quality Initiative (POQI) I Workgroup

[illegible]



Pressure and Flow-based Protocols

Overview

Study design

Multicenter randomized controlled trial

Patient population

Low-to moderate risk patients undergoing major elective surgery (abdominal, urological, gynecological or orthopedic)

Target parameters

Stroke volume, cardiac index, mean arterial pressure

Intervention

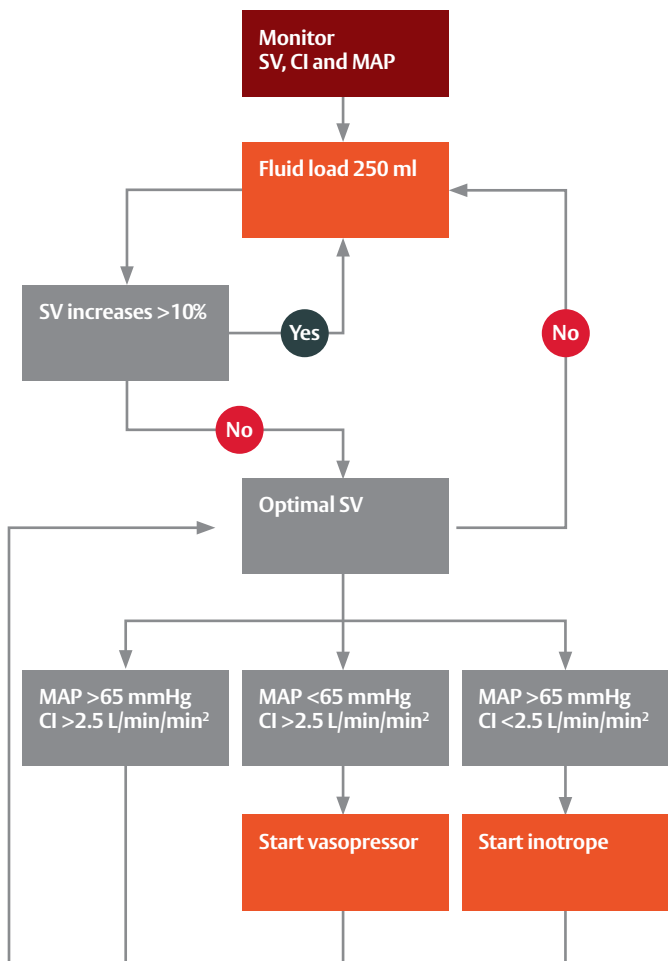
Fluid, vasopressors, inotropes

Primary outcomes

Decrease in postoperative complications (8.6% vs 16.6%) and decrease in hospital length of stay (4-10 days vs 5-12 days)

A total of 450 patients participated in this study

During the intraoperative period, patients randomized to the control group received continuous infusion of balanced crystalloid fluids (Ringer's lactate) at 3-5 ml kg/ h for laparoscopic surgery, or 5-7ml kg/ h for open surgery



Overview

Study design

Single-center randomized controlled trial

Patient population

Undergoing head and neck oncologic surgery with primary FTT (free tissue transfer) reconstruction

Target parameters

Stroke volume variation, cardiac index, systemic vascular resistance, mean arterial pressure

