



Non-invasive cardiac output monitoring device “ICON” in trauma patients: a feasibility study

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Abstract

Purpose Assessment of hemodynamics is crucial for the evaluation of major trauma patients. Cardiac output (CO) monitoring provides additional information and may improve volume resuscitation. The goal of this prospective pilot study was to evaluate the feasibility of a new non-invasive CO monitoring (NICOM) device in the emergency department (ED).

Methods Single-center prospective observational pilot study including 20 trauma patients admitted to a level 1 trauma center. CO was continuously monitored for 60 min after ED admission using the new NICOM device ICON[®]. This device measures changes of the thoracic bioimpedance to calculate CO. Conventional vital signs were recorded simultaneously. Feasibility, safety, reliability, user-friendliness, and impact of the device on standard ED procedures were assessed.

Results Thirteen (65%) patients were male, median age was 57.5 (IQR 25), and median ISS was 10.5 (IQR 14.8). Median CO over time was 9.8 l/min (IQR 4.6). No adverse effects were recorded. The device proved to be user-friendly with no negative impact on routine ED care. In four patients, detachment of electrodes was observed, and in four patients, the CO recording was temporary discontinued. Short-term changes of the CO were observed 44 times after the placement of electrodes and during patient transfers.

Conclusions Non-invasive CO monitoring proved to be feasible and safe for the initial hemodynamic evaluation of trauma patients. Problems with the NICOM device were detachment of electrodes and temporary signal loss. Due to the small sample size and relatively low injury burden of the patients included in this study, further prospective investigation is warranted.

Keywords Initial care · Emergency department · Non-invasive hemodynamic monitoring · Cardiac output · Trauma

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Introduction

Hemorrhagic shock is a major cause of death in trauma patients, accounting for approximately 30–40% of deaths within the first 24 h after injury [1]. Early trauma mortality in patients with hemorrhagic shock is caused by ongoing hemorrhage, coagulopathy, and inadequate resuscitation [1]. Therefore, early recognition of hemorrhage is of paramount importance and allows for prompt therapeutic intervention.

Arterial blood pressure, heart rate, and the shock index are commonly used in the ED to diagnose hypotension and shock. However, multiple variables including the etiology of shock, severe pain, pharmacologic side effects (e.g., disoprivane, benzodiazepines, and opiates), or preexisting co-morbidities may impact these traditional parameters. Therefore, additional diagnostic tools may help to evaluate hemodynamics more precisely and to improve resuscitation.

It has been shown that cardiac output (CO) is substantially different in hypotensive patients with or without blood loss [2].

Low CO indicates blood loss, whereas normal or elevated CO implies that blood loss is unlikely and that there may be other reasons for hypotension [2]. The cardiac index [3–10], oxygen saturation [3, 4, 7–9], transcutaneous oxygen [3, 4, 6, 8, 9], and mean arterial pressure [4, 6, 8, 9] have been shown to be significantly higher, while the transcutaneous carbon dioxide [3–6, 8] and heart rate [4–6, 8] have been shown to be significantly lower in survivors than in non-survivors.

For CO measurement, pulmonary artery catheter thermodilution is considered to be the clinical gold standard [11, 12]. Unfortunately, the invasive and time-consuming nature of this method along with the training needed to operate the device makes its use unsuitable in the ED [3, 4, 11]. Non-invasive devices that measure CO and other hemodynamic parameters have been described in the literature [11, 13, 14]. Most systems use the thoracic electrical bioimpedance or bio-reactance to determine CO [11, 13]. Devices of this kind have been used and evaluated in trauma patients [2–4, 6, 7, 15–17]. The accuracy of the devices has been tested against invasive methods, such as pulmonary artery catheter thermodilution, and has been reported as satisfactory [3, 6, 15, 17]. However, the thoracic electrical bioimpedance method requires the placement of 11 electrodes on the patients' skin and the devices were big in size and rather unhandy to use bedside [3–9, 15–18]. Thus, the techniques in these earlier studies were not very user-friendly and were not widely implemented for the initial evaluation of major trauma patients.

