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ORIGINAL RESEARCH

Monitoring of pulse pressure variation using a new smartphone application (Capstesia) versus stroke volume variation using an uncalibrated pulse wave analysis monitor: a clinical decision making study during major abdominal surgery

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Abstract

Pulse pressure variation (PPV) and stroke volume variation (SVV) can be used to assess fluid status in the operating room but usually require dedicated advanced hemodynamic monitors. Recently, a smartphone application (Capstesia™), which automatically calculates PPV from a picture of the invasive arterial pressure waveform from any monitor screen (PPV_{CAP}), has been developed. The purpose of this study was to compare PPV_{CAP} with SVV from an uncalibrated pulse wave analysis monitor (SVV_{PC}). In 40 patients undergoing major abdominal surgery, we compared PPV_{CAP} with SVV_{PC} at post-induction, pre-incision, post-incision, end of surgery, and during every hypotensive episode (mean arterial pressure < 65 mmHg). We classified PPV_{CAP} and SVV_{PC} into three categories reflecting the thresholds used for the decision to administer fluids: no fluid administration (PPV and SVV < 9%), gray zone (PPV and SVV 9–13%), and fluid administration (PPV and SVV > 13%). The agreement between SVV_{PC} and PPV_{CAP} for these three categories was measured by the number of concordant paired measurements divided by the total number of paired measurements and Cohen's kappa coefficient. In the 549 pairs of PPV–SVV data obtained, the overall agreement of PPV_{CAP} with SVV_{PC} was 79%, and the kappa coefficient was moderate (0.55). The highest agreement and kappa coefficient value were observed after the induction of anesthesia before surgical incision. PPV_{CAP} and SVV_{PC} would have resulted in completely opposite clinical decisions regarding fluid administration in 1% of the cases. In this clinical decision making study in patients undergoing major abdominal surgery, we observed a moderate agreement between PPV_{CAP} and SVV_{PC} with regard to categories used to guide fluid administration.
Trial Registration: Clinical Trials.gov (NCT03137901).

Keywords Mobile technology · Feature extraction technology · Monitoring · Fluid responsiveness

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1 Introduction

Hemodynamic instability occurs frequently during major surgical procedures and requires rapid correction based on underlying pathophysiologic alterations. It is therefore important to be able to rapidly evaluate to what extent hypovolemia, decreased vasomotor tone and impaired ventricular function contribute to the impaired cardiovascular status and, in turn, to decide whether fluids, vasopressors or inotropes should be given. Prediction of fluid responsiveness (i.e., whether an increase in cardiac preload by fluid administration will result in an increase in blood flow) is a key element in this process.

Variations in the arterial blood pressure waveform [pulse pressure variation (PPV) and stroke volume variation (SVV)] can be used to predict fluid responsiveness in patients with sinus rhythm and controlled mechanical ventilation [1–5] and have formed an integral part of various goal-directed therapy protocols during surgery [6–10]. Hand measurement of PPV is not practical and assessment solely by visual estimation is quite unreliable [11]. Because PPV is not routinely displayed on patient monitors, its continuous determination usually requires a dedicated (often costly) advanced hemodynamic monitoring system.

Recently, a new smartphone application, called Capstesia™ (Galenic App, Vitoria-Gasteiz, Spain) has been developed to automatically calculate PPV from a digital picture of the arterial blood pressure waveform from any monitor screen [12]. In an initial simulation study, we showed that PPV calculated using the Capstesia™ application (PPV_{CAP}) was a valid substitute for PPV calculated manually [13]. Recently, we demonstrated that PPV_{CAP} was a weak predictor of fluid responsiveness in patients undergoing cardiac surgery, but that prediction of fluid responsiveness was reliable before cardiopulmonary bypass [14]. Lastly, Shah et al. demonstrated a close correlation between SVV from the Vigileo and PPV_{CAP} in patients undergoing cancer surgery [15].

The goal of this observational study was to compare PPV_{CAP} with SVV derived from a minimally invasive pulse wave analysis technology (SVV_{PC}) in patients undergoing major open abdominal surgery. Our hypothesis was that using either PPV_{CAP} or SVV_{PC} would result in identical clinical decisions regarding fluid administration.

