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Continuous non-invasive monitoring of blood pressure in the operating room: a cuffless optical technology at the fingertip

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Abstract: Routine monitoring of blood pressure during general anaesthesia relies on intermittent measurements with a non-invasive brachial cuff every five minutes. This manuscript provides first experimental evidence that a physiology-based pulse wave analysis algorithm applied to optical data (as provided by a standard fingertip pulse oximeter) is capable of accurately estimating blood pressure changes in-between cuff readings. Combined with the routine use of oscillometric cuffs, the presented novel approach is a candidate technology to increase patient safety by providing beat-to-beat hemodynamic measurements without the need of invasive monitoring procedures.

Keywords: beat-to-beat; blood pressure; cuffless; general anesthesia; operating room; pulse wave analysis.

1 Introduction

Blood pressure and heart rate monitoring belong to the minimal standards for basic anaesthetic monitoring [1]. Still today, the non-invasive measurement of blood pressure is performed with brachial inflation cuffs placed around the arm. However, these devices only provide intermittent measurements of blood pressure during the interventions, i.e. every 2–5 min. For patient safety reasons, beat-to-beat blood pressure readings are mandatory in critical patients during long and complex interventions. Unfortunately, the routine procedure to obtain

reliable continuous blood pressure readings relies on arterial invasive catheters, with their non-negligible associated morbidity issues [2]. Non-invasive and continuous blood pressure measurement devices have been tested in the past, but their accuracy and reliability have been repeatedly questioned [3], in particular when aiming at replacing existing procedures. Even more, high costs and cumbersomeness of existing non-invasive beat-by-beat devices impede their introduction into daily anaesthesia practices.

This manuscript presents first experimental evidence on the feasibility of tracking beat-by-beat changes of blood pressure in humans during induction of general anaesthesia by simple optical means. The presented technology relies on the physiological analysis of transmission photoplethysmographic signals measured at the fingertip. Such signals are recorded by commercial pulse oximeters, which are routinely applied to almost every patient. While the presented approach does not aim at replacing oscillometric gold-standard monitoring, it introduces an appealing approach to continuously estimate blood pressure measurements in-between two cuff inflations, thus allowing the detection of sudden blood pressure changes and thereby increasing the patient's safety.

Because no additional monitoring equipment is required in the operating room, this optical technology appears as an appealing candidate to improve non-invasive monitoring capabilities during general anaesthesia. Figure 1 illustrates the status of the novel technology within the constellation of existing monitoring means in the operating room.

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2 Materials

The clinical study (ClinicalTrials.gov NCT02651558) described in this section is compliant with all relevant Swiss ethics, regulations and institutional policies and in accordance with the tenets of the Helsinki Declaration.

	Technique	Advantages	Limitations
	Oscillometric brachial cuff	Accurate non-invasive	Intermitent
133	Arterial line	Gold-standard	Invasive
V 3	Volume clamp	Non-invasive	Inaccurate expensive
	Physiological PWA	Non-invasive inexpensive deployed in OR	Under validation

Figure 1: Summary of available blood pressure (BP) monitoring technologies in the operating room.

Informed consent was obtained from all individuals before enrolment at CHUV - University Hospital of Lausanne.

Patients were placed on the operating table and monitoring was carried out via the Philips monitor IntelliVue MX800. Monitoring consisted of a 3-lead electrocardiogram, non-invasive blood pressure cuff measurements at the left arm and oxygen fingertip saturation readings at the right index. Under local anaesthesia, a dedicated catheter (BD Arterial Cannula 20G/1.1 mm imes 45 mm, Becton Dickinson Infusion Therapy Syst. Inc., UT, USA) was inserted into the right radial artery, allowing beat-to-beat continuous blood pressure monitoring. General anaesthesia was then provided by the anaesthetist in charge of the patient, in accordance with the standard practice of the department: propofol (2 mg/kg) for induction, fentanyl (3 µg/kg) for analgesia, and rocuronium (0.6 mg/kg) for neuromuscular blockade; endotracheal intubation followed.

Recording of continuous invasive blood pressure signals, non-invasive fingertip photoplethysmographic signals (i.e. Pleth Wave), and electrocardiogram was performed at 500 Hz by ixTrend® - software for Philips IntelliVue monitors. As the clinical study is ongoing, only the first three patients showing good raw signal quality (by an unsupervised quality index) were used to show first experimental evidence.

3