Intervention

Fluid, vasopressor, inotrope

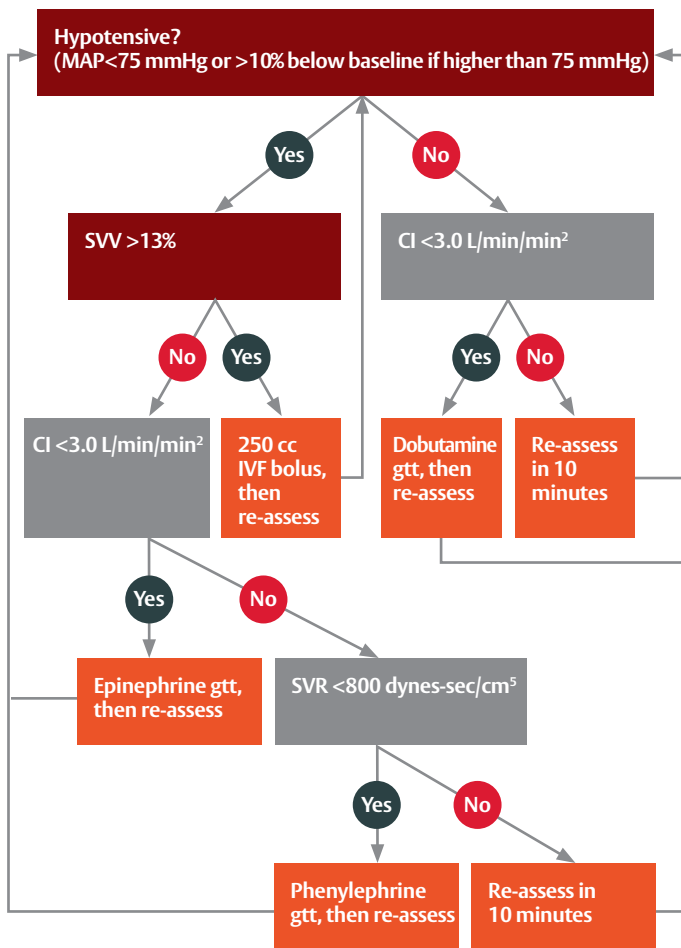
Primary outcomes

Decrease in ICU length of stay (1.4 days vs 2.4 days)
and decrease in duration of mechanical ventilator requirement
(1.72 days vs 0.81 days)

A total of 94 patients participated in this study

Maintenance of plasmalyte-A was administered based on the patient's body weight and estimated evaporative losses based on incision

Albumin (25%) was given if the patient's preoperative albumin is <2.5 g/dL based on the following formula: $(2.5 \text{ g/dL} - \text{actual albumin g/dL}) \times \text{weight (kg)} \times 0.8$



Overview

Study design

Randomized, controlled trial

Patient population

Undergoing elective craniotomy for brain tumor resection, brain abscess or intracranial aneurysm

Target parameters

Cardiac index, stroke volume variation, mean arterial pressure

Intervention

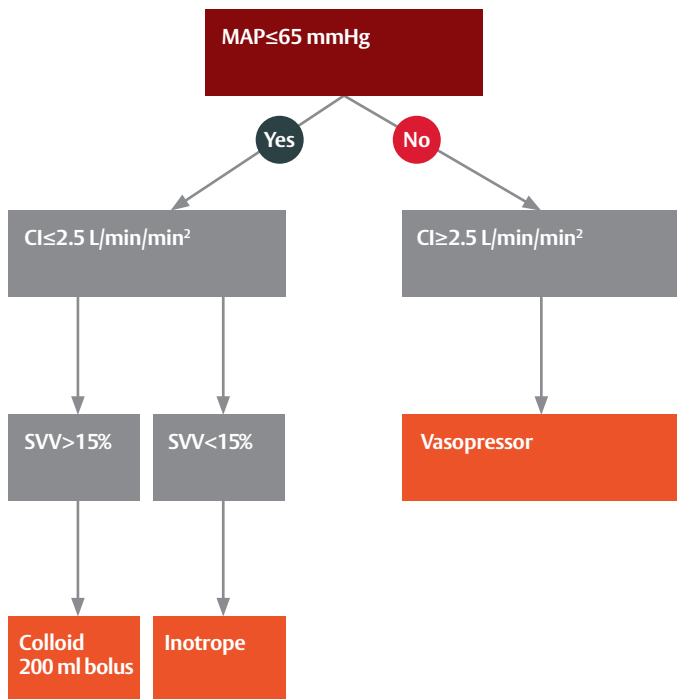
Fluid (colloid), vasopressor, inotrope

Primary outcomes

Decreased ICU length of stay (3 days vs 6 days) and decrease in total number of postoperative complications (46 vs 99)