2 Materials and methods

2.1 Ethics, study design and setting, patient enrollment

Following approval by the institutional ethics committee on April, 6 2017 (Ethics Committee approval number: P2017/224) and registration on May 3, 2017 at clinicaltrials.gov (NCT03137901—PI: Alexandre Joosten) this prospective method comparison study was conducted from May 10, 2017 throughout June 30, 2017 in the Department of Anesthesiology, Erasme University Hospital, Université Libre de Bruxelles, Brussels, Belgium. Patients were eligible for inclusion in the study if they were over 18 years of age, scheduled for elective major abdominal surgery (including pancreatectomy, cystectomy, nephrectomy, adrenalectomy, and prostatectomy), and were equipped with a radial arterial catheter for clinical reasons not related to the study. Exclusion criteria were abdominal laparoscopic surgery, pregnancy, presence of significant valvular heart disease, cardiac arrhythmias, and left ventricular ejection fraction < 30%. All patients signed informed consent.

2.2 Induction and maintenance of general anesthesia

All patients received spinal analgesia with 300 µg of morphine (according to the hospital guidelines for open major abdominal surgery). Bispectral electrodes were placed on the forehead and connected to a depth of anesthesia monitoring (BIS™ monitor; Aspect Medical System Inc, Natick, MA, USA). Anesthesia was induced with sufentanil (0.2 µg/kg), propofol (2 mg/kg) and rocuronium (0.6 mg/kg) and maintained with sevoflurane or desflurane and sufentanil boluses. Any necessary adjustments to anesthetic delivery were made at the discretion of the primary anesthesia providers to keep the BIS level stable between 40 and 60. All patients were mechanically ventilated using a volume control mode with a tidal volume of 7–8 mL/kg of predicted body weight and a positive end expiratory pressure of 5 cm H_2O using the Zeus Infinity C700 Anesthesia workstation machine (Dräger Medical GmbH, Lübeck, Germany). Respiratory rate was adjusted to achieve an end tidal partial pressure of carbon dioxide between 32 and 36 cmH_2O.

All patients were monitored with a five-lead electrocardiogram, heart rate, pulse oximetry, and a radial arterial catheter linked to a minimally invasive pulse wave analysis monitor via the Flotrac™ sensor (EV1000; Edwards Lifesciences, Irvine, CA, USA). The EV1000 monitor has been

