Minimally invasive cardiac output technologies in the ICU: putting it all together

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Purpose of review
Haemodynamic monitoring is a cornerstone in the diagnosis and evaluation of treatment in critically ill patients in circulatory distress. The interest in using minimally invasive cardiac output monitors is growing. The purpose of this review is to discuss the currently available devices to provide an overview of their validation studies in order to answer the question whether these devices are ready for implementation in clinical practice.

Recent findings
Current evidence shows that minimally invasive cardiac output monitoring devices are not yet interchangeable with (trans)pulmonary thermodilution in measuring cardiac output. However, validation studies are generally single centre, are based on small sample sizes in heterogeneous groups, and differ in the statistical methods used.

Summary
Minimally and noninvasive monitoring devices may not be sufficiently accurate to replace (trans)pulmonary thermodilution in estimating cardiac output. The current paradigm shift to explore trending ability rather than investigating agreement of absolute values alone is to be applauded. Future research should focus on the effectiveness of these devices in the context of (functional) haemodynamic monitoring before adoption into clinical practice can be recommended.

Keywords
cardiac output, circulatory shock, functional haemodynamic monitoring, minimally invasive cardiac output monitoring

INTRODUCTION

Haemodynamic monitoring is mandatory in managing circulatory distressed ICU patients [1▪▪–3▪▪]. It provides insight in cardiac function and both vascular filling and tone. In addition, advanced haemodynamic variables might determine the nature and extent of elements contributing to circulatory shock.

Physical examination and simple haemodynamic variables such as heart rate and blood pressure are essential to diagnose circulatory shock. Yet, these variables are unreliable in assessing the patient's volume status [4] and predicting cardiac output (*CO*) [5,6]. Biochemical assessment of circulatory markers such as lactate is helpful in diagnosing circulatory insufficiency, but cannot differentiate between different types of shock. The arsenal of the clinician could be greatly expanded by using more advanced haemodynamic variables, of which *CO* itself is the most frequently studied.

For decades, the pulmonary artery catheter (PAC) was used to monitor *CO*. Despite being considered the gold standard, its use is currently recommended in a limited number of critically ill patients [7–9]. Since installation of the PAC can lead to serious complications [10], less invasive alternatives for haemodynamic monitoring and *CO* measurements have been developed. For example, transpulmonary thermodilution, which does not require right heart catheterization, is now widely accepted [11,12]. Furthermore, there are devices that do not require central venous catheterisation, or are even completely noninvasive [13–15]. Theoretically, these

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KEY POINTS

- Minimally invasive haemodynamic monitoring devices are not yet interchangeable with established invasive cardiac output monitoring devices.
- Interpreting multiple validation studies is complex due to small sample sizes in heterogeneous groups and inconsistent statistical methodology.
- Future research should focus on evaluating trending ability of new devices in context of functional haemodynamic monitoring instead of absolute cardiac output values.

devices approach the criteria of an 'ideal' haemodynamic monitoring device (Table 1) [16]. Importantly though, the reliability of minimally invasive devices has been questioned [17], especially in heterogeneous and complex ICU patients.

The present review provides an overview of the currently available minimally invasive and non-invasive haemodynamic monitoring devices for measuring *CO*, their underlying technology, their performance in recent validation studies, and their benefits and shortcomings in the ICU. We defined 'minimally invasive' as devices not requiring central venous catheterisation.

VALIDATION OF NEW CARDIAC OUTPUT MONITORING DEVICES

Appropriate statistical analyses are of utmost importance when validating agreement of a novel CO monitoring device against an established reference technique. Earlier method-comparison studies estimated agreement between devices by regression analysis, which only measures the strength of a relation between variables, and does not reflect the degree of agreement. This changed when Bland and Altman introduced their Bland–Altman plot [18]. This plot estimates agreement in terms of bias and limits of agreement by plotting the measurements' mean against the difference of measurements of both methods, assessing agreement based on the closeness of individual data points without necessitating defining a gold standard. Unfortunately, the Bland–Altman plot does not take the magnitude of observations into consideration, e.g. low versus high *CO* values. To overcome this issue, Critchley introduced percentage errors (calculated as the limits of agreement divided by the measurements' mean) to compensate agreement for the magnitude of measurement [19]. They established the cut-off point for interchangeability at 28.3%. However, some authors suggest that a higher cut-off percentage is still clinically acceptable, partly because the variation in the reference method itself is frequently not taken into account [20,21,22▪▪].

