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ORIGINAL RESEARCH

Continuous noninvasive arterial blood pressure monitoring using the vascular unloading technology during complex gastrointestinal endoscopy: a prospective observational study

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Abstract

The innovative vascular unloading technology (VUT) allows continuous noninvasive arterial blood pressure (AP) monitoring. We aimed to investigate whether the VUT enables AP changes to be detected earlier compared with intermittent AP monitoring in patients undergoing gastrointestinal endoscopy. In this prospective observational study, we recorded continuous AP measurements with the VUT (CNAP system; CNSystems Medizintechnik AG, Graz, Austria) and intermittent AP measurements with upper arm cuff oscillometry in 90 patients undergoing complex gastrointestinal endoscopy (Department of Interventional Endoscopy at the University Medical Center Hamburg-Eppendorf, Hamburg, Germany). A "hypotensive phase" was defined as a time period of at least 30 s during which ≥ 50% of the VUT-AP values were in a predefined range of hypotension, i.e., AP value a) ≥ 10% below the last oscillometric value and b) ≤ 65 mmHg for mean AP or ≤ 90 mmHg for systolic AP. In the 5-min-interval between two oscillometric measurements, one or more hypotensive phases were detected in 26 patients (29%) for mean AP and in 27 patients (30%) for systolic AP. Hypotensive phases had a mean duration of 195 ± 99 s for mean AP and 197 ± 97 s for systolic AP with a mean procedure duration of 36 (± 21) min. Continuous noninvasive AP monitoring using the VUT enables hypotensive phases to be detected earlier compared with intermittent AP monitoring during complex gastrointestinal endoscopy. These hypotensive phases may be missed or only belatedly recognized with intermittent AP monitoring. Continuous noninvasive AP measurement facilitates detecting hemodynamic instability more rapidly and therefore may improve patient safety.

Keywords Hemodynamic monitoring · Volume clamp method · Hypotension · Oscillometry · Arterial pressure

1 Introduction

The arterial blood pressure (AP) of patients undergoing gastrointestinal endoscopy under sedation is conventionally monitored using noninvasive intermittent oscillometric measurements. As an alternative to noninvasive intermittent measurements, invasive continuous AP measurements with an arterial catheter can be used in patients with high risk for hemodynamic instability or cardiovascular complications.

The vascular unloading technology (VUT), also called volume clamp method, is an innovative finger-cuff technology that enables AP to be monitored continuously and noninvasively based on an enhanced Peňáz principle [1–3]. The VUT allows continuous hemodynamic monitoring based on the analysis of the noninvasively recorded AP waveform in patients so far merely monitored using intermittent AP measurements [4–6]. In this context, besides its validation in

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surgical patients under general anesthesia [7–9] and patients treated in the intensive care unit [10–12], the VUT has been described as a promising new AP monitoring technology in patients under spinal anesthesia for caesarean section [13] and in emergency department patients [5].

However, data on the applicability and measurement performance in patients under conscious sedation during complex interventional procedures are very sparse, and until now, have only been collected in a limited number of patients [14].

Therefore, the aim of the present study was to investigate whether continuous noninvasive AP monitoring using the VUT enables AP changes and especially hypotensive phases to be detected earlier compared with intermittent AP monitoring in patients undergoing complex gastrointestinal endoscopy.

2 Methods

2.1 Study design, inclusion and exclusion criteria

This observational study was performed between December 2014 and January 2016 in the Department of Interventional Endoscopy at the University Medical Center Hamburg-Eppendorf (Hamburg, Germany). The study protocol was reviewed and approved by the ethics committee (Ethikkommission der Ärztekammer Hamburg, Hamburg, Germany; Chairperson: Prof. R. Stahl; ethics committee number PV4701). Adult patients scheduled for complex gastrointestinal endoscopy in whom intermittent oscillometric AP monitoring was planned in the absence of contraindications for monitoring using the VUT (severe edema of the hands or the fingers, peripheral vascular pathology such as vascular implants or Raynaud syndrome) were eligible for inclusion in the study. Patients with clinically relevant AP differences (≥ 10 mmHg) between the left and the right arm were not eligible for study inclusion. Verbal and written informed consent to participate in the study was obtained from the patients.

