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Review Article

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Continuous noninvasive pulse wave analysis using finger cuff technologies for arterial blood pressure and cardiac output monitoring in perioperative and intensive care medicine: a systematic review and meta-analysis

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Abstract

Background: Finger cuff technologies allow continuous noninvasive arterial blood pressure (AP) and cardiac output/index (CO/CI) monitoring.

Methods: We performed a meta-analysis of studies comparing finger cuff-derived AP and CO/CI measurements with invasive measurements in surgical or critically ill patients. We calculated overall random effects model-derived pooled estimates of the mean of the differences and of the percentage error (PE; CO/CI studies) with 95%-confidence intervals (95%-CI), pooled 95%-limits of agreement (95%-LOA), Cochran's Q and I^2 (for heterogeneity).

Results: The pooled mean of the differences (95%-CI) was 4.2 (2.8 to 5.62) mm Hg with pooled 95%-LOA of −14.0 to 22.5 mm Hg for mean AP (Q=230.4 [P<0.001], I^2=91%). For mean AP, the mean of the differences between finger cuff technologies and the reference method was ≤5±8 mm Hg in 9/27 data sets (33%). The pooled mean of the differences (95%-CI) was −0.13 (−0.43 to 0.18) L min^{-1} with pooled 95%-LOA of −2.56 to 2.23 L min^{-1} for CO (Q=66.7 [P<0.001], I^2=90%) and 0.07 (0.01 to 0.13) L min^{-1} m^{-2} with pooled 95%-LOA of −1.20 to 1.15 L min^{-1} m^{-2} for CI (Q=5.8 [P=0.326], I^2=0%). The overall random effects model-derived pooled estimate of the PE (95%-CI) was 43 (37 to 49)% (Q=48.6 [P<0.001], I^2=63%). In 4/19 data sets (21%) the PE was ≤30%, and in 10/19 data sets (53%) it was ≤45%.

Conclusions: Study heterogeneity was high. Several studies showed interchangeability between AP and CO/CI measurements using finger cuff technologies and reference methods. However, the pooled results of this meta-analysis indicate that AP and CO/CI measurements using finger cuff technologies and reference methods are not interchangeable in surgical or critically ill patients.

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Keywords: blood pressure; cardiac index; haemodynamic monitoring; intensive care unit; intraoperative; monitoring; noninvasive; pulse contour analysis

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Editor's key points

- Finger cuff technologies are increasingly used for the noninvasive measurement of arterial blood pressure and cardiac output in surgical or critically ill patients.
- This review assessed the interchangeability of these noninvasive technologies with other (invasive) techniques.
- The pooled results of this analysis indicate that finger cuff technologies and invasive reference methods are not interchangeable in these acute care conditions.

Continuous arterial blood pressure (AP) measurement is an integral part of haemodynamic monitoring in patients treated in perioperative and intensive care medicine. Besides AP monitoring, the assessment and optimisation of cardiac output (CO) or cardiac index (CI) is recommended in high-risk surgical patients and patients with complex shock.[1–5]

The established clinical reference method for continuous AP monitoring is the direct invasive measurement using an arterial catheter usually placed in the radial, brachial, or femoral artery.[6] For the measurement of CO/CI, invasive indicator dilution methods—intermittent pulmonary artery thermodilution and transpulmonary thermodilution—are considered the clinical reference methods, but their widespread use is limited by their invasiveness.[4,7,8]

During the past years, innovative finger cuff technologies (also called vascular unloading technique or volume clamp method) have become available and enable AP and CO/CI to be estimated continuously using pulse wave analysis in a completely noninvasive manner.[4–6,9–11] In short, these finger cuff technologies continuously record the AP waveform using a finger cuff that measures the diameter of the finger artery with an integrated infrared photodiode and light detector. The finger cuff high-frequently adjusts its pressure to keep the blood volume in the finger artery constant throughout the cardiac cycle. From the pressure adjustments required to maintain a constant blood volume in the finger artery, the AP waveform can be derived and analysed to estimate AP and CO/CI (Fig. 1).[5,6,9–11]

Numerous validation studies describing the agreement of finger cuff technology-derived AP and CO/CI measurements with invasive reference measurements have been published. The partly contradicting results of these validation studies make it difficult for the clinician to estimate the usefulness and applicability of this innovative technology in different clinical settings and patient populations. For the selection of the optimal haemodynamic monitoring method for the individual patient, it is crucial to be aware of the measurement performance and limitations of each technology.[4,12] We therefore performed a systematic review and meta-analysis of clinical studies comparing continuous noninvasive finger cuff technology-derived AP and CO/CI measurements with invasive reference measurements in adult surgical or critically ill patients.

Methods

Study design and registration

Following the guidelines set forth in Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA),[13] we performed a systematic review and meta-analysis of clinical studies using either the ClearSight system (Edwards Lifesciences, Irvine, CA, USA [formerly known as Nexfin; BMEye, Amsterdam, The Netherlands]) or the CNAP system (CNSystems Medizintechnik, Graz, Austria) comparing continuous noninvasive finger cuff technology-derived AP and CO/CI measurements with invasive reference measurements in adult surgical or critically ill patients. This systematic review and meta-analysis was registered at the International Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42019119266).

Eligibility criteria

Studies included in our systematic review and meta-analysis had to fulfil the following *a priori* defined eligibility criteria:

(1) Published studies on the ClearSight system or CNAP system in adult (age ≥18 yr) surgical or critically ill patients comparing:
   (a) Continuous noninvasive AP measurements with invasive AP measurements obtained with an arterial catheter reporting data on mean AP (MAP), systolic AP (SAP), and diastolic AP (DAP).
   (b) Continuous noninvasive CO or CI measurements with invasive CO or CI measurements obtained with pulmonary artery or transpulmonary thermodilution.
(2) Studies reporting extractable mean of the differences and standard deviation (SD) of the mean of the differences and/or 95%-limits of agreement (95%-LOA) of the mean of the differences between noninvasive and invasive AP or CO/CI measurements.
(3) Studies performed in perioperative or intensive care medicine (operating room [OR] or intensive care unit [ICU]).

We restricted the search and subsequent bibliographic review to studies (no correspondence or case reports) published in English between January 1, 2000 and December 31, 2018.