An alternative method to provide validation of a new monitoring device is assessing its trending ability, that is the ability to track changes in *CO*. Most commonly, this is performed using a four-quadrant plot or a polar plot [23]. The four-quadrant plot allows reading off the direction and magnitude of change in *CO* values of both the reference technology and the studied technology and the calculation of the concordance rate, i.e. the ratio of data points in the upper right quadrant or lower left quadrant to all data points. A concordance rate of 90% or higher is considered clinically acceptable, yet a widely accepted definition has not been established yet. A polar plot illustrates direction and magnitude of changes in polar coordinates, that is each data point is described by an angle and a radius. The polar plot allows reading off the angular bias and the radial limits of agreement.

Table 1. The key properties of an 'ideal' hemodynamic monitoring system

Provides measurement of relevant variables
Provides accurate and reproducible measurements
Provides interpretable data
Is easy to use
Is readily available
Is operator-independent
Has a rapid response-time
Causes no harm
Is cost-effective
Should provide information that is able to guide therapy

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MINIMALLY INVASIVE PULSE CONTOUR ANALYSIS TECHNOLOGIES

Pulse contour analysis (PCA) monitoring is based on the principle that the area under the systolic part of the arterial pressure curve is related to stroke volume. This is derived from the theorem that arterial pulse pressure and its pulse wave contour are primarily determined by left ventricular stroke volume and arterial impedance [24]. Several manufacturers use the abovementioned relation between arterial waveform and stroke volume to estimate *CO* without the need for calibration. Hence, these devices do not require a special arterial catheter or central venous cannulation. However, they are dependent on a good quality of the arterial waveform signal which can be distorted in up to 30% of the cardiac

ICU patients [25]. Furthermore, arrhythmias and severe aortic valvular disease greatly impair measurements.

FloTrac/Vigileo/EV1000 system (Edwards Lifesciences, Irvine, CA, USA)

Stroke volume is estimated by measuring the standard deviation of the mean arterial pressure multiplied by a factor based on arterial waveform characteristics and demographical variables to correct for arterial compliance and tone. The latest algorithm version (4.0) calculates this factor every 20 s and is compatible with either the EV1000 or Vigileo monitor. FloTrac-derived *CO* has been widely studied with over 70 validation studies in different clinical circumstances. A systematic review showed acceptable agreement in patients with hypodynamic and normodynamic circulations (percentage errors 25 and 30%, respectively), but poor performance in hyperdynamic circulations (percentage error 51%) [26]. Recent studies performed with algorithm version 4.0 confirm these results, however showed an improvement in trending ability with a concordance rate of nearly 90% compared to 30–50% with earlier versions [27,28].

LiDCOrapid (LiDCO, Cambridge, UK)

The working mechanism of the LiDCO system is comparable to the FloTrac, although it uses pulse power analysis rather than pulse pressure [29]. It therefore applies the PulseCO algorithm for calculating nominal stroke volume from arterial pressure waveform characteristics. It also incorporates a nomogram of demographic data for calibrating the nominal stroke volume. Validation studies in the ICU have not yet been performed. During surgery, LiDCOrapid performed similar to FloTrac in both *CO* measurements as well as tracking changes in *CO*. It did not reach statistical agreement with (trans)pulmonary thermodilution (percentage errors 38–60%) [30–32].

ProAQT/PulsioFlex (Pulsion/MAQUET, Rastatt, Germany)

The ProAQT/PulsioFlex incorporates an algorithm derived from the PiCCO-PCA technology to consider the relationship between the area under the arterial pressure curve and stroke volume without the need for calibration. Second, it analyses the arterial waveform characteristics to incorporate peripheral resistance and uses a demographic database to quantify vessel compliance. Recent validation studies in the ICU showed contradicting results, yet pointing towards moderate agreement (percentage errors 31–59%) and trending ability (concordance rates 72–89%) [33,34].

MostCare (Vygon, Vytech, Padua, Italy)

The pressure recording analytical method (PRAM) technology utilized in the MostCare device estimates *CO* using a number of physical variables, including the force of left ventricular ejection, arterial impedance counteracting the pulsatile blood inflow, arterial compliance, and peripheral small vessel resistance. What distinguishes PRAM from other PCA technologies is that PRAM takes into account both pulsatile and continuous contribution of the physical forces underlying the relationship between pressure curve morphology and blood flow [35]. A literature review showed contradicting results on which a meta-analysis could not be performed [35]. Further, a large multicenter observational study including 400 patients showed acceptable agreement between MostCare and transthoracic echocardiography with a percentage error of 27% [36▪].