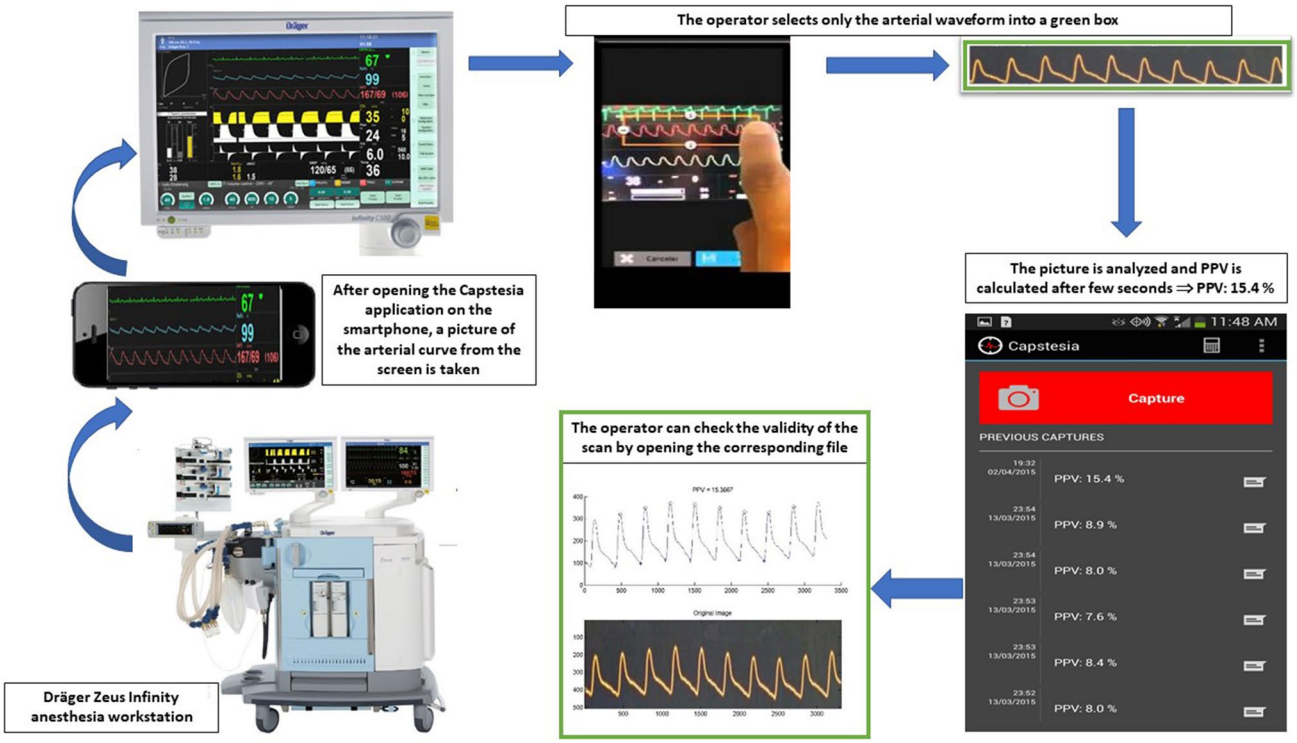

Fig. 1 Steps to obtain a PPV_{CAP} value. PPVCAP = pulse pressure variation calculated by the Capstesia™ application

implemented in our academic university hospital since April 2015 and is now the gold standard to guide fluid therapy in patients undergoing major abdominal surgery. Fluid administration consisted in a baseline balanced crystalloid (Plasmalyte, Baxter, Belgium) infusion at 3 ml/kg/h and additional 250 ml colloid bolus (Volulyte, Fresenius Kabi GmbH, Germany) when SVV is > 13% (Supplemental Fig. 1 describes the hemodynamic protocol used in our institution).

2.3 Assessment of SVV using invasive pulse wave analysis

The EV1000 monitor automatically calculates SVV by using the maximum and minimum stroke volume in a ventilation cycle. Then, the SVV value displayed on the EV-1000 screen is averaged for all ventilation cycles in a 20-s window (corresponding to three–five respiratory cycle). EV1000 calculates stroke volume from pressure waveform characteristics and is not a direct measure of flow; however, SVV is commonly used for clinical decision-making with regard to fluid administration [6, 8, 10, 16–18].

2.4 Assessment of PPV using the Capstesia smartphone application

The Capstesia application was downloaded on a Samsung S4™ (Samsung Electronics Co., Ltd., Samsung Town, Seoul), which has a 13 megapixel photo camera. The method used to measure PPV from the cropped picture of the arterial waveform has been described in detail previously [13]. Briefly, after taking a photograph of the arterial waveform on the monitor screen and cropping it to the signal of interest, the picture is sent to the Capstesia™ server via a mobile internet connection. After a few seconds, the PPV_{CAP} is displayed on the smartphone interface (Fig. 1). We checked each image to identify obvious processing errors. Care was taken to ensure that at least eight arterial peaks were included in each image, thus enabling an entire respiratory variation of the arterial curve to be analyzed. The sweep speed of the patient monitor was changed from 25 mm/sec (standard setting) to 12.5 mm/sec prior to taking the photo.

2.5 Study measurements

We performed measurements at five different time points: post-induction, pre-incision, post-incision, end of surgery, and during every hypotensive episode (defined as mean arterial pressure < 65 mmHg). At each time point, we took three pictures of the patient's monitor screen displaying the arterial waveform with the Capstesia™ application to create three PPV_{CAP} raw values (corresponding to the average of three respiratory cycles). Simultaneously, we recorded the three corresponding SVV values (corresponding to the average of nine–fifteen respiratory cycles).

2.6 Statistics

Patient characteristics are presented as median and [25th and 75th] percentiles for continuous data and as absolute and relative frequencies for categorical data.