Information sources and search strategy

We systematically searched the electronic databases PubMed, Web of Science, and the Cochrane Library. The full electronic search strategy for PubMed as an example is provided in Supplement S1. The literature search was done separately for AP and CO/CI. In addition, we searched the reference lists of the identified studies and the reference lists of previous reviews to find additional eligible studies that we had not identified initially.

Study selection

Four investigators (BS, JYN, JJV, TWLS) screened all studies identified in the electronic databases by title and abstract. They then studied the full text of the remaining studies and assessed the eligibility for inclusion based on the predefined inclusion criteria. Discrepancies were resolved by detailed discussion of the original data among the team of authors.

Data collection process and data items

Five different authors (PH, KK, JCH, AK, JJV) independently extracted the data from studies finally included using an electronic data sheet (Excel; Microsoft Corporation, Redmond, WA, USA). These authors reviewed each other's data for consistency and resolved inconsistencies by discussion of the original data.

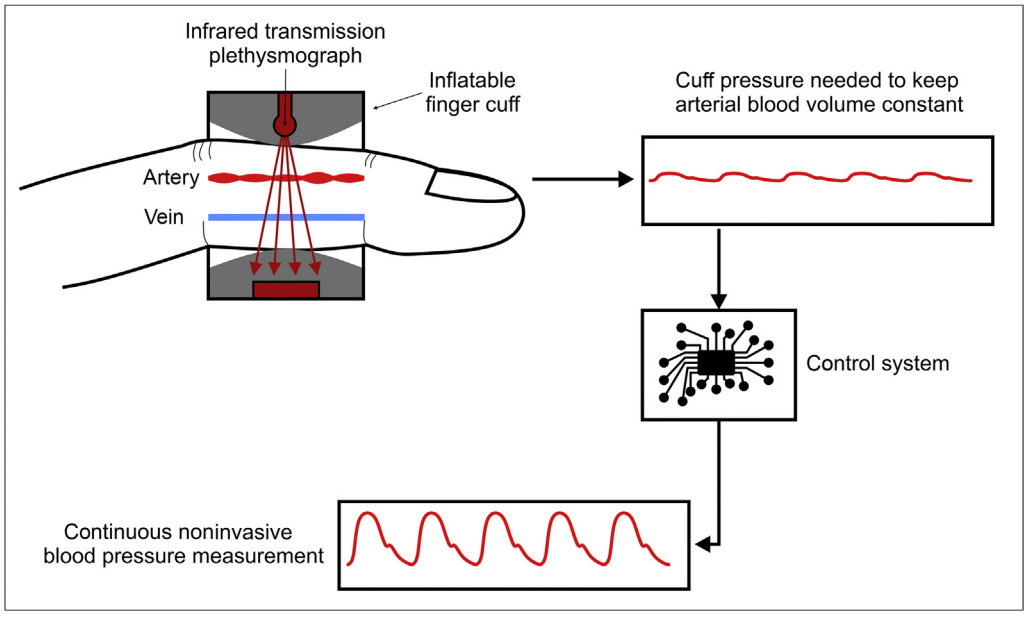

Fig 1. Schema illustrating the principle of finger cuff technologies using the volume clamp method (also known as vascular unloading technique). The inflatable finger cuff measures the diameter of the finger artery with an integrated infrared transmission plethysmograph. This leads to high-frequent adjusts of the cuff pressure to keep the blood volume in the finger artery constant throughout the cardiac cycle. From the pressure adjustments needed to maintain a constant blood volume in the finger artery the arterial blood pressure waveform can be derived and analysed to estimate arterial blood pressure and cardiac output.

The extracted data included: measured haemodynamic variables (MAP, SAP, DAP, CO, CI), study device, the study setting (OR or ICU), reference method to which the test method was compared (invasive AP, pulmonary artery or transpulmonary thermodilution), patient population, number of patients, total pairs of measurements, arterial catheter measurement site (relative to measurement site of the finger cuff technology), mean of the differences between the test and the reference method, SD of the mean of the differences between the test and the reference method, and respective lower and upper 95%-LOA. For CO/CI studies we additionally extracted the percentage error (PE).[14]

We recalculated the mean of the differences in studies describing the mean of the differences as reference minus test method, so that all mean of the differences were defined as test method minus reference method. For studies only presenting the mean of the differences and the 95%-LOA we calculated the SD of the mean of the differences as (upper 95%-LOA minus mean of the differences)/1.96. For two studies on CO not reporting the PE,[15,16] we recalculated the PE as: 1.96 SD of the mean of the differences between the test and the reference method divided by the mean of the CO value of the test and the reference method.

Risk of bias in individual studies

The quality of the included studies was assessed according to Quality Assessment of Diagnostic Accuracy Studies guidelines (QUADAS-2)[17] after adapting the assessment questions to method comparison studies for AP and CO/CI (as described previously[18,19]). The original QUADAS-2 guidelines include four domains for the assessment of risk of bias and three domains for the assessment of concerns related to applicability. Each domain contains signalling questions that are marked yes, no, or unclear; the used questionnaire is detailed in Supplement S2. Three investigators (BS, PH, KK) performed an independent quality assessment on each included study, and discrepancies were resolved by detailed discussion. Risk for each of the bias and applicability domains is classified as low, high, or unclear based on the results of the signalling questions.

Principle summary measures

Summary measures were the mean of the differences of the individual included studies. The mean of the differences with the accompanying SD and sample size were summarised using a random effects model for means as outcomes with restricted maximum likelihood as the estimator. The resulting overall random effects model-derived pooled estimate of the mean of the differences serves as a measure for the accuracy of the tested method in comparison with the reference method. We also calculated the respective 95%-confidence intervals (95%-CI) for every mean of the differences of each individual study to account for the varying sample sizes between the included studies and summarised them with the random effects model. We report the 95%-CI of the overall random effects model-derived pooled estimate of the mean of the differences. The 95%-CI was calculated as 1.96 standard error of the mean ($SD/\sqrt{n}$). In addition, the pooled 95%-LOA were calculated as means of the lower and upper 95%-LOA of the individual studies.