2.2 Arterial blood pressure measurements, data recording and processing

During the complete gastrointestinal endoscopic procedure, we recorded continuous noninvasive AP measurements using the VUT (CNAP system; CNSystems Medizintechnik AG, Graz, Austria) as described previously [12, 15]. In parallel, and in accordance with our clinical routine practice, the patients' AP was monitored with intermittent upper arm cuff oscillometry integrated in the standard patient monitoring system Infinity Delta (Dräger Medical GmbH, Lübeck, Germany). The upper arm cuff for the oscillometric AP measurements was attached to the arm on the side not used for VUT measurements. The measurement interval was set to 5 min by default according to the standard procedure of the endoscopy department. If the physicians or nurses in charge considered it to be clinically indicated, they manually initiated additional measurements.

VUT-AP values were stored in a "beat-to-beat" format to a comma separated value digital text file. To be able to synchronize the VUT-AP measurements with the oscillometric AP measurements we synchronized the internal clocks of all devices by reference to a network time protocol (NTP) server. VUT measurements obtained during calibration of the CNAP system (calibration intervals were set at 45 min) were excluded before data analysis. In addition, obvious artifacts caused by movement of the extremity used for VUT measurements were excluded.

VUT measurements were blinded to the endoscopy team. Hemodynamic interventions were not predefined and management was left to the discretion of the endoscopy team.

2.3 Definition of "hypotension" and "hypotensive phase"

"Hypotension" was defined as an AP value (a) $\geq 10\%$ below the last measured oscillometric value and (b) ≤ 65 mmHg for the mean AP or ≤ 90 mmHg for the systolic AP [both (a) and (b) needed to be present to fulfill the definition of hypotension]. This definition of hypotension was pre-selected prior to the beginning of the study and is not based on the data itself.

A "hypotensive phase" measured with the continuous noninvasive VUT in the interval between two intermittent AP measurements was defined as a time period of at least 30 s during which $\geq 50\%$ of the AP values were in the defined range of hypotension, i.e. met the above given definition of "hypotension".

2.4 Statistical analysis

Data (patient characteristics, procedural data, data on AP measurements) are either shown as absolute numbers with percentages or mean ± standard deviation. For data collection and statistical analyses we used Microsoft Excel 2011 (Microsoft Corp., Redmond, WA, USA) and IBM SPSS Statistics, Version 23 (IBM Corp., Armonk, NY, USA). Figures were created using gnuplot 5.0 (http://www.gnuplot.info), Microsoft Excel 2011, and Adobe Photoshop CS4 (Adobe Systems Incorporated, San Jose, CA, USA).

3 Results

3.1 Patients

We enrolled 95 patients in this study and excluded five patients from the final analysis (no valid VUT-AP signal in two patients; technical problems with VUT-AP recording in one patient; technical problems with standard patient monitoring system in one patient; excessive movement during endoscopic procedure in one patient). Thus, 90 patients were included in the final analysis (Table 1).

3.2 Procedural data

In 69 patients (77%) endoscopic retrograde cholangiopancreatography (ERCP) was performed, in 11 patients (12%) percutaneous transhepatic cholangiography and drainage (PTCD), in 8 patients (9%) esophagogastroduodenoscopy (EGD), and in 1 patient each (1%) colonoscopy and endosonography.

The mean duration of the endoscopic intervention was 36 ± 21 min (25th–75th percentile, 21–46 min).

All patients (except for two who received midazolam) were sedated by using fractionated application of propofol by the endoscopic team. The mean dose of the fractionated administered propofol adjusted to the duration of the intervention was 13 ± 7 mg/kg/h.