To investigate the value of PPV_{CAP} with regard to clinical decision making (using SVV_{PC} as the reference), we used two strategies:

First, we classified PPV_{CAP} and SVV_{PC} into three different categories reflecting thresholds used for the decision to administer fluids in clinical practice: no fluid administration (PPV and SVV < 9%), a gray zone of uncertainty (PPV and SVV 9–13%), and fluid administration (PPV and SVV > 13%) [19]. The agreement between SVV_{PC} and PPV_{CAP} for these three categories was measured by (a) the accuracy (i.e., the number of concordant paired measurements divided by the total number of paired measurements) and (b) Cohen's kappa. A Cohen's kappa value of < 0 indicates no agreement, 0–0.20 slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1.00 almost perfect agreement [20]. Second, we used an alternating regressions approach to model the conversion of methods, i.e., the agreement of methods under the assumption of a constant bias. The probabilities P ($SVV_{PC} < 9 \mid PPV_{CAP}$), P ($9 < SVV_{PC} < 13 \mid PPV_{CAP}$) and P ($SVV_{PC} > 13 \mid PPV_{CAP}$) that the SVV_{PC} value (reference method) is truly within one of the three categories given an observed PPV_{CAP} value (test method) were assessed from the corresponding model [21]. The chosen sample size of 40 coincides with general recommendations about the required sample size to obtain stable results [21]. Statistical analyses were performed using R 3.4.3 (R Foundation for Statistical Computing, Vienna, Austria) and the MethComp package for alternating regression analysis.[1].

[1] Carstensen et al. [22]

Table 1 Distribution of PPVCAP and SVVPC values according to the three predefined categories

Time points	SVV_{PC}	PPV_{CAP}		
		< 9	9–13	> 13
Overall	< 9	333	27	2
	9–13	64	67	14
	> 13	3	4	35
Post-induction				
	< 9	82	8	0
	9–13	5	13	3
	> 13	2	1	6
Pre-incision				
	< 9	84	2	0
	9–13	16	12	2
	> 13	0	0	4
Post-incision				
	< 9	79	6	1
	9–13	19	12	3
	> 13	0	0	0
End of surgery				
	< 9	58	7	1
	9–13	19	16	2
	> 13	0	0	11
Hypotension				
	< 9	30	4	0
	9–13	5	14	4
	> 13	1	3	14

PPV_{CAP} pulse pressure variation calculated using the Capstesia™ application, *SVV_{PC}* stroke volume variation derived from invasive uncalibrated pulse contour analysis

3 Results

We recorded 549 pairs of PPV-SVV data in 40 patients (median [25th and 75th] percentiles) age 65 [55–73] years; median weight 70 [63–83] kg; median height 169 [161–179] cm; median body mass index 25 [23–28] kg/m^2. The median tidal volume (predicted body weight) was 7.5 [7.1–7.6] ml/kg. The number of hypotensive episodes was 28 among the 40 patients.

The overall agreement between PPV_{CAP} and SVV_{PC} was 79% and the Kappa coefficient 0.55. The distribution of PPV_{CAP} and SVV_{PC} values according to the three predefined categories is shown in Table 1, and the diagnostic accuracy and Kappa coefficient for each time point in Table 2. The highest agreement and kappa coefficient were observed after the induction of general anesthesia and before surgical incision (accuracy 84%, kappa 0.61). Using PPV_{CAP} or SVV_{PC} would have resulted in completely opposite clinical decisions regarding fluid administration in only 1% of all

Table 2 Diagnostic accuracy and kappa value

	Overall	Post-induction	Pre-incision	Post-incision	End of surgery	Hypotension
Diagnostic accuracy	79%	84%	83%	76%	75%	77%
Kappa value	0.55	0.61	0.55	0.35	0.52	0.65

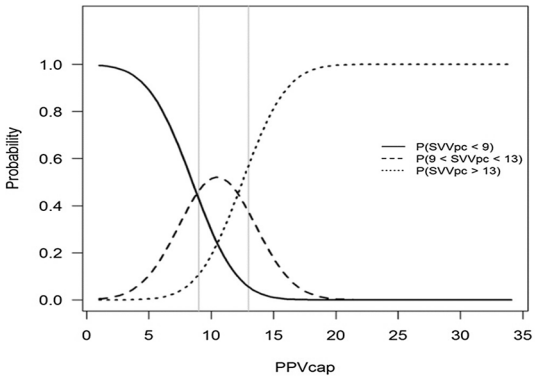

Fig. 2 Plot of the probability of SVV_{PC} categories depending on the measured PPV_{CAP} value. This figure shows the probability that the SVV_{PC} value is actually within one of the three categories given a measured PPV_{CAP} value. Example how to read the figure: When the PPV_{CAP} is 15%, the probability that the SVV_{PC} is < 9% is close to 0%, the probability that the SVV_{PC} is 9–13% is around 20%, and the probability that the SVV_{PC} is > 13% is around 70%

measurements. In the remaining disagreements, one of the two variables measured was in the gray zone.