DOPPLER ULTRASOUND

Modified echocardiography is rapidly gaining more attention in the ICU, both in clinical practice as in research [37]. The so-called critical care ultrasound has been advocated to be superior in diagnosing undifferentiated shock and concurrently provides insight in a patient's cardiac function. We acknowledge the importance of critical care ultrasound, yet it cannot be considered a haemodynamic monitoring device since continuous monitoring is not feasible. The USCOM (Coffs Harbour, Australia) – a noninvasive *CO* monitor which utilizes transaortic Doppler flow tracing - was excluded from this review for the same reason, although it is suggested that probe fixation allows continuous *CO* monitoring.

Oesophageal Doppler monitoring

Oesophageal Doppler monitoring (EDM), predominantly performed by the CardioQ device (Deltex Medical, UK), provides continuous estimation of blood flow in the descending aorta through an oesophageal Doppler probe which estimates aortic blood flow velocity. To approximate the diameter of the descending aorta, a proprietary nomogram containing the patient's age, height, and weight is used. These parameters are converted into descending aortic blood flow and subsequently (by adding an estimated fraction of blood flow to the upper body)

CO. EDM was initially developed for the operating room because it required a sedated patient to maintain correct probe positioning. Early results during surgery were promising and EDM was incorporated in the NICE guidelines [38]. However, few studies incorporated correct Bland–Altman analysis and a recent validation study showed poor agreement compared to invasive monitoring [39]. EDM trending ability might however be sufficient, with a concordance rate of 92%. We were not able to identify recent method-comparison studies in the ICU, making it difficult to evaluate current performance in the critically ill patient.

NONINVASIVE CARDIAC OUTPUT TECHNOLOGIES IN THE ICU

ClearSight (Edwards Lifesciences, Irvine, CA, USA)

The ClearSight technique, formerly known as Nexfin, uses a disposable finger cuff with an integrated photoplethysmograph and is compatible with the EV1000 platform. The working mechanism of the volume clamp method is to provide equal pressure on both sides of the artery to maintain a constant arterial volume [40]. The pressure required to maintain a constant volume is recalculated to the arterial pressure wave. Here, a correction is applied to adjust for arterial waveform variations in the course of the arterial tree, and ultimately, the brachial arterial pressure waveform is reflected. The technology has recently been reviewed and a pooled percentage error of 45% was found, yet with acceptable concordance rates ranging between 87 and 100% [41].

CNAP (CNSystemsMedizintechnik AG, Graz, Austria)

The CNAP system eliminates vasomotoric influences by the use of concentrically interlocking loops and the so called VERIFI-algorithm [42,43]. This algorithm continuously analyses the shape of the arterial waveform and thereby allows differentiation between blood volume shifts due to changes in arterial pressure and those because of changes of the arterial diameter. The resulting finger cuff derived arterial pressure signal is calibrated by a transfer function to oscillometrically obtained arterial pressure values using an upper arm cuff. A proof-of-concept analysis showed acceptable agreement compared to transpulmonary thermodilution (uncalibrated percentage error 45%), but further research is required to verify the algorithm [42].

T-Line TL-200 (Tensys Medical Inc., San Diego, CA, USA)

The TL-200 system incorporates radial artery applanation tonometry [44] to acquire the arterial waveform by using a disposable wrist splint that stabilises the wrist and placing a pressure sensor above the radial artery. Similar to manual pulse palpation, pressure is then applied to compress the radial artery over the radial bone until transmural pressure is reduced to a minimum, thus maximizing pulse transfer to the sensor. Few validation studies have been performed in the ICU thus far, and showed percentage errors slightly above clinical interchangeability (percentage error 34–45%) [45,46]. Aside moderate agreement, the major downside of T-line is that slight patient movement interrupts *CO* measurements.

THORACIC ELECTRICAL BIOIMPEDANCE

Standard bioimpedance systems apply a high-frequency electric current of known amplitude and frequency across the thorax and measure changes in voltage during the cardiac cycle. These changes are caused by pulsatile variations in intrathoracic blood volume, altering thoracic electrical conductivity. Results during surgery were promising, however, bioimpedance has been found to be inaccurate in the ICU [19,47,48▪▪]. Electrical interference of other devices and increased lung water renders these devices ineffective in measuring *CO* in critically ill patients, leading to a halt of ICU validation studies.