For CO/CI studies, the PE was summarised using a random effects model for proportions with DerSimonian–Laird as the estimator.[20] We report the overall random effects model-derived pooled estimate of the PE with 95%-CI. We used the

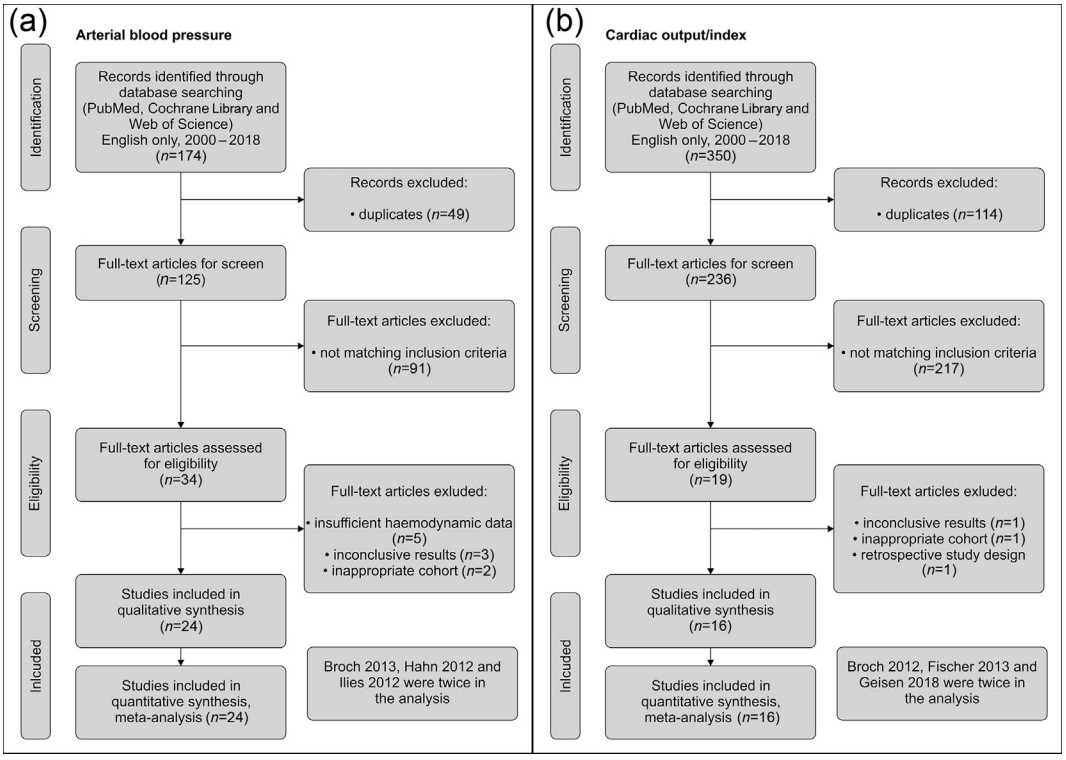

Fig 2. Flowchart of the literature search with the number of the included studies based on the PRISMA statement. (a) Flowchart for studies on arterial blood pressure (b) Flowchart for studies on cardiac output/index.

established 30% PE threshold to define clinical interchangeability between the test and the reference method.[14] However, as it was proposed to use a 45% PE threshold to define clinical interchangeability when comparing noninvasive methods for CO/CI estimation with thermodilution reference methods, we also considered the 45% PE threshold.[21]

For AP, clinically acceptable agreement was defined based on the Association for the Advancement of Medical Instrumentation (AAMI) standard as a mean of the differences and SD between finger cuff technologies and the reference method of $\leq 5 \pm 8$ mm Hg.[22]

To test heterogeneity and inconsistency, Cochran's Q and I^2 were calculated.

Synthesis of results

The database consists of all relevant data to perform the meta-analysis. A random effects model was computed for each outcome to obtain overall random effects model-derived pooled estimates. Cochran's Q as a measure of heterogeneity and I^2 as a measure of consistency are reported.

Risk of publication bias across studies

To address the potential problem of selective reporting, we provided funnel plots with corresponding Eggers regression test for asymmetry.[23]

Additional analysis; subgroup analysis

Subgroup analyses were performed to identify potential causes of heterogeneity across the selected studies. For AP, we performed subgroup analysis according to the factor 'device' (ClearSight *vs* CNAP), the factor 'setting' (ICU *vs* OR), and the factor 'catheter measurement site' (radial contralateral *vs* radial ipsilateral relative to the ClearSight/CNAP). Studies reporting CO or CI were analysed separately. For CO, we performed subgroup analyses according to the factor 'reference method' (pulmonary artery thermodilution with pulmonary artery catheter *vs* transpulmonary thermodilution) and the factor 'setting' (ICU *vs* OR).

Statistical software

All calculations were performed using the software R version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria, 2019) with the Meta-Analysis Package for R (metafor) version 2.1–0.[24]

Results

Arterial blood pressure

Study selection

We identified 125 articles from the initial electronic database search after removal of duplicates (Fig. 2a). After evaluating these articles in full text, we excluded 91 articles. Of the remaining 34 articles, 24 fulfilled our predefined inclusion

criteria and were included in the meta-analysis. Three studies were divided in different sections for the analysis for the following reasons: different software versions of the test device,[25] measurements before and after cardiopulmonary bypass,[26] and measurements during induction and maintenance of general anaesthesia.[27]

Study characteristics

The total number of patients was 1164 in all studies on AP combined with a median of 42 patients included per study (range, 10 to 182 patients). The median number of measurement pairs was 3938 (inter-quartile range, 345 to 7116), but measurement pairs were missing or unclear in five studies.[28–32] We reached out to the authors, none of whom answered our request. Sixteen studies were performed in the OR and eight in the ICU. Patients included in OR studies were heterogenous with regard to the type of surgery, but most patients underwent major general, vascular, or cardiac surgery. Ten studies evaluated the ClearSight system and 14 studies the CNAP system. For the ClearSight system, no software versions were reported in the included studies. At least six different software versions were reported for the CNAP system. The characteristics of the included studies are shown in Table 1.

Risk of bias in individual studies

The risk of bias in the individual studies was assessed using the QUADAS-2 tool and is shown in Supplement S3. In one study, the risk of bias in the 'flow and timing' section was unclear.

Overall meta-analysis

Table 1 shows the individual mean of the differences with SD and 95%-LOA for MAP, SAP, and DAP for all included studies.