The probability that the actual SVV_{PC} value was within one of the three categories given a PPV_{CAP} measurement is displayed in Fig. 2.

4 Discussion

In this study, we compared PPV_{CAP} and SVV_{PC} to guide fluid administration in patients undergoing major abdominal surgery. For the three clinically relevant PPV–SVV categories (PPV–SVV < 9%, 9–13%, and > 13%), we observed an overall agreement of 79% and a moderate agreement according to Cohen's kappa coefficient. At all measurement time points, Cohen's kappa coefficient indicated fair, moderate or substantial agreement [20].

This is the first study comparing clinical decision making assessing PPV_{CAP} with SVV_{PC} from an uncalibrated pulse wave analysis monitor in patients undergoing major open abdominal surgery. We previously showed that PPV_{CAP} was a valid substitute for manually calculated PPV in a simulation study [13]. However, this simulation study was performed under carefully "standardized" conditions, used a fixed distance of the smartphone camera from the screen displaying the waveform, and only analyzed consistent arterial blood pressure waveforms not influenced by changes in vascular tone or heart rate variability. Recently, we have also tested PPV_{CAP} before a fluid challenge in patients undergoing cardiac surgery. Our main finding was that PPV_{CAP} was able to predict fluid responsiveness before cardiopulmonary bypass, comparably to PPV measured by an invasive calibrated pulse wave analysis device. Finally, Shah et al. recently assessed PPV_{CAP} in oncosurgical patients before skin incision, during a 50 min study period. The authors showed a significant correlation between SVV_{PC} and PPV_{CAP} ($r = 0.732$, $P < 0.001$). The aim of the present study rather was to investigate the value of PPV_{CAP} with regard to clinical decision making in the operating room under "real-life" conditions in patients undergoing non-cardiac surgery for whom a goal directed fluid therapy approach is the gold standard. In this specific setting, PPV_{CAP} showed an overall moderate agreement with SVV_{PC}. As we chose to investigate the value of PPV_{CAP} with regard to clinical decision-making rather than absolute agreement with SVV_{PC}, we did not perform a Bland–Altman analysis but rather calculated the diagnostic accuracy and kappa coefficient with regard to three categories that have previously been suggested for assessing fluid responsiveness [19]. In this context, it is much more important if the simultaneously observed PPV_{CAP} and SVV_{PC} fall within the same category than if they are different by a certain number of percentage points; e.g., a difference between PPV_{CAP} and SVV_{PC} of 6% may be irrelevant if PPV is 2% and SVV is 8%, but highly clinically relevant if PPV is 8% and SVV is 14%. Some might question the gray zone approach per se or the boundaries we chose for the PPV and SVV categories [23]. In contrast to Cannesson et al. [19], who established the PPV gray zone of 9–13% we used in our study, Biais et al. [24] proposed a PPV gray zone between 4 and 17%. These latter thresholds, however, were derived from patients receiving mechanical ventilation in the intensive care unit and may, in part, be due to heterogeneity in the methods used to assess PPV and in the applied tidal volumes. Because we performed our study in surgical patients treated in a standardized way (including controlled mechanical ventilation), we deliberately chose to use the gray zone of 9–13% in our study.

One major advantage of assessing PPV using a smartphone application is that it could enable PPV to be used for hemodynamic therapy without the need for additional often costly sensors and hemodynamic monitoring systems. The clinical reference method to record and analyze the arterial blood pressure waveform and calculate PPV in patients undergoing surgery under general anesthesia is currently

invasive pulse wave analysis, which requires placement of an arterial catheter and use of dedicated hemodynamic monitoring software [25, 26]. As an alternative to the invasive assessment of PPV, non-invasive pulse wave analysis—that still requires an advanced hemodynamic monitoring system—has recently been validated in surgical [27] and critically ill [28] patients. Smartphone applications able to process and analyze arterial blood pressure waveforms from any monitor might make PPV-guided hemodynamic therapy available for a broader spectrum of surgical patients who would normally not be monitored with a sophisticated hemodynamic monitoring system. Using the smartphone application, however, is more work- and time-intensive than automated continuous PPV measurements. Future studies are needed to evaluate and validate the Capstesia™—derived estimation of stroke volume and cardiac output.