To improve the bioimpedance signal, bioreactance technology has been developed, which measures phase shifts of an oscillating current that occurs when it traverses the thorax. These phase shifts are not altered by the amount of thoracic fluids and only occur due to pulsatile flow [49]. The only commercially available device incorporating bioreactance is the NICOM (Cheetah Medical, Newton Center, MA, USA). A large multicenter trial confirmed agreement approaching clinically acceptable levels during surgery [50]. More recently, acceptable agreement was found in awake primigravida [51] and septic patients in the emergency department [52], showing that bioreactance is also feasible in awake patients. The few validation studies performed in the ICU showed percentage errors above clinical acceptability (between 39 and 82%) [53,54]. Aside one small study evaluating trending ability in the ICU showing promising results [55▪▪], future research is required to consider agreement of NICOM in the critically ill.

PARTIAL CARBON DIOXIDE REBREATHING/NICO

The NICO system applies a modified carbon dioxide (CO_2) version of the Fick equation to estimate *CO*. NICO uses an extra loop introduced in the ventilatory circuit to intermittently create a partial CO_2 rebreathing system. Arterial cannulation is necessary to estimate pulmonary shunting. The NICO system is limited to sedated, intubated, and mechanically ventilated patients and cannot be used in patients with severe lung disease because of increased pulmonary shunting. To our best knowledge, the latest validation study dates back to 2012 and showed percentage errors that were not clinically acceptable in the ICU (43–49%) [56]. This was in accordance with earlier NICO validation studies performed in the ICU (38–46%) [57–59]. For now, it appears that the NICO is rarely used in the ICU because of insufficient agreement and limited usability.

PULSE WAVE TRANSIT TIME

The esCCO technology (Nihon Kohden, Tokyo, Japan) provides completely noninvasive continuous CO monitoring. It is based on the inverse relation between the stroke volume and pulse wave transit time (PWTT), i.e. the time between the appearance of the R-wave on the electrocardiogram and arrival of the pulse wave at the finger level. The measured PWTT can be used with blood pressure, heart rate and patient-specific parameters to estimate *CO*. Considering it only requires these basic haemodynamic variables, there is no necessity for additional sensors which makes esCCO extremely user-friendly. Earlier validation studies performed in ICU patients showed insufficient agreement in estimating *CO* with percentage errors ranging from 50 to 80% [60–62]. Recently, the trending ability of PWTT was assessed and showed promising results in the ICU with concordance rates of 87 and 93% and improved percentage errors between 35 and 40% [63,64] (Table 2).

THE PREDICAMENT OF VALIDATING CARDIAC OUTPUT MONITORING DEVICES

For now, both less and noninvasive haemodynamic monitoring devices are not interchangeable with thermodilution techniques in estimating *CO* when strictly applying the currently proposed agreement criteria. A remarkable side note is that noninvasive techniques apparently perform equally compared to minimally invasive techniques. However, it must be emphasised that interpreting multiple validation studies is difficult as strikingly stated by Saugel [14]:

> Available validation studies (...)are heterogeneous in terms of the criterion standard method used, the study setting and patient population, the observed results, and the conclusions presented by the authors based on the study findings.

Validating new devices in the ICU pose even more difficulties. First, PAC is still considered the gold standard in *CO* estimation and considered the reference method of choice in validation studies. Yet, it is argued that PAC might not be as reliable and accurate in estimating *CO* as once thought [65,66]. This seems especially true in evaluating fluid responsiveness or in case of rapidly changing haemodynamics.

Second, nearly all minimally invasive haemodynamic monitoring devices rely on one or multiple proprietary algorithms to assess *CO*. Although they are advanced and mimic human physiology considerably, they are established and tested on healthy individuals only. It can be anticipated that these models might not suit the critically ill patient in shock with altered physiology.

Finally, the ICU population can be considered one of the most heterogeneous patient categories, making interpreting multiple validation studies very difficult. This is exemplified by a recent meta-analysis [48▪▪] reporting a significant amount of heterogeneity which could not be explained by subgroup or sensitivity analyses.