Table 1 Patient characteristics

American Society of Anesthesiology class 1, 2, 3, 4; n (%)	2 (2%), 23 (26%), 46 (51%), 19 (21%)
Age, years	59 ± 16 (49–72)
Sex female/male, n (%)	31 (34%)/59 (66%)
Height, cm	173 ± 8 (168–178)
Actual body weight, kg	74 ± 17 (62–84)
BMI, kg/m^2	25 ± 5 (21–27)

Data are given as mean ± standard deviation (25th–75th percentile) or absolute numbers with percentages

3.3 Arterial blood pressure measurements and detection of hypotensive phases

In the 90 patients, we recorded a total of 231,198 beat-to-beat AP measurements with the VUT and a total of 717 AP measurements with oscillometry measured every 5 min in each patient. The baseline hemodynamic variables are shown in Table 2. The cumulative recording time of VUT-AP measurements in all patients was 192,620 s (3210 min or 54 h). The mean of the mean AP values obtained with the VUT and with oscillometry was 93 ± 24 mmHg and 97 ± 20 mmHg, respectively (systolic AP 121 ± 32 mmHg and 126 ± 25 mmHg, respectively).

In the 5-min-interval between two oscillometric measurements, one or more hypotensive phases were detected in 26 patients (29%) for mean AP and in 27 patients (30%) for systolic AP.

For the 26 patients in whom the VUT technology detected hypotensive phases according to the MAP-based definition, Fig. 1 illustrates the occurrence of hypotensive phases over the time of the endoscopic intervention and the severity of the hypotensive phases (difference between last oscillometric value and VUT-derived MAP values).

Hypotensive phases between two oscillometric measurements had a mean duration of 195 ± 99 s for mean AP and 197 ± 97 s for systolic AP. Of all 231,198 VUT-AP measurements, we observed 25,611 (11%) mean AP values and 32,277 (14%) systolic AP values during hypotensive phases.

Figure 2 exemplarily shows two episodes of AP measurements of two patients to illustrate that the continuous assessment of AP with the VUT enabled AP changes and hypotensive phases to be immediately detected that would have been belatedly recognized (Fig. 2a) or even missed (Fig. 2b) with intermittent oscillometric AP monitoring.

Patients of an American Society of Anesthesiology (ASA) physiological status class ≥ 3 had more hypotensive phases than patients with ASA class 2 (20 of 65 patients, i.e. 31% vs. 5 of 23 patients, i.e. 22%).

Table 2 Hemodynamic variables at baseline

	Mean arterial pressure (mmHg)	Systolic arterial pressure (mmHg)	Diastolic arterial pressure (mmHg)	Heart rate (beats per minute)
Vascular unloading technology	100 ± 18	126 ± 26	81 ± 16	80 ± 15
Oscillometry	103 ± 19	136 ± 24	79 ± 16	77 ± 15

Data are given as mean ± standard deviation

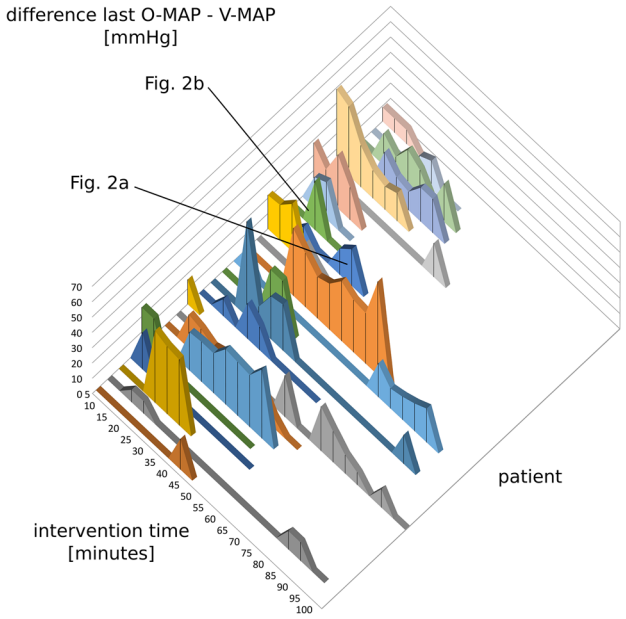

Fig. 1 Hypotensive phases (time course and severity). This figure illustrates the occurrence of hypotensive phases over the time of the endoscopic intervention (x-axis) and the severity of the hypotensive phases (y-axis), i.e., the difference between the last oscillometric mean arterial pressure (MAP) value (O-MAP) and the vascular unloading technology (VUT)-derived MAP values (V-MAP) for the 26 patients (z-axis) in whom the VUT detected hypotensive phases according to the MAP-based definition

4 Discussion

In this study, we observed that continuous noninvasive AP monitoring using the VUT enables hypotensive phases to be detected earlier compared with intermittent AP monitoring during complex gastrointestinal endoscopy. These hypotensive phases may be belatedly recognized or even missed with intermittent AP monitoring.