A total of 145 patients participated in this study

Maintenance fluid: crystalloid 3 mL/kg/hr, with a maximum of 2 colloid boluses in the case of hypotension with low CI and high SVV



Overview

Study design

Single-center randomized controlled trial

Patient population

Undergoing major cardiac surgery with the use of cardiopulmonary bypass and at high risk for AKI (acute kidney injury)

Target parameters

Stroke volume variation, cardiac index, mean arterial pressure

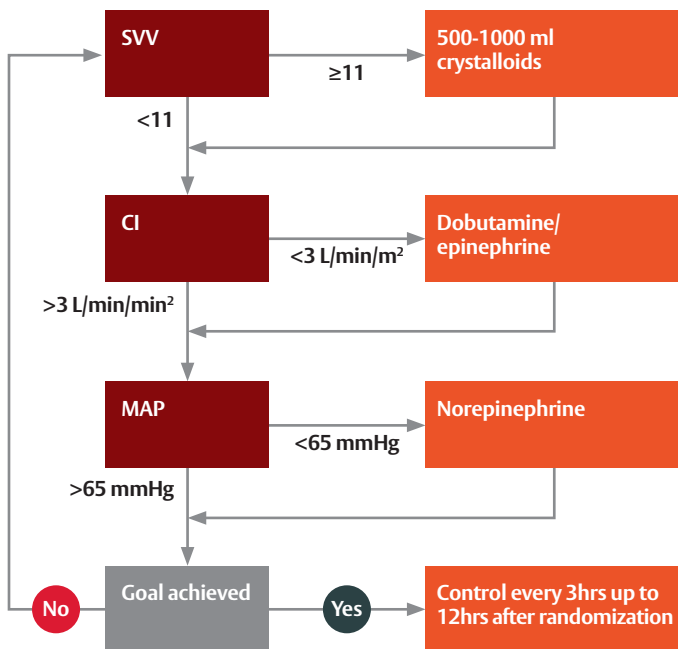
Intervention

Fluid, vasopressor, inotrope

Primary outcomes

Decrease in occurrence of AKI within 72 hours after surgery
(55.1% vs 71.7%)

A total of 276 patients participated in this study



Overview

Study design

Randomized, controlled trial

Patient population

High-risk patients undergoing coronary artery bypass surgery or valve repair

Target parameters

Cardiac index, stroke volume index, central venous pressure

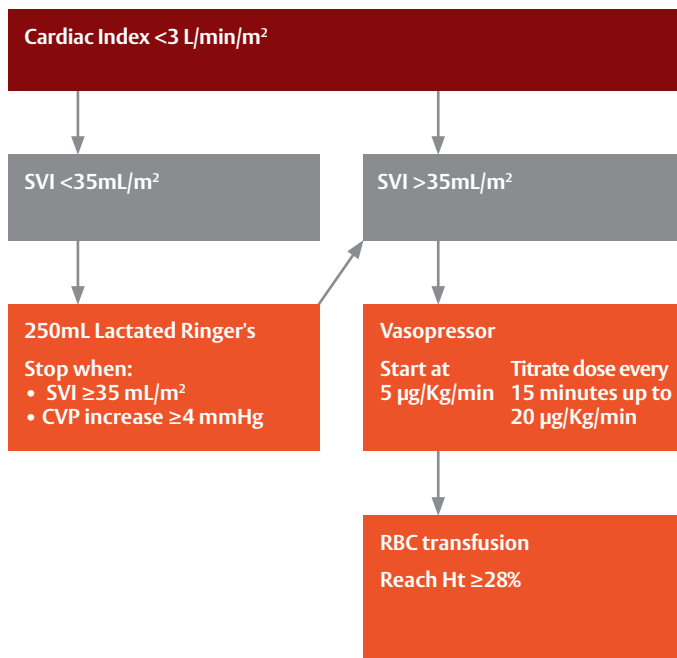
Intervention

Fluids, inotropes, RBC transfusions

Primary outcomes

Decrease in overall rate of complications (11% vs 22%) and decrease in hospital length of stay (9 days vs 12 days)