Electrical velocimetry is a modification of the thoracic electrical bioimpedance method [19] that has been validated in previous clinical studies. These studies reported a good correlation with measurements by transesophageal Doppler echocardiography in adults [20] and children [21], by the direct Fick-oxygen method in children [22], and by thermodilution [23]. The new-generation NICOM devices using electrical velocimetry are handheld size [21, 24] and require only four adhesive electrodes to be placed on the patients' skin [20, 21, 23]. However, despite the mentioned advantages, new-generation NICOM devices were not yet assessed for the initial hemodynamic evaluation in trauma patients. Furthermore, it is unclear whether the reliability of this new technology is comparable to the traditional thoracic electrical bioimpedance method using 11 electrodes.

The goal of this prospective observational pilot study was, therefore, to evaluate the feasibility of using the new NICOM device ICON[®] for the initial evaluation of hemodynamics in trauma patients.

Methods

Patients

This study was approved by the cantonal ethics committee of Bern, Switzerland (KEK no. 353/2015). Informed consent was obtained from all individual participants included in the study.

This is a prospective observational pilot study including adult (age > 18 years) trauma patients that were admitted directly to the ED of the Bern University Hospital, which is a Swiss level 1 trauma center, between June and August of 2016. Patients with both blunt and penetrating injuries were included. Exclusion criteria were transfer from an outside hospital, cardiac pacemakers, and resuscitation using cardiac defibrillation prior to hospital admission. The study aimed to include 20 consecutive trauma patients due to the time frame of the study and its conception as a pilot study.

Outcomes

The primary outcome was the feasibility assessment of implementing the new NICOM device for the initial evaluation of hemodynamics in trauma patients in the ED. Feasibility was tested in the following categories: safety of the device, reliability of the device, user-friendliness, and interference with standard of care for trauma patients. Secondary outcomes were the compatibility of the new NICOM device with computer tomography scanning, and the recording of events that interfere with the devices' CO measurements.

CO measurements

The NICOM device was installed as soon as the patient arrived in the trauma bay of the ED, at the same time as the conventional vital sign monitoring equipment was applied. CO was continuously recorded during the first 60 min after ED arrival, or until the patient was transferred to another service.

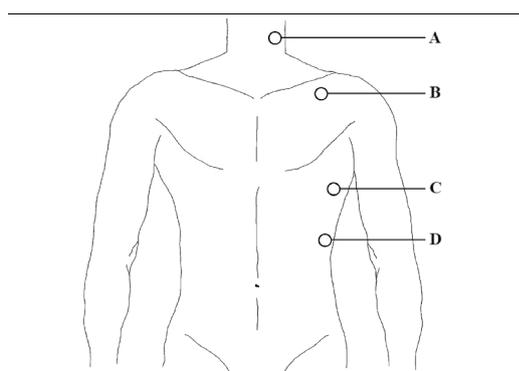
In the current study, the NICOM device ICON[®] (Osypka Medical GmbH, Berlin, Germany) was used, which is a handheld-sized device (205 mm × 110 mm × 38 mm, weight 750 g). After attachment of four adhesive surface electrodes, the device measures changes of thoracic electrical bioimpedance during the cardiac cycle. Based on the change of thoracic electrical bioimpedance, it calculates the cardiac stroke volume. At the same time, the device continuously records the heart rate. The CO is then calculated by the multiplication of stroke volume and heart rate.

Of the four attached electrodes, two act as stimulating electrodes. One is placed on the neck or forehead (a) and

the other one on the left abdomen, approximately 10–15 cm below the xiphoid level (d). The remaining two electrodes are placed directly below the left clavicle (b) and on the lower left thorax at the level of the xiphoid (c) (Fig. 1). A high-frequency (50 kHz) low amperage (2 mA) alternating electrical current is applied on the left side of the thorax via the stimulating electrodes (a, d). The voltage (E) caused by the current (I) is then registered by the sensing electrode closest to the stimulating electrode. Changes to the thoracic electrical bioimpedance (Z) during the cardiac cycle leads to voltage variations between the sensing electrodes. Per Ohm's law, the ratio of the varying voltage (E) to the applied current (I) equals changes in thoracic electrical bioimpedance ($Z = E/I$), which is recorded by the device [24].