Our study confirms that hypotension is a common complication in patients undergoing complex endoscopic procedures. A study on cardiopulmonary events during gastrointestinal endoscopy reported an incidence rate of hypotension of 150 per 100,000 esophagogastroduodenoscopies and 480 per 100,000 colonoscopies [16]. However, our data indicate that the incidence might be underestimated due to the intermittent measurement method that is typically applied during endoscopy and that may miss hypotensive phases.

The occurrence of even short periods of low AP during surgical interventions—often referred to as "intraoperative hypotension"—has been demonstrated to be associated with post-interventional organ failure [17, 18] and mortality [19], especially in patients with altered blood flow autoregulation due to chronic hypertension [20]. In accordance, in patients undergoing complex gastrointestinal endoscopic interventions, even short periods of peri-interventional hypotension may also affect patient outcome. In addition, marked changes in AP may prevent completion of the endoscopic procedure. Therefore, a consensus group strongly agreed that hypotension should be included in a list of safety indicators [21]. In addition, it was agreed that recording instances of hypotension is a general indicator of quality that might enable analysis to determine whether hypotension is associated with subsequent adverse events [21].

Our study further shows that monitoring and recording of AP during gastrointestinal endoscopy might be improved using innovative VUT devices for continuous and noninvasive assessment of AP. Continuous recording of AP may improve the hemodynamic management of patients undergoing complex gastrointestinal endoscopic procedures by identifying hypotensive phases earlier thus providing the opportunity for immediate therapeutic interventions. These results are in line with a previous smaller study demonstrating that intermittent oscillometric AP monitoring fails to detect rapid changes in AP during interventional endoscopy and that these changes are recognized earlier when using continuous VUT monitoring [14]. Similarly, in emergency department patients, we previously showed that continuous noninvasive AP monitoring using VUT enables clinically relevant hypotensive phases to be immediately recognized [5].

Of note, our study was not conceived as a method comparison study comparing AP values observed using the VUT and oscillometry.

Although this is, so far, the largest study investigating the VUT in the setting of gastrointestinal endoscopy, several limitations of the study need to be mentioned. First, this was a monocentric study performed in a university medical center with experience in advanced noninvasive hemodynamic monitoring. This might limit the generalizability of the findings and the conclusions. In addition, this was an observational study aimed at evaluating whether the VUT can be used during gastrointestinal endoscopy to identify hypotensive phases; we did not link this diagnostic detection of hypotension to therapeutic interventions or clinical patient outcome. Thus, future research on this topic should evaluate whether therapeutic interventions based on VUT-derived AP measurements can improve patient outcome compared with hemodynamic management based on intermittent AP monitoring.

5 Conclusion

Continuous noninvasive AP monitoring using the VUT enables hypotensive phases to be detected earlier compared with intermittent AP monitoring during complex gastrointestinal endoscopy. These hypotensive phases may be belatedly recognized or even missed with intermittent AP monitoring.