Some limitations of our study warrant discussion. First, we compared PPV_{CAP} to SVV_{PC}. SVV_{PC} from the EV1000 monitor is a variable we use in our institution and is part of our goal-directed fluid management strategy. We do not use other devices displaying the PPV value, explaining why we chose this dynamic index as a reference. Some may argue that these are two different variables and that the range applied to PPV may not be applicable when SVV is used to determine fluid responsiveness. However, our goal was to compare decision-making regarding fluid administration in patients having major open abdominal surgery and not the ability to predict fluid responsiveness. In addition, we did not perform fluid loading according to the initial value of PPV_{CAP} or SVV_{PC}. One may argue that SVV depends on the vascular impedance contrary to PPV. However, EV1000 does not calibrate the vascular impedance at each beat; the correlation between PPV and SVV is therefore very close, explaining similar threshold value when both PPV and SVV are studied [29]. Two meta-analysis showed SVV values between 8.5 and 15.5% to predict fluid responsiveness, a gap closed to the one used in this study [30, 31]. Indeed, a PPV or SVV cut-off of >12 or 13% is routinely used as the first target to optimize fluid administration in such patients [6, 8, 10]. Second, although measured during the same period of time (between one and two minutes), as SVV_{PC} was based on 9–15 respiratory cycles, and PPV_{CAP} was based on three respiratory cycles, perfect synchronization between values of PPV_{CAP} and SVV_{PC} was not possible. Third, although we included a reasonable number of patients undergoing major abdominal surgery, this is a small single center study and our results should, therefore, not unconditionally be transferred to other settings or groups of surgical patients, especially patients with alterations in vasomotor tone, such as patients with sepsis or liver failure. Moreover, our results may be influenced by the fact that we already had experience in the use of the Capstesia™ smartphone application from our previous studies when we started performing the present clinical study [13, 14]. The clinical applicability of the application when used by inexperienced healthcare providers needs to be assessed in future studies. Fourth, patients were ventilated with a median tidal volume of 7.5 ml/kg of predicted body weight, which is below the commonly accepted threshold of 8 ml/kg (prerequisite for reliable measurements of SVV and PPV).

Finally, to corroborate our results, decision making based on PPV_{CAP} should also be evaluated using other pulse wave analysis algorithms as the reference method.

5 Conclusion

In this clinical decision making study in patients undergoing major abdominal surgery, we observed a overall agreement of 79% and a moderate agreement according to Cohen's kappa coefficient between PPV_{CAP} and SVV_{PC} with regard to categories used to guide fluid administration. In only 1% of all measurements would the two dynamic indices have resulted in completely opposite clinical decisions regarding fluid administration. Further studies are needed to confirm the potential of this application.

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Author contributions AJ: Designed the study, analyzed the data and drafted the manuscript. AJ, OD: Designed the study, analyzed the data and edited the manuscript. JLV, SS, JR, LVO: Analyzed the data and edited the manuscript. AH: Analyzed the data (statistical analysis) and edited the manuscript. BS: Analyzed the data and drafted the manuscript. All authors read and approved the final version of the manuscript.

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Compliance with ethical standards

Conflict of interest *Alexandre Joosten*: Consultant for Edwards Lifesciences (Irvine, CA, USA). *Olivier Desebbe*: Collaborates with Medtronic (Dublin, Ireland) as a consultant and received honoraria for giving lectures. *Jean-Louis Vincent* is Editor-in-Chief of Critical Care. He has no other conflicts related to this article. *Joseph Rinehart*: Ownership interest in Sironis, a company developing closed-loop medical software, consultant for Edwards Lifesciences (Irvine, CA, USA). *Bernd Saugel*: Collaborates with Pulsion Medical Systems (Feldkirchen, Germany) as a member of the medical advisory board and received honoraria for giving lectures and refunds of travel expenses from Pulsion Medical Systems. BS received institutional research grants, unrestricted research grants, and refunds of travel expenses from Tensys Medical (San Diego, CA, USA). BS received honoraria for giving lectures and refunds of travel expenses from CNSystems Medizintechnik (Graz, Austria). BS received honoraria for giving lectures and research support from Edwards Lifesciences (Irvine, CA, USA). All other authors have no conflicts of interest to declare.

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