Traditionally, the change of thoracic electrical bioimpedance was interpreted as volumetric changes of the ascending aorta during the cardiac cycle, i.e., the systolic dilation of the aorta, which has been described as the Windkessel effect [20, 24, 25]. The NICOM device utilized in this study uses a modification of this technique called electrical velocimetry to analyze the changes of thoracic conductivity. With electrical velocimetry, the variation of thoracic electrical bioimpedance due to the alternating orientation of the erythrocytes relative the aorta during the cardiac cycle is measured. During diastole, before the aortic valve opening, red blood cells are randomly distributed in the aorta, which results in higher electrical resistance of the blood and higher thoracic electrical bioimpedance. During systole erythrocytes align their disk-shaped bodies parallel to the axial blood flow. This results in a lower electrical resistance and lower thoracic electrical bioimpedance [19, 20, 24].

The maximum rate of change of the thoracic electrical bioimpedance is interpreted as the ohmic equivalent of the



Electrode A is placed on the neck, electrode B directly below the left clavicle, electrode C on the lower left thorax at the level of the xiphoid, electrode D approximately 10–15 cm below the xiphoid level

Fig. 1 Placement of ECG surface electrodes. Electrode a is placed on the neck, electrode b directly below the left clavicle, electrode c on the lower left thorax at the level of the xiphoid, and electrode d approximately 10–15 cm below the xiphoid level

mean blood flow velocity in the ascending aorta during systole. The NICOM device uses mathematical equations derived from this interpretation to calculate stroke volume [19, 20, 23–25].

In addition to the CO, the NICOM device also calculates the cardiac index (CI).

Vital signs measurements

Conventional vital signs were monitored every 10 min. Blood pressure was monitored with blood pressure cuffs or intraarterially if an arterial line was in place. Heart rate was recorded by a three-lead ECG.

Feasibility assessment

Four categories were assessed using a standardized form: safety of the device (adverse effects on patients or staff), reliability of the device (adhesion of the electrodes, continuity of data recording), user-friendliness (problems with device handling, mobility of device), and interference with the standard of care for trauma patients in the ED (delay or interruption of diagnostic or therapeutic procedure, acceptance of the device by ED staff).

Assessment of computer tomography compatibility

The devices surface electrodes were taken off or left in place for computer tomography scanning based on the radiology staff's evaluation. In case of anticipated metal artifacts by the radiology staff, the electrodes were removed before the computer tomography scan. All computer tomography scans that were performed with the surface electrodes in place were assessed for metal artifacts.

Interference with CO measurements

After completion of the observation period, the CO measurements recorded by the ICON[®] device were systematically assessed in search of short-term events. These events were defined as rapid CO changes of $\pm \geq 1.5$ l/min during maximally 30 s. To systematically search for factors that interfered with CO measurements in the ED, the above described events were then matched with ED staff protocols and the study investigator's observations.

Statistical analysis

Normality of distribution was assessed using histograms, skewness, and the Shapiro–Wilk test. Variables were reported as medians, interquartile ranges (IQR), or numbers and percentages, as appropriate.

The changes of the CO, heart rate, blood pressure, and shock index over time were assessed using separate linear regression analysis. Analysis over time included the whole observation period (60 min), as well as the first 60 and 120 s of the observation. Results of the regression analysis were expressed as regression coefficient (RC) and 95% confidence intervals (CI).

p values < 0.05 were considered statistically significant.

Statistical analyses were performed using SPSS Statistics (IBM Corporation, Armonk, NY, USA) and Microsoft Excel (Microsoft Corporation, Redmond, WA, USA).

Results

Baseline characteristics

A total of 20 consecutive trauma patients were enrolled in this study. Median age was 57.5 years (IQR 25), 13 patients (65%) were male sex, and median ISS was 10.5 (IQR 14.8). All patients included suffered from blunt trauma. Two patients were intubated in the ED. Eight patients required admission to the critical care unit. The median duration of non-invasive CO monitoring was 60 min (IQR 12), depending on the length of stay in the trauma bay and radiology suite. The median hospital length of stay (LOS) was 6 days (IQR 12). The median intensive care unit LOS was 3 days (IQR 3). Baseline characteristics of included patients are outlined in Table 1.