For MAP, the overall random effects model-derived pooled estimate of the mean of the differences (95%-CI) was 4.19 (2.76 to 5.62) mm Hg with pooled 95%-LOA of −13.99 to 22.47 mm Hg. Heterogeneity across the included studies was high (heterogeneity: Q=230.4 [P<0.001], I^2=91%) (Fig. 3a). For SAP, the pooled estimate of the mean of the differences (95%-CI) was −1.63 (−3.92 to 0.66) mm Hg with pooled 95%-LOA of −29.78 to 26.54 mm Hg (heterogeneity: Q=200.8 [P<0.001], I^2=91%) (Fig. 3b). For DAP, the pooled estimate of the mean of the differences (95%-CI) was 6.03 (4.04 to 8.01) mm Hg with pooled 95%-LOA of −12.15 to 24.29 mm Hg (heterogeneity: Q=736.2 [P<0.001], I^2=96%) (Fig. 3c).

For MAP, the mean of the differences and SD between finger cuff technologies and the reference method was ≤5±8 mm Hg in nine of 27 data sets (33%) of the included studies. In two of 27 data sets (7%) of the included studies, the mean of the differences and SD between finger cuff technologies and the reference method was ≤5±8 mm Hg for all three AP components (MAP, SAP, and DAP).

Risk of publication bias across studies

Funnel plots indicating the risk of publication bias across studies including Eggers regression test are shown in Supplement S4 for MAP (P=0.773), in Supplement S5 for SAP (P=0.813), and in Supplement S6 for DAP (P=0.066).

Subgroup analyses

We performed subgroup analyses according to different types of devices used in the studies. For the ClearSight system, the overall random effects model-derived pooled estimate of the mean of the differences (95%-CI) was 4.92 (2.37 to 7.47) mm Hg with pooled 95%-LOA of −11.05 to 21.11 mm Hg for MAP, 0.00 (−4.46 to 4.45) mm Hg with pooled 95%-LOA −25.05 to 25.18 mm Hg for SAP, and 7.79 (5.41 to 10.17) mm Hg with pooled 95%-LOA of −8.31 to 24.04 mm Hg for DAP. Heterogeneity was high in this subgroup of studies (MAP: Q=76.9 [P<0.001], I^2=91%; SAP: Q=95.3 [P<0.001], I^2=92%; DAP: Q=113.2 [P<0.001], I^2=92%) (Supplements S7–9). For the CNAP system, the overall random effects model-derived pooled estimate of the mean of the differences (95%-CI) was 3.74 (2.01 to 5.47) mm Hg with pooled 95%-LOA of −16.02 to 23.41 mm Hg for MAP, −2.67 (−5.06 to −0.27) mm Hg with pooled 95%-LOA of −33.03 to 27.47 mm Hg for SAP, and 4.81 (1.99 to 7.63) with pooled 95%-LOA of −14.78 to 24.46 mm Hg for DAP. Heterogeneity was high (MAP: Q=152.0 [P<0.001], I^2=90%; SAP: Q=92.3 [P<0.001], I^2=87%; DAP: Q=562.9 [P<0.001], I^2=96%) (Supplements S10–12).

Results of the subgroup analysis 'setting' and 'catheter measurement site' are shown in Supplements S13–24.

Cardiac output/index

Study selection

We identified 236 articles from the initial electronic database search after removal of duplicates (Fig. 2b). After evaluating these articles in full text, we excluded 217 articles. Of the remaining 19 articles, 16 fulfilled our predefined inclusion criteria and were included in the systematic review. Three studies were divided in different sections for the following reasons: measurements before and after cardiopulmonary bypass,[49] measurements before and after a fluid challenge,[50] and measurements reported separately for fluid challenge responders and non-responders.[51]

Study characteristics

The total number of patients was 549 in all studies on CO and CI combined with a median of 34 patients included per study (range, 19 to 51 patients). The number of measurement pairs was indicated in all but two studies and was 2041 in total with a median of 94 (inter-quartile range, 66 to 147) per study. Five of the 16 studies were performed in the OR (mostly during cardiothoracic surgery; one in patients having laparoscopic gastric bypass surgery). The other studies were performed in the ICU either in critically ill or postoperative patients. The reference indicator dilution method was pulmonary artery thermodilution via a pulmonary artery catheter in seven studies and transpulmonary thermodilution in nine studies. Un-indexed CO was reported in 12 studies, CI (indexed to body surface area) in four studies. The characteristics of the included studies are shown in Table 2.

Risk of bias in individual studies

The risk of bias in the individual studies was assessed using the QUADAS-2 tool and is shown in Supplement S3. In two studies, the risk of bias in the 'flow and timing' section was unclear.

Table 1 Summary of the included studies and data for arterial blood pressure measurement. ClearSight is formerly known as Nexfin. A or B refers to different subsections of a study that has been included twice in the analysis. CPB, cardiopulmonary bypass; DAP, diastolic arterial blood pressure; ICU, intensive care unit; 95%-LOA, 95%-limits of agreement; MAP, mean arterial blood pressure; MD, mean of the differences; OR, operating room; SAP, systolic arterial blood pressure; SD, standard deviation.