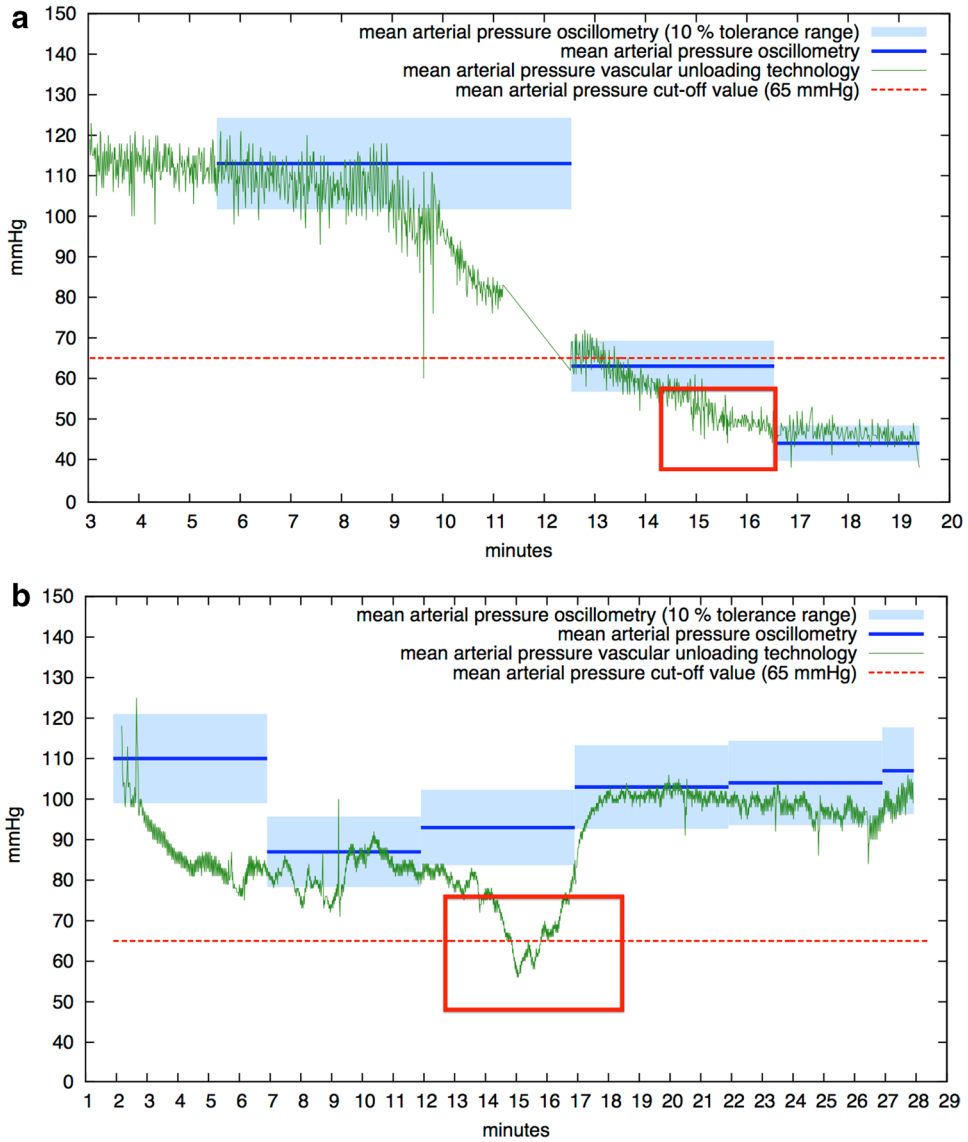

Fig. 2 Arterial pressure measurements during complex gastrointestinal endoscopy (two example patients). **a, b** Exemplarily show two episodes of mean arterial pressure measurements of two patients. Continuous assessment of arterial pressure with the vascular unloading technology allowed detecting arterial pressure changes and hypotensive phases (red square) that would have been belatedly recognized (**a**) or even missed (**b**) with intermittent oscillometric arterial pressure monitoring. **a** Additionally shows that the vascular unloading technology-derived mean arterial pressure measurement was interrupted by movement/positioning of the patient around 11 and 12 min of the intervention

By this earlier detection of hypotensive phases, continuous noninvasive AP measurement facilitates detecting hemodynamic instability more rapidly and therefore may improve patient safety.

Compliance with ethical standards

Conflict of interest JYN and BS received refunds of travel expenses from CNSystems Medizintechnik AG (Graz, Austria). BS received honoraria for giving lectures from CNSystems Medizintechnik AG (Graz, Austria). All other authors have no conflict of interest to disclose. CNSystems Medizintechnik AG (Graz, Austria) provided the technical equipment needed for this study. The company was not involved in the study design, in the collection, analysis, and interpretation of data, writing of the manuscript, and in the decision to submit the manuscript for publication.

Ethical approval This method comparison study was reviewed and approved by the ethics committee (Ethikkomission der Ärztekammer Hamburg, Hamburg, Germany). 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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