Reliability

The electrodes were placed on the intended anatomic location in every case, also in patients with a cervical collar in place, as the electrodes could be placed through the ventral opening of the collars. In four cases, displacement of the electrodes was observed due to sweat, chest hair, and manipulation of the electrodes by a patient. In addition to the electrode displacement, temporary signal loss occurred for unknown reasons in four cases. Except for these incidents, the device recorded CO continuously. No electrode displacement or signal loss was observed in patients with chest tubes or thoracic trauma.

Integration into ED procedures

The ICON[®] device was easy to use and easy to handle during patient transfers from or to the stretcher in all cases. Installation, operation, and monitoring could be performed by one person. The ICON[®] did not affect the standard of care in the ED, including both diagnostic and therapeutic

Table 1 Baseline characteristics

Patient characteristics	
Age (years)	58 (25)
Sex (male/female) ^a	13/7 (65.0/35.0)
Injury characteristics	
Blunt trauma	20 (100)
ISS	10.5 (14.8)
Chest trauma	6 (30)
Pneumothorax ^a	2 (10)
Hemopneumothorax ^a	1 (5)
Rib fractures ^a	4 (20)
Sternal fracture ^a	1 (5)
Management characteristics	
Duration of observation (min)	60 (12)
Intubation ^a	2 (10)
Chest tube ^a	2 (10)
Arterial line ^a	2 (10)
ICU stay ^a	7 (35)
Hospital LOS (days)	6 (12)
ICU LOS (days)	3 (3)

Values are medians (interquartile ranges) unless indicated otherwise

ISS Injury Severity Score, LOS length of stay, ICU intensive care unit

^aValues are numbers (percentages)

interventions. During the first minutes of patient stay in the trauma bay, primary survey, installation of conventional vital signs monitoring, communication with staff and patient and secondary survey (head to toe) were not hindered. The transfer to the Lodox full-body X-ray scanner in the trauma bay or to the CT scanner in the radiology suite was not delayed and possible as usual. Specialist consultations, ECG monitoring of the heart, intubation and interventions in the trauma bay were performed as normal. The device was also readily accepted by the ED staff.

Computer tomography compatibility

In nine cases, computer tomography (CT) scanning was performed with the NICOM surface electrodes in place. The artifacts caused by the devices' electrodes were comparable to the artifacts caused by conventional ECG electrodes. The artifacts resemble bright streaks that emit from the location of the ECG surface sensor and are visible in the subcutaneous fatty tissue and muscular tissue. No artifacts of the electrodes were reported in the CT scan reports of the nine patients that underwent CT scanning, particularly no artifacts on the lung or upper abdominal imaging including the liver and spleen. Figure 2 shows artifacts caused by a conventional ECG electrode and by an ICON[®] electrode.

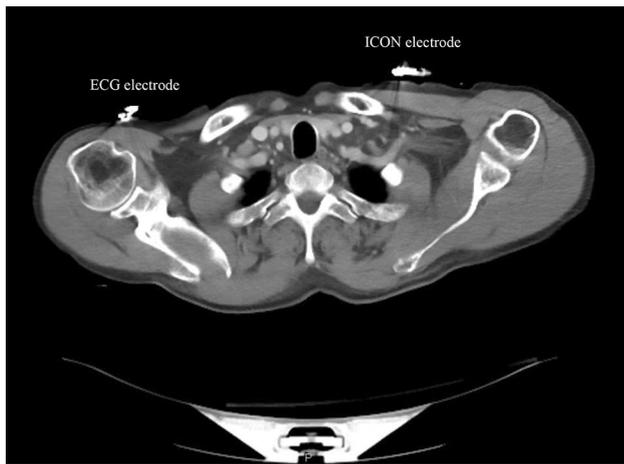


Fig. 2 Metal artifacts. Metal artifacts caused by a conventional ECG electrode (left) and an ICON® electrode (right)

Table 2 Problems with device

Electrode detachment	4 (20)
Sweat	2 (10)
Chest hair	1 (5)
Manipulation of electrodes by patient	1 (5)
Temporary signal loss	8 (25)
Electrode detachment	4 (20)
Unknown reason	4 (20)
Interference with CO measurements	44 (95)
Calibration after startup of device	20 (80)
Patient transfer	17 (60)
Calibration after electrode detachment	4 (15)
Unknown reason	3 (10)

Values are numbers (percentages)

CO cardiac output

Interference with CO monitoring

Forty-four events ($\Delta CO_{\pm} \geq 1.5$ l/min over 30 s) were identified and matched with ED staff protocols and the study investigator's observations.