Altogether, it can be questioned whether the accuracy of minimally invasive *CO* monitoring devices will ever approach (trans)pulmonary derived *CO* measurements in the near future, an opinion supported by a recent meta-analysis [48▪▪]. There was only a marginal increase in accuracy of new devices when compared to previously performed meta-analyses in 1999 and 2010 [19,47]. Moreover, when interpreting validation studies published in the past 12 months, we could not detect a significant increase in agreement of *CO* measurements. However, we did find a growing interest in evaluating trending ability without focussing on the agreement of single *CO* values. We commend this tendency in method-comparison studies to focus on trending ability and believe that future research should be aimed at validating agreement in context of functional haemodynamic monitoring, i.e. assessing the response of the cardiovascular system to a well defined intervention [67,68▪]. In common practice, this refers to answering the question whether a patient is or is probably not responding to fluids. Fluid responsiveness is a topic which relevancy has been emphasised in recent reviews [4,69▪,70,71]. In this context, the inability to accurately measure

Table 2. An overview of the minimally and noninvasive hemodynamic monitoring devices currently used or studied in the ICU

Technique	Sensor/device	Advantages	Disadvantages	Requirements	Accuracy in the ICU[a]
Pulse contour analysis	FloTrac (EV1000/Vigileo), ProAQT (Pulsioflex), LiDCOrapid, MostCare.	No external calibration needed Provide dynamic indices, e.g. stroke volume variation	Require high quality arterial waveform signal Cannot be used in patients with severe aortic valvular disease, intra-aortic balloon pumps Use limited in arrhythmias, spontaneous ventilation	Arterial catheter, algorithm and monitoring device	⊕⊕⊕⊕⊕
	ClearSight/NexFin and CNAP	Completely noninvasive	Decreased accuracy in severe peripheral vasoconstriction or oedematous fingers	Disposable or reusable finger cuff, heart reference unit (ClearSight)	⊕⊕⊕⊕⊕
	T-line TL-200	Completely noninvasive	Movement of the arm impairs measurements significantly	Disposable wrist splint	⊕⊕⊕⊕⊕
Doppler ultrasound	Transthoracic echocardiography	Completely noninvasive Also assesses cardiac structure and function	Operator-dependent Limited image quality due to various conditions commonly encountered in the ICU Intermittent measurements, no continuous monitoring	Ultrasound machine	⊕⊕⊕⊕⊕
	Oesophageal Doppler/ CardioQ		Accuracy limited in rapidly changing haemodynamics and strongly dependent on correct probe placement Probe not easily tolerated in conscious patients	Oesophageal probe placed via oral or nasal route	⊕⊕⊕⊕⊕
Bioimpedance	Thoracic electrical bioimpedance	Completely noninvasive	Inaccurate in patients with (thoracic) fluid overload Requires sedated patients to minimize movement Affected by electronic equipment Cannot be used in arrhythmias	Electrodes applied at the base of the neck (thoracic inlet) and the costal margins (thoracic outlet)	⊕⊕⊕⊕⊕
	Bioreactance/NICOM	Completely noninvasive	Limited accuracy in low-flow states Disturbance due to electrical noise	Four dual-electrode 'stickers' (two on both sides of the chest)	⊕⊕⊕⊕⊕
Partial carbon dioxide rebreathing	NICO		Decreased accuracy in patients with pulmonary shunting - Only applicable when CO_2 is above 30 mm Hg (~4 kPa) Cannot be used in patients who cannot tolerate a short rebreathing period	Arterial catheter and mechanical ventilation	⊕⊕⊕⊕⊕
Pulse wave transit time	esCCO	Completely noninvasive Can be calibrated by using invasive techniques to improve accuracy	Accuracy limited when not calibrated	Basic hemodynamic variables	⊕⊕⊕⊕⊕

[a]According to our subjective interpretation of currently available data derived from validation studies assessing cardiac output measurements compared to an established reference technique.

absolute values of *CO* can be compensated by providing acceptable trending abilities to track changes in *CO* following interventions. An excellent example is a recent method-comparison study [55▪▪]; despite being single centre and having a small sample size, it demonstrated how to evaluate trending ability of multiple devices following varying therapeutic interventions.

CONCLUSION

Recent literature concerning the myriad of minimally invasive haemodynamic monitoring devices is showing inconsistent results. Although the accuracy of *CO* measurements in terms of absolute values does not seem to improve lately, the focus is shifting towards evaluating trending ability with recent studies showing increasingly encouraging results. Future research is required to further evaluate trending ability in larger samples before incorporating these devices in clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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- ▪ of special interest
- ▪▪ of outstanding interest

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