First author	Year	Journal	Device	Setting	Patient population	Patients (*n*)	MD of MAP (SD) (mm Hg)	Upper 95%-LOA MAP (mm Hg)	Lower 95%-LOA MAP (mm Hg)	MD of SAP (SD) (mm Hg)	Upper 95%-LOA SAP (mm Hg)	Lower 95%-LOA SAP (mm Hg)	MD of DAP (SD) (mm Hg)	Upper 95%-LOA DAP (mm Hg)	Lower 95%-LOA DAP (mm Hg)
Biais	2010	*Ann Fr Anesth Reanim*	CNAP	OR	Major vascular surgery	25	1.8 (10.3)	22	−18.3	−7.2 (12.7)	17.7	−32.2	7.5 (10.1)	27.3	−12.4
Jeleazcov	2010	*Br J Anaesth*	CNAP	OR	Elective abdominal, cardio- or neurosurgery	78	−1.6 (11)	19.96	−23.16	6.7 (13.9)	33.94	−20.54	−5.6 (11.4)	16.74	−27.94
Schramm	2011	*Blood Press Monit*	CNAP	OR	Transfemoral aortic valve implantation	29	−0.8 (15)	29	−31	−11 (18)	25	−47	6 (16)	38	−26
Gayat	2012	*Acta Anaesthesiol Scand*	CNAP	OR	Major scheduled surgery	52	8 (13.5)	35	−18	2 (21.5)	45	−41	11 (11.5)	34	−12
Hahn (A)	2012	*Br J Anaesth*	CNAP	OR	Major orthopaedic surgery CNAP V3.0	50	2.9 (10.6)	23.7	−17.9	−3.4 (16)	27.9	−34.8	4.4 (10.8)	25.5	−16.8
Hahn (B)	2012	*Br J Anaesth*	CNAP	OR	Major orthopaedic surgery CNAP V3.5	50	3.1 (9.45)	21.6	−15.4	−0.9 (13.2)	24.9	−26.8	2.8 (8.6)	19.7	−14.1
Ilies (A)	2012	*Br J Anaesth*	CNAP	OR	General anaesthesia induction	85	10.21 (11.3)	35.87	−15.45	3.31 (16.5)	43.01	−36.39	10.78 (10.7)	35.44	−13.88
Ilies (B)	2012	*Br J Anaesth*	CNAP	OR	General anaesthesia maintenance	85	4.34 (6.8)	23.83	−15.16	−4.17 (10)	26.63	−34.98	5.81 (6)	23.38	−11.75
Fischer	2012	*Br J Anaesth*	ClearSight	ICU	Post-CPB surgery	44	4.6 (6.5)	17.3	−8.1	−5.7 (14.4)	22.5	−34	8.9 (7)	22.6	−4.7
Martina	2012	*Anesthesiology*	ClearSight	OR	Cardiac surgery	50	2.2 (6.4)	14.74	−10.34	−0.5 (6.7)	12.63	−13.63	2.8 (6.4)	15.34	−9.74
Schramm	2013	*Anesth Analg*	CNAP	OR	Transfemoral aortic valve implantation	33	3.9 (11.3)	26.5	−18.7	−6.3 (18.9)	31.5	−44.1	7.4 (10.5)	28.4	−13.6
Broch (A)	2013	*Minerva Anestesiol*	ClearSight	OR	Elective coronary surgery (before CPB)	50	10.9 (13)	36.5	−14.6	11.4 (17.1)	44.9	−22	13 (13.5)	39.5	−14.6
Broch (B)	2013	*Minerva Anestesiol*	ClearSight	OR	Elective coronary surgery (after CPB)	50	13.5 (11.3)	35.7	−8.6	15.1 (17.9)	50.3	−20.2	13.7 (12.1)	37.4	−10
Ameloot	2014	*Minerva Anestesiol*	ClearSight	ICU	Critically ill patients	45	2.3 (6.2)	14.7	−10.1	−8.3 (13.8)	18.7	−35.3	9.4 (6.9)	22.9	−4.1
Kumar	2015	*Indian J Anaesth*	CNAP	OR	Cardiac surgery	60	0.02 (5.68)	11.17	−11.12	−5.98 (10.36)	14.33	−26.29	3.72 (6.1)	15.68	−8.23
Wagner	2015	*J Clin Monit*	CNAP	ICU	Critically ill patients	55	1 (9)	19	−16	−10 (16)	21	−42	7 (9)	24	−10
Smolle	2015	*Anesth Analg*	CNAP	ICU	Critically ill patients	40	4.6 (6.7)	17.8	−8.7	−3.2 (10.1)	16.6	−23.1	7 (6.7)	20.2	−6.1
Ilies	2015	*Eur J Anaesthesiol*	CNAP	ICU		104	6.1 (7.6)	22.4	−10.1	−4.3 (11.6)	21.7	−30.4	9.4 (8)	26.4	−7.5

Continued

Table 1 Continued

First author	Year	Journal	Device	Setting	Patient population	Patients (*n*)	MD of MAP (SD) (mm Hg)	Upper 95%-LOA MAP (mm Hg)	Lower 95%-LOA MAP (mm Hg)	MD of SAP (SD) (mm Hg)	Upper 95%-LOA SAP (mm Hg)	Lower 95%-LOA SAP (mm Hg)	MD of DAP (SD) (mm Hg)	Upper 95%-LOA DAP (mm Hg)	Lower 95%-LOA DAP (mm Hg)
					After cardiovascular surgery										
Araz	2015	*Exp Clin Transplant*	CNAP	OR	Living-donor liver transplantation	40	−0.4 (10.4)	19.98	−20.78	0.3 (16)	31.66	−31.06	0.4 (10.55)	21.08	−20.28
Lakhal	2016	*Anesth Analg*	CNAP	ICU	Critically ill patients	182	7.2 (6.4)	19.8	−5.3	−4.3 (13.8)	22.7	−31.4	−9.7 (7.8)	5.6	−25
Balzer	2016	*J Int Med Res*	ClearSight	OR	Orthopaedic surgery	20	1 (13)	25.5	−24	−5 (16)	26.5	−36.9	5 (12)	29.6	−19.5
De Wilde	2016	*Anaesthesia*	ClearSight	ICU/ recovery unit	After major abdominal surgery	19	0.82 (5.03)	10.93	−9.29	−3.3 (7.83)	12.44	−19.04	2.42 (4.2)	10.86	−6.02
Heusdens	2016	*Br J Anaesth*	ClearSight	OR	Carotid endarterectomy	24	3.5 (5.2)	13.69	−6.69	−3.3 (10.8)	17.87	−24.47	6.1 (5.7)	17.27	−5.07
Rogge	2017	*Anesth Analg*	CNAP	OR	Laparoscopic bariatric surgery	29	7.9 (9.6)	27	−11.2	4.8 (15.8)	36	−26.5	9.5 (10.3)	29.9	−10.9
Berkelmans	2017	*J Clin Monit*	ClearSight	ICU	Critically ill patients	10	1 (5)	11	−10	−6 (10)	15	−26	4 (6)	16	−7
Sakai	2018	*J Med Invest*	ClearSight	OR	Robot-assisted laparoscopic radical prostatectomy	10	9.26 (11.61)	32.02	−13.5	2.99 (15.8)	34.04	−28.06	12.03 (10.84)	33.27	−9.21
Noto	2018	*Eur J Anaesthesiol*	ClearSight	OR	Awake carotid endarterectomy	30	6.8 (6.7)	20.1	−6.3	3 (9.7)	22.1	−16	9 (5.4)	19.7	−1.5