Eighteen events took place immediately after switching the ICON® device on at the beginning of CO monitoring, and two events after switching it on again after the computer tomography scan in the radiology suite.

Fifteen events occurred during patient's transfers from or to the trauma bay stretcher, to the computer tomography scanner or to the hospital bed.

Another two events occurred while repositioning the patient for X-ray, three after exchange of the electrodes due to displacement, and one due to signal processing

problems of the ICON® device because of sweaty skin. For three short-term events, no explanation was found.

Table 2 summarizes all recorded problems during the observation period.

Initial CO measurements

Over the first minute of the observation period, a significant decrease of the CO was found (RC -0.034 , CI -0.052 to -0.016), $p < 0.001$). During the first 2 min of the observation period, the CO changed significantly but less pronounced (RC -0.010 , CI -0.015 to -0.004), $p = 0.001$). Figure 3 shows the CO measurements over the first and second minute of observation.

CO and vital signs over time

The median CO over time was 9.8 l/min (IQR 4.6), the median cardiac index over time 4.99 l/min/m² (IQR 1.93), the median systolic blood pressure 129 mmHg (IQR 32), and the median heart rate 78/min (IQR 18). Systolic blood pressure (RC 0.160, CI -1.999 to 2.318, $p = 0.884$), heart rate (RC 0.404, CI -0.862 to 1.670, $p = 0.529$), shock index (RC 0.002, CI -0.010 to 0.014, $p = 0.751$), CO (RC 0.014, CI -0.246 to 0.273, $p = 0.918$), and cardiac index (RC -0.0002 , CI -0.013 to 0.012, $p = 0.975$) did not significantly change over time. The CO over time is outlined in Fig. 4.

Discussion

The goal of this prospective observational pilot study was to evaluate the feasibility of using the non-invasive cardiac output monitoring device ICON® for the initial evaluation of hemodynamics in trauma patients, as well as to assess the compatibility of the device with computer tomography scanning, and the device's integration into standard ED procedures.

In the current study, CO monitoring using the ICON® proved to be feasible. There were no safety concerns. The device was user-friendly and did not affect standard ED procedures. Problems with the device were electrode detachment and temporary signal loss due to electrode displacement or for unknown reasons.

The safety of non-invasive CO monitoring devices using thoracic electrical bioimpedance has been addressed in previous studies [4, 6, 8, 9, 15, 16, 18, 22]. As in these previous studies, there were no safety concerns with the use of the non-invasive CO monitoring device in the current study.

To our knowledge, non-invasive CO monitoring based on electrical velocimetry for the initial evaluation of trauma patients in the ED has not been evaluated so far.