A total of 126 patients participated in this study



Overview

Study design

Randomized, controlled trial

Patient population

Undergoing elective major orthopedic surgery including total hip arthroplasty, spinal fusion surgery, femoral fracture surgery and sacral tumor surgery and with an anticipated blood loss >800 ml

Target parameters

Stroke volume variation, MAP, HR, CVP, urine output

Intervention

Fluid (colloid)

Primary outcomes

Decreased volume of intraoperative fluids, maintained intraoperative hemodynamic stability and improved perioperative gastrointestinal function

A total of 80 patients participated in this study

Maintenance fluid: crystalloid 5ml/kg/hr

Goal-directed therapy to maintain MAP $>65\text{mmHg}$, HR $<100\text{bpm}$, CVP $8\text{-}14\text{ mmHg}$, urine output $>0.5\text{ ml/kg/h}$ and an SVV $\leq 10\%$ (supine position) or $\leq 14\%$ (prone position)

SVV $>10\%$ (supine position) or $>14\%$ (prone position)

Yes

Colloid 4 ml/kg
bolus over 5 mins

No

Re-evaluate every 5 minutes

Overview

Study design

Single-center, prospective, randomized trial

Patient population

ASA II & III patients undergoing cytoreductive surgery (CRS) with hyperthermic intraperitoneal chemotherapy (HIPEC)

Target parameters

Cardiac index, stroke volume index, stroke volume variation

Intervention

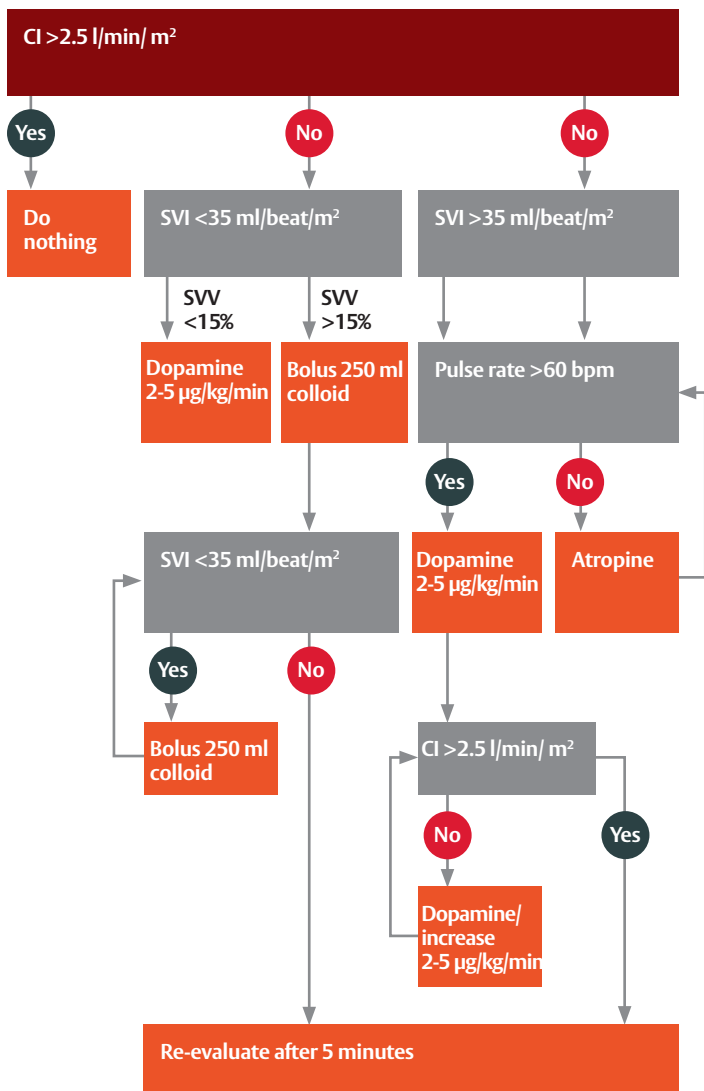
Fluid (colloid), inotrope, chronotrope

Primary outcomes

Decrease in postoperative major abdominal complications (10.5% vs 38.1%) and decrease in hospital length of stay (19 days vs 29 days)