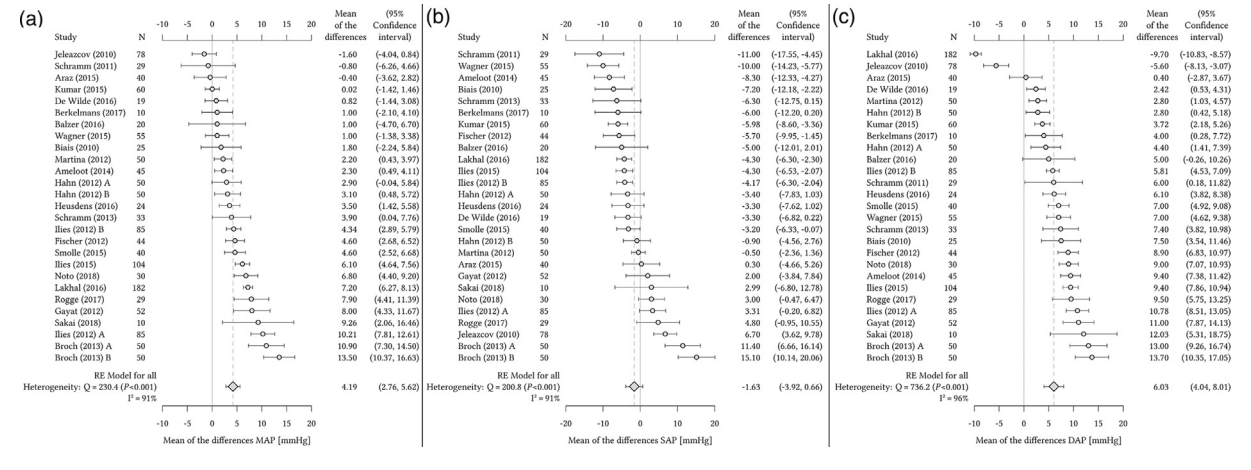

Fig 3. Forest plot showing the results of the meta-analysis for the mean arterial blood pressure (MAP; a), systolic arterial blood pressure (SAP; b), and diastolic arterial blood pressure (DAP; c) measured in mm Hg with mean of the differences (dots) with 95%-confidence interval (bars) per individual study in relation to the overall random effects (RE) model-derived pooled estimate (vertical dotted line). Heterogeneity is displayed with Q and I^2. N=number of participants per study. Hahn and colleagues,[25] Ilies and colleagues,[26] and Broch and colleagues[27] are treated as two studies in the analysis (A and B).[25–48]

Overall meta-analysis

The synthesis of the results was performed separately for studies reporting CO and CI. Table 2 shows the individual mean of the differences with SD and 95%-LOA for studies reporting CO and CI and the PE.

For CO, the overall random effects model-derived pooled estimate of the mean of the differences (95%-CI) was −0.13 (−0.43 to 0.18) L min^{-1} with pooled 95%-LOA of −2.56 to 2.23 L min^{-1} (heterogeneity: Q=66.7 [P<0.001], I^2=90%) (Fig. 4a).

For CI, the overall random effects model-derived pooled estimate of the mean of the differences (95%-CI) was 0.07 (0.01 to 0.13) L min^{-1} m^{-2} with pooled 95%-LOA of −1.20 to 1.15 L min^{-1} m^{-2} (heterogeneity: Q=5.8 [P=0.326], I^2=0%) (Fig. 4b).

The overall random effects model-derived pooled estimate of the PE (95%-CI) was 43 (37–49)% (heterogeneity: Q=48.6 [P<0.001], I^2=63%) (Fig. 4c).

Four of 19 data sets (21%) of the included studies fulfilled the requirement for clinical interchangeability between the test and the reference method defined as a PE of ≤30%.[14] Ten of 19 data sets (53%) of the included studies revealed a PE of ≤45%.[21]

Risk of publication bias across studies

Funnel plots indicating the risk of publication bias across studies including Eggers regression test are shown in Supplement S25 for CO (P=0.015), Supplement S26 for CI (P=0.324), and Supplement S27 for PE (P=0.207).

Subgroup analyses

We performed subgroup analyses according to different reference methods used in the studies. For pulmonary artery thermodilution, the overall random effects model-derived pooled estimate of the mean of the differences (95%-CI) was 0.16 (−0.02 to 0.33) L min^{-1} with pooled 95%-LOA of −1.71 to 2.02 L min^{-1} (Supplement S28). For transpulmonary thermodilution, it was −0.52 (−1.08 to 0.03) L min^{-1} with pooled 95%-LOA of −3.56 to 2.48 L min^{-1} (Supplement S29). The heterogeneity was lower in the pulmonary artery thermodilution subgroup (heterogeneity: Q=13.9 [P=0.03], I^2=61%) than in the transpulmonary thermodilution subgroup (heterogeneity: Q=27.1 [P<0.001], I^2=84%).

Results of the subgroup analysis 'setting' are provided in Supplements S30 and S31.

Discussion

In this systematic review and meta-analysis, we investigated the agreement of continuous noninvasive finger cuff technology-derived AP and CO/CI measurements with AP and CO/CI measurements using invasive reference methods in adult surgical or critically ill patients. The finger cuff technology has been proposed as a noninvasive method to continuously monitor AP and estimate CO/CI using pulse wave analysis in perioperative and intensive care medicine.[5,9,10,62] It is based on the principle of the volume clamp method (sometimes also referred to as vascular unloading technique)[63] and uses an inflatable finger cuff to keep the blood volume in the finger artery constant.[5,6,9,10,62] This is facilitated by measuring the diameter of the finger artery with an infrared light source and detector and high-frequently adjusting the cuff pressure. The AP at the level of the finger can be determined from the cuff pressure required to maintain the volume—or more precisely the diameter—of the finger artery constant. Two commercially available systems, the ClearSight and the CNAP system, were included in this meta-analysis.

The ClearSight system uses finger AP to reconstruct brachial AP and corrects for the difference in height between the level of the finger and the level of the heart using a proprietary mathematical algorithm and a heart reference system.[64–66] In addition, a proprietary algorithm called 'Physiocal' is applied to analyse characteristics of the AP waveform and adjust the finger cuff pressure according to changes in vascular tone.[9,33,66–69] Pulse wave analysis

Table 2 Summary of the included studies and data for cardiac output/index measurement. ClearSight is formerly known as Nexfin. A or B refers to different subsections of a study that has been included twice in the analysis. CABG, coronary artery bypass grafting; CO, cardiac output; CI, cardiac index; CPB, cardiopulmonary bypass; ICU, intensive care unit; 95%-LOA, 95%-limits of agreement; MD, mean of the differences; NYHA, New York Heart Association classification; OR, operating room; PATD, pulmonary artery thermodilution; PE, percentage error; SD, standard deviation; TPTD, transpulmonary thermodilution.

First author	Year	Journal	Device	Reference method	Setting	Patient population	Patients (*n*)	CO/CI	Mean of CO or CI (SD) (L min^{-1} or L min^{-1} m^{-2})	Upper 95%-LOA (L min^{-1} or L min^{-1} m^{-2})	Lower 95%-LOA (L min^{-1} or L min^{-1} m^{-2})	PE (%)
Bogert	2010	*Anaesthesia*	ClearSight	PATD	ICU	Post-CABG	25	CO	0.44 (0.81)	2.03	−1.15	20
Sokolski	2011	*J Cardiovasc Med (Hagerstown)*	ClearSight	PATD	ICU	NYHA 3/4	25	CO	0.1 (0.4)	0.88	−0.68	28
Broch (A)	2012	*Anaesthesia*	ClearSight	TPTD	OR	CABG before CPB	40	CI	0.06 (0.27)	0.49	−0.6	23
Broch (B)	2012	*Anaesthesia*	ClearSight	TPTD	OR	CABG after CPB	40	CI	0.09 (0.37)	0.63	−0.81	26
Fischer	2012	*Br J Anaesth*	ClearSight	TPTD	ICU	Post-CPB surgery	24	CI	−0.01 (0.63)	1.22	−1.25	50
Monnet	2012	*Crit Care*	ClearSight	TPTD	ICU	Patients with acute circulatory failure	38	CI	−0.2 (1)	1.76	−2.16	57
Ameloot	2013	*Sci World J*	ClearSight	TPTD	ICU	Critically ill patients	45	CO	−0.4 (1.2)	1.95	−2.75	36
Bubenek-Turconi	2013	*Anesth Analg*	ClearSight	PATD	ICU	Post-cardiac on-pump surgery	28	CO	0 (1)	2.1	−2.1	38
Fischer (A)	2013	*Acta Anaesthesiol Scand*	ClearSight	TPTD	ICU	Post-cardiac surgery before fluid challenge	37	CI	0.21 (0.57)	1.33	−0.91	55
Fischer (B)	2013	*Acta Anaesthesiol Scand*	ClearSight	TPTD	ICU	Post-cardiac surgery after fluid challenge	37	CI	0.01 (0.74)	1.46	−1.44	58
Maass	2014	*J Cardiothorac Vasc Anesth*	ClearSight	PATD	OR/ICU	Cardiac surgery	50	CO	−0.35 (1.51	2.66	−3.36	58
Hofhuizen	2014	*J Crit Care*	ClearSight	TPTD	ICU	Post-cardiac surgery	19	CO	−0.26 (1.13)	1.95	−2.47	38.9
Wagner	2016	*J Clin Monit*	CNAP	TPTD	ICU	Critically ill patients	38	CO	−1.4 (1.8)	2.1	−4.9	45
Schraverus	2016	*Anaesthesia*	ClearSight	TPTD	OR	Obese patients having laparoscopic gastric bypass surgery	30	CO	0.6 (1.62)	3.86	−2.67	46
Wagner	2017	*J Clin Monit*	CNAP	PATD	ICU	Post-cardiac surgery	51	CO	0.5 (1.3)	3	−1.9	49
Geisen (A)	2018	*J Cardiothorac Vasc Anesth*	ClearSight	TPTD	ICU	Post-CABG, fluid challenge responder	22	CO	−0.67 (1.58)	2.49	−3.83	59.9
Geisen (B)	2018	*J Cardiothorac Vasc Anesth*	ClearSight	TPTD	ICU	Post-CABG, fluid challenge non-responder	22	CO	−1.11 (1.83)	2.54	−4.76	60.9
Truijen	2018	*Anaesthesia*	ClearSight	PATD	OR	Coronary artery bypass surgery	26	CO	0.24 (0.82)	1.85	−1.37	37
Sperna Weiland	2018	*Minerva Anestesiol*	ClearSight	PATD	OR	Elective cardiothoracic surgery	51	CO	0.1 (0.8)	1.6	−1.4	37

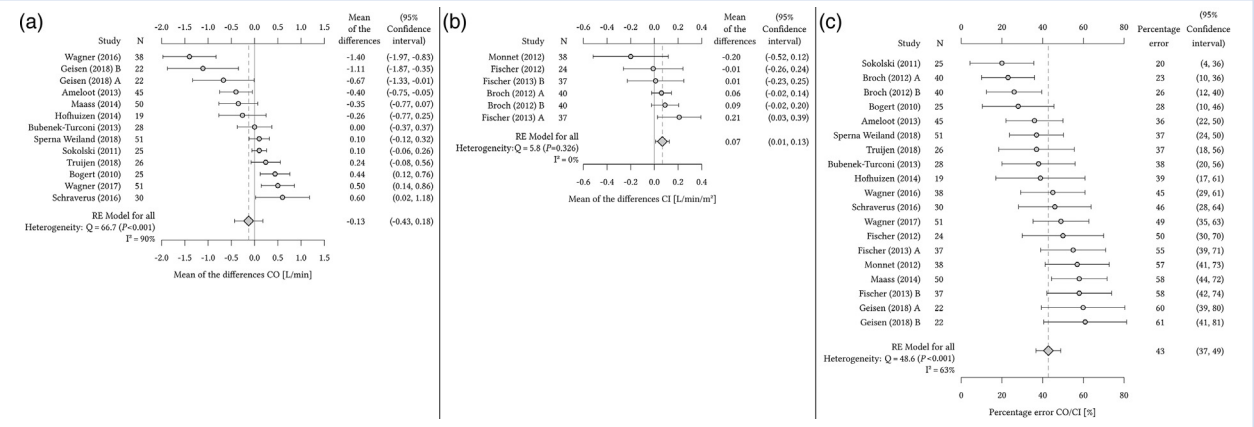

Fig 4. Forest plot showing the results of the meta-analysis for the cardiac output (CO; a) measured in L min^{-1}, cardiac index (CI; b) expressed in L min^{-1} m^{-2}, and the percentage error (PE; c) in percent with mean of the differences (dots) with 95%-confidence interval (bars) per individual study in relation to the overall random effects (RE) model-derived pooled estimate (vertical dotted line). Heterogeneity is displayed with Cochran's Q and I^2. N=number of participants per study. Broch and colleagues,[49] Fischer and colleagues,[50] and Geisen and colleagues[51] are treated as two studies in the analysis (A and B).[15,16,40,49–61]

assuming a 'three-element Windkessel model' is used to estimate CO.[66,70,71]

The CNAP system contains a finger cuff and an oscillometric upper arm cuff that is used to calibrate the finger SAP and DAP values to brachial AP using a proprietary transfer function and to derive MAP. The CNAP system adjusts to changes in vasomotor tonus by repeatedly checking the optimal 'unloading volume' using so-called 'concentrically interlocking control loops'[72] and an algorithm called 'vasomotoric elimination and reconstructed identification of the initial setpoint' (VERIFI).[73] Pulse wave analysis considering AP waveform characteristics is used to estimate CO.

In recent years, numerous clinical method comparison studies have investigated the measurement performance of these finger cuff technologies, yet in different clinical settings and using different reference methods. We limited the meta-analysis to studies comparing a finger cuff technology to a clinical 'gold standard' reference method, that is invasive AP measurement obtained with an arterial catheter for AP and pulmonary artery or transpulmonary thermodilution for CO and CI.

A major problem in research comparing finger cuff technology-derived continuous AP measurements with invasive reference measurements is that guidelines or checklists on how to perform method comparison studies are missing. The AAMI standard[74] is often used to define clinically acceptable agreement between a test method and a reference method.[25,34,35] The AAMI standard defines clinically acceptable agreement as a mean of the differences between a test method and a reference method of ≤5 mm Hg with a SD of ≤8 mm Hg for all three components of AP, that is SAP, MAP, and DAP. However, the AAMI standard only covers non-automated, automated, or electronic sphygmomanometers 'that are used with an occluding cuff for the indirect determination of arterial blood pressure' and thus do not cover measurement devices using the finger cuff technology. To the best of our knowledge, a new AAMI and International Organization of Standardization (ISO) standard for the evaluation and validation of continuous noninvasive AP measurement devices will become available in late 2020.

This meta-analysis showed that there was substantial statistical heterogeneity across the studies included in the analysis, that is there was substantial variability in the AP and CO/CI measurement performance between studies. Several patient-, clinical setting-, and device-related factors may contribute to the observed heterogeneity. Studies were performed in very different patient populations, including patients having cardiac, vascular, major abdominal, spine, or orthopaedic surgery. Apart from patient population, the clinical circumstances under which the agreement of AP measurements was investigated may further aggravate study heterogeneity (e.g., the use of vasopressors and inotropes). Device-related factors, such as the use of different software versions of monitors, may further enlarge heterogeneity. Finally, although we did not identify substantial differences in the measurement performance between the ClearSight system and the CNAP system, the use of different monitoring systems might also affect study heterogeneity.

In CO/CI method comparison studies, there is a wide variability in reference methods to which finger cuff methods are compared. This is of importance, because not only the precision of method of the test method but also the precision of method of the reference method is of importance when performing comparative statistics.[75] We deliberately chose to include only studies in which reference CO/CI was obtained with pulmonary artery thermodilution or transpulmonary thermodilution, as these are considered the most accurate clinical methods to determine CO/CI. In the subgroup analysis, the overall random effects model-derived pooled estimate of the mean of the differences for CO was slightly lower in studies using pulmonary artery thermodilution as reference technique compared with studies using transpulmonary thermodilution.

There are several limitations of this meta-analysis. This meta-analysis solely focuses on investigating the absolute agreement between the test and the reference methods. We did not analyse the ability of the test methods to follow relative changes in AP or CO/CI over time, that is we did not investigate trending ability. In recent years, there has been a gradual change in focus in method comparison studies from

analysing absolute agreement towards analysing relative changes in haemodynamic variables over time or after an intervention (e.g., fluid challenge, passive leg raising test, vasoactive medication).[76] Another limitation is a possible population selection bias as we only included studies using invasive reference methods. As pulmonary artery thermodilution is now rarely used in noncardiac surgery patients, many studies on CO/CI were performed in patients having cardiac surgery. In addition, we solely focused on the statistical agreement between the test and the reference methods and did not investigate if finger cuff technologies can improve the quality of care or patient outcome.[77] Furthermore, not all studies included in this meta-analysis meticulously report and describe the criteria used to exclude AP data recorded with either the test or reference method.

Conclusions

Heterogeneity across the studies included in this meta-analysis was high. Several studies showed interchangeability between arterial pressure and cardiac output/cardiac index measurements using noninvasive finger cuff technologies and invasive reference methods (MAP: one-third of studies; CO/CI: one-fifth of studies for 30% percentage error threshold, half of the studies for 45% percentage error threshold). However, the overall pooled results of this meta-analysis indicate that arterial pressure and cardiac output/cardiac index measurements using noninvasive finger cuff technologies and invasive reference methods are not interchangeable in adult surgical or critically ill patients.

Authors' contributions

Conception of the review: BS, JYN, TWLS
Literature search: BSS, JYN, PH, KK, AK, JCH, JJV, TWLS
Data extraction: PH, KK, AK, JCH, JJV
Statistical analysis: GS
Writing of the manuscript: BSS, JYN, PH, KK, JJV, GS, TWLS
Revision of the manuscript for important intellectual content: AK, JCH.

Declarations of interest

BS has received honoraria for consulting, honoraria for giving lectures, and refunds of travel expenses from Edwards Lifesciences Inc. (Irvine, CA, USA). BS has received honoraria for consulting, institutional restricted research grants, honoraria for giving lectures, and refunds of travel expenses from Pulsion Medical Systems SE (Feldkirchen, Germany). BS has received institutional restricted research grants, honoraria for giving lectures, and refunds of travel expenses from CNSystems Medizintechnik GmbH (Graz, Austria). BS has received institutional restricted research grants from Retia Medical LLC. (Valhalla, NY, USA). BS has received honoraria for giving lectures from Philips Medizin Systeme Böblingen GmbH (Böblingen, Germany). BS has received honoraria for consulting, institutional restricted research grants, and refunds of travel expenses from Tensys Medical Inc. (San Diego, CA, USA). JYN has received refunds of travel expenses from CNSystems Medizintechnik GmbH (Graz, Austria) and Tensys Medical Inc. (San Diego, CA, USA). TWLS received research grants and honoraria from Edwards Lifesciences (Irvine, CA, USA) and Masimo Inc. (Irvine, CA, USA) for consulting and lecturing and from Pulsion Medical Systems SE (Feldkirchen, Germany) for lecturing. The remaining authors declare that they have no conflicts of interest.

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Appendix A. Supplementary data

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