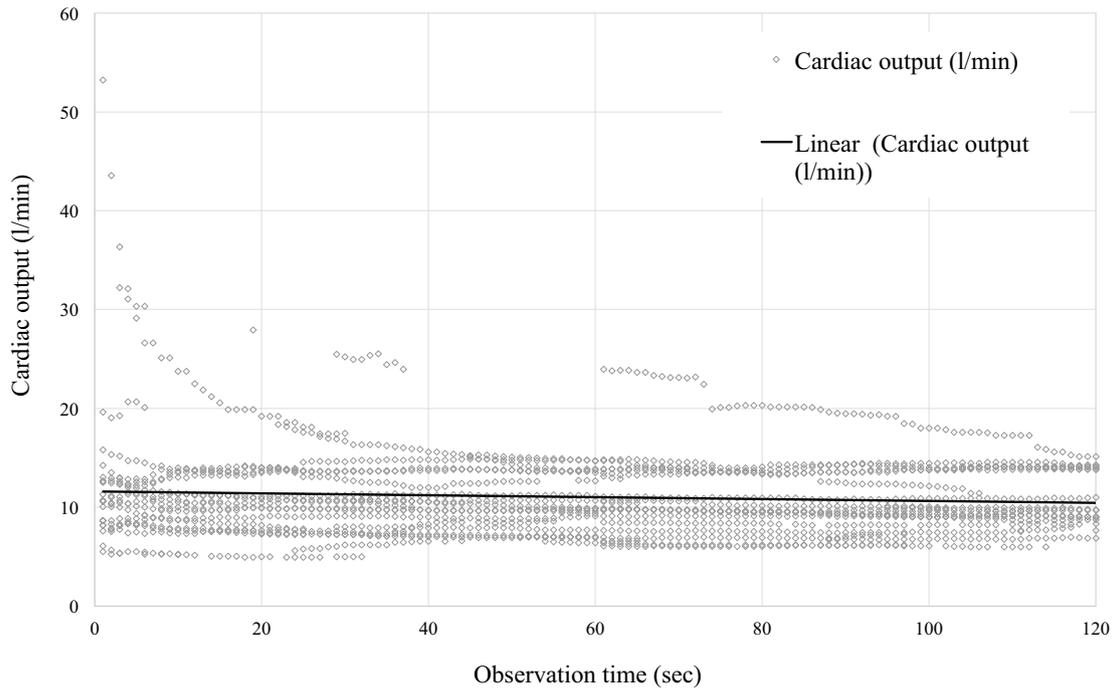


Fig. 3 Cardiac output over first 2 min of observation. Cardiac output in liters per minute as a linear function of observation time in seconds measured with non-invasive cardiac output monitoring device in 20

patients over first 2 min of observation in the trauma bay of the emergency department

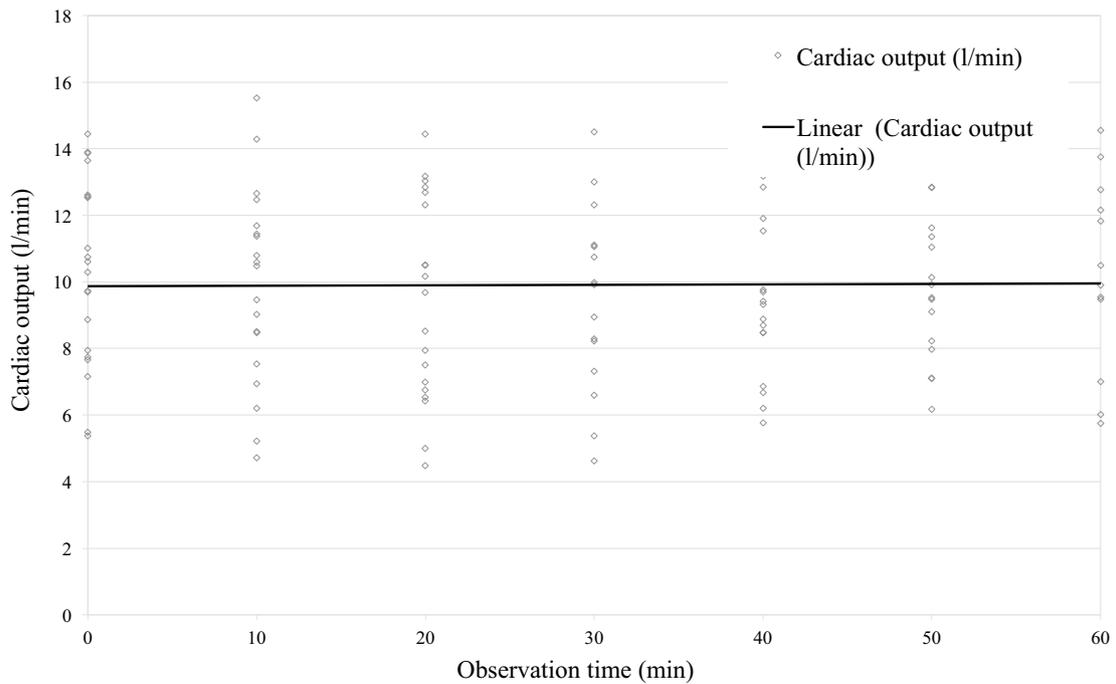


Fig. 4 Cardiac output during observation. Cardiac output in liters per minute as a linear function of observation time in seconds measured with non-invasive cardiac output monitoring device in 20 patients in the trauma bay of the emergency department

We found that the ICON[®] could be integrated well into standard ED procedures. Considering the results of the current study, non-invasive CO monitoring proved to be a promising new technique for the initial evaluation of hemodynamics in trauma patients. Non-invasive CO monitoring may allow to better understand hemodynamics in trauma patients, especially in the elderly with co-morbidities, and to adjust volume resuscitation to the patients' actual requirements.