A total of 80 patients participated in this study

Maintenance fluid crystalloid 4ml/kg/h



Overview

Study design

Quality improvement program
(before-after comparison)

Patient population

Undergoing emergency or elective abdominal, orthopedic, gynecologic, urologic or vascular surgery

Target parameters

Stroke volume

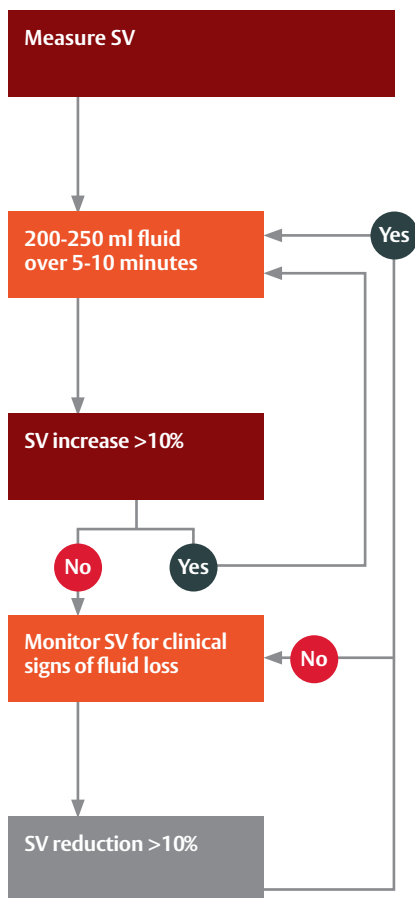
Intervention

Fluid

Primary outcomes

3.7-day decrease in hospital length of stay (25%)

A total of 1,307 patients participated in this study



Overview

Study design

Prospective quality improvement study

Patient population

Undergoing open colectomy, pancreatectomy, pelvic surgery with cancer debulking or liver resection and equipped with an arterial line

Target parameters

Stroke volume variation, blood pressure, cardiac index

Intervention

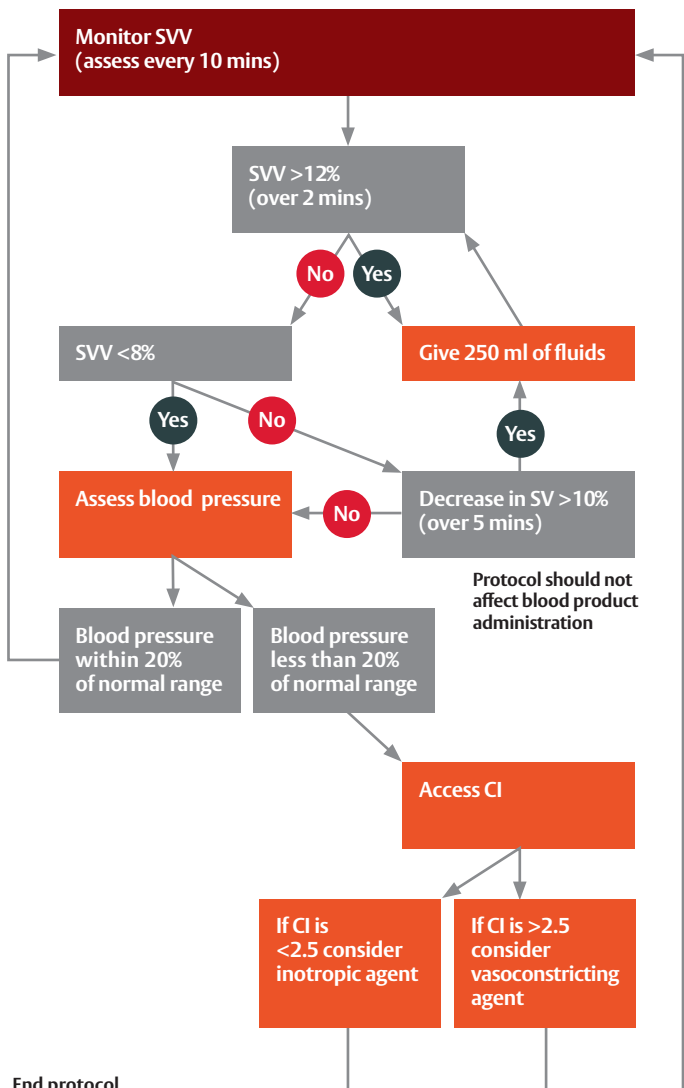
Fluid

Primary outcomes

Decrease in hospital length of stay by 18% and decrease in ICU length of stay by 16%

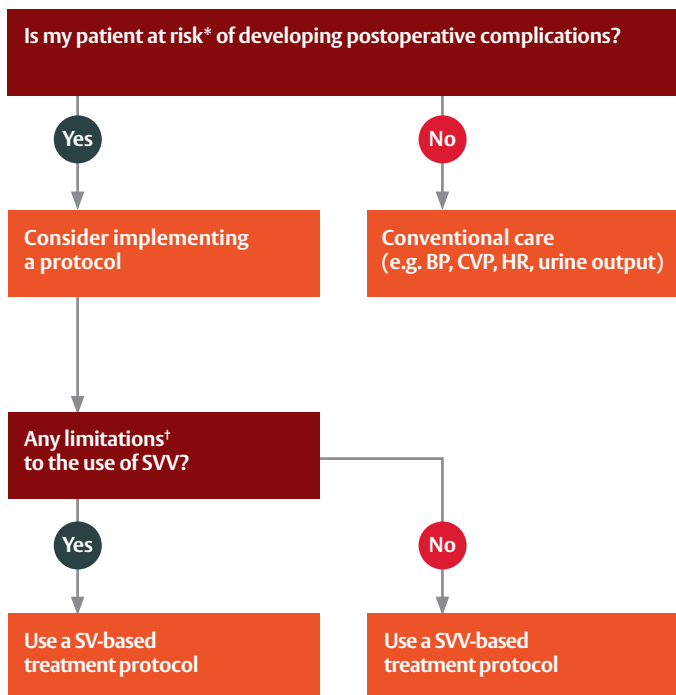
A total of 327 patients participated in this study

Maintenance fluid: crystalloid 3cc/kg/hr



Application of stroke volume versus stroke volume variation protocols

The following algorithm is provided to help you select the most appropriate perioperative goal-directed therapy (PGDT) protocol for your patient. When choosing a protocol, the clinician should consider method of ventilation as well as other patient variables (positioning, minimally-invasive surgery, etc.).



*At risk due to comorbidities or the surgical procedure itself.

†Factors that may impact reliability of SVV: Spontaneous breathing, tidal volume <8 ml/kg, open chest, cardiac arrhythmias, right ventricular failure and abdominal pressure.

Abbreviations: BP: Blood Pressure; CVP: Central Venous Pressure; HR: Heart Rate; SV: Stroke Volume; SVV: Stroke Volume Variation.

References

Protocol summaries

1. Calvo-Vecino J, Ripolles-Melchor J, Mythen M, Casans-Frances R, Balik A, Artacho J, Martinez-Hurtado E, Serrano Romero A, Fernandez Perez C, Asuero De Lis S. Effect of goal-directed haemodynamic therapy on postoperative complications in low-moderate risk surgical patients: a multicentre randomised controlled trial (FEDORA trial). *BJA*. 2018. doi:10.1016/j.bja.2017.12.2018.
2. Hand W, Stoll W, McEvoy M, McSwain J, Sealy C, Skoner J, Hornig J, Tennant P, Wolf B, Day T. Intraoperative goal-directed hemodynamic management in free tissue transfer for head and neck cancer. *Wiley Online Library* [published 2016]. doi: 10.1002/hed.24362.
3. Luo J, Xue J, Liu J, Liu B, Liu L, Chen G. Goal-directed fluid restriction during brain surgery: a prospective randomized controlled trial. *Ann. Intensive Care* 2017. doi:10.1186/s13613-017-0239-8.
4. Meersch M, Schmidt C, Hoffmeier A, Van Aken H, Wempe C, Gerss J, Zarbock A. Prevention of cardiac surgery-associated AKI by implementing the KDIGO guidelines in high risk patients identified by biomarkers: the PrevAKI randomized controlled trial. *Intensive Care Med*. 2017. doi:10.1007/s00134-016-4670-3.
5. Osawa E., Rhodes A, Landoni G, Filomena G, Fukushima J, Park C, Almeida J, Nakamura R, Strabelli T, Pileggi B, Leme A, Fominskiy E, Sakr Y, Lima M, Franco R, Chan R, Piccioni M, Mendes P, Menezes S, Bruno T, Gaiotto F, Lisboa L, Dallan L, Hueb A, Pomerantzeff P, Filho R, Jatene F, Auler J, Hajjar L. Effect of perioperative goal-directed hemodynamic resuscitation therapy on outcomes following cardiac surgery: a randomized clinical trial and systematic review. *Society of critical care medicine and wolters kluwer heath inc*. 2016. doi: 10.1097/CCM.0000000000001479
6. Peng K, Li J, Cheng H, Ji F. Goal-directed fluid therapy based on stroke volume variations improves fluid management and gastrointestinal perfusion in patients undergoing major orthopedic surgery. *Med Princ. Prat*. 2014. doi: 10.1159/000363573.

Flow-based protocols

7. Colantonio L, Claroni C, Fabrizi L, Marcelli M, Sofra M, Giannarelli D, Garofalo A, Forastiere E. A randomized trial of goal directed vs standard fluid therapy in cytoreductive surgery with hyperthermic intraperitoneal chemotherapy. *J Gastrointest Surg*. 2015. doi: 10.1007/s11605-015-2743-1.
8. Kuper M, Gold SJ, Callow C, et al. Intraoperative fluid management guided by oesophageal Doppler monitoring. *BMJ*. 2011;342:d3016.
9. Cannesson M, Ramsingh D, Rinehart J, Demirjian A, Vu T, Vakharia S, Imagawa D, Yu Z, Greenfield S, Kain Z. Perioperative goal-directed therapy and postoperative outcomes in patients undergoing high-risk abdominal surgery: a historical prospective, comparative effectiveness study. *et al. critical care* 2015. doi: 10.1186/s13054-015-0945-2.

Edwards provides this information for your convenience. It is not intended to describe, recommend, or suggest any use, feature, or benefit of Edwards products and does not constitute any medical advice. The information provided is not meant to be a substitute for professional advice and is not to be used alone for medical diagnosis or medical treatment. Medicine is an ever-changing science. As new research and clinical experience broaden our knowledge, changes in treatment and drug therapy are required. In view of the possibility of human error or changes in medical sciences, Edwards cannot warrant that the information is in every respect accurate or complete, and Edwards thus cannot be responsible for any errors or omissions or the results obtained from the use of such information. Extensive effort has been exerted to make this information as accurate as possible. However, the accuracy and completeness of the information provided cannot be guaranteed. This is to be used as a guide only, and healthcare professionals should use sound clinical judgment and individualize therapy to each specific patient care situation. Edwards makes no claims whatsoever, expressed or implied, about the authenticity, accuracy, reliability, completeness, or timeliness of the material, calculations, software, text, graphics, or other information given.

Notes:

[illegible]

[illegible]

Edwards, Edwards Lifesciences and the stylized E logo are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2018 Edwards Lifesciences Corporation.
All rights reserved. PP--US-3037 v1.0

Edwards Lifesciences • edwards.com
One Edwards Way, Irvine CA 92614 USA



Edwards