A point that warrants detailed discussion and has not been discussed in previous studies is whether the ECG surface electrodes can be placed as intended as most trauma patients arrive with cervical collars to protect the cervical spine. Since the stiff neck covers the neck, it was questionable whether the device could be installed at all. In the current study, the ventral opening of the stiff necks proved large enough to place the neck ECG surface electrode with ease.

Other studies commented on the continuous, real-time display of measurements by non-invasive cardiac output monitoring devices, calling it a major strength [3, 4, 6, 7, 9, 15, 17, 18, 20, 22, 23]. The ICON[®] does also display vital signs in real-time. In addition, the ICON[®] has the advantage of being handheld sized, and only requires four electrodes to be placed on the patients' skin. Also, the advantage of being deployable very early in the ED [3–5, 8, 9, 15, 16, 18], which was a major motivator for the current study, was proven correct for the ICON[®] as well. Another advantage of the ICON[®] was its compatibility with the computer tomography scanner, which allows continuous CO monitoring, even during computer tomography scanning. Due to the small size and user-friendliness of the ICON[®], we believe that the device may be operated by the ED staff with no additional personal required, once it has been introduced into the clinical practice.

Motion artifacts, agitation, restlessness, and shivering have been previously described as important limitations for all non-invasive devices using the thoracic electrical bioimpedance method [6, 7, 11, 15, 23]. Other reported patient-related factors that can interfere with CO monitoring using thoracic electrical bioimpedance are anxiety, hyperventilation, extensive pulmonary edema, pleural effusion, valvular heart disease, dysrhythmias, extensive chest wall edema, and chest tubes parallel to the aorta [6, 7, 9, 15].

In the current study, calibration of the device and patient transfers were found to interfere with CO measurements. The interference with the CO monitoring during the calibration of the device is reflected by the significant decrease of the CO during the first 2 min of the observation (Fig. 3). However, interruptions of the CO monitoring were short and did not affect the overall assessment of hemodynamics of the included patients.

Limitations

The current study—designed as a pilot study—included only a small number of patients. In addition, included patients were hemodynamically stable over the observation period and had a relatively low median ISS. Because of these limitations, the results of this study cannot be extrapolated to trauma patients in general, especially to patients with a higher injury burden. Furthermore, no patient included suffered from massive hemothorax, massive pneumothorax, flail chest or cardiac tamponade. The feasibility of non-invasive CO monitoring using the ICON[®] for the initial hemodynamic evaluation in trauma patients, therefore, remains unclear in patients with these injuries.

However, taking into account the results of this study, non-invasive CO monitoring in trauma patients in the ED proves to be a promising technique and should be further investigated in larger clinical studies.

Conclusion

Non-invasive CO monitoring proved to be feasible and safe for the initial hemodynamic evaluation of trauma patients in the ED. Problems with the new NICOM device were detachment of electrodes and temporary signal loss. However, due to the inherent limitations of this study, including the small sample size and relatively low injury burden of the patients included, further studies investigating this promising non-invasive technique to evaluate hemodynamics in trauma patients are warranted.

Author contributions MK planned the study protocol, conducted the clinical data collection, assisted in the statistical analysis of data, drafted and composed the manuscript. TH participated in the planning of the study protocol, performed the statistical analysis of data, and revised the manuscript critically. AE revised the manuscript critically. BS conceived the study, participated in the planning of the study protocol, and revised the manuscript critically. All authors read and approved the final manuscript.

Compliance with ethical standards

Conflict of interest Matthias Kuster, Tobias Haltmeier, Aristomenis Exadaktylos, and Beat Schnüriger declare that they have no conflict of interest or financial ties.

Ethical approval This study was approved by the cantonal ethics committee of Bern, Switzerland (KEK No. 353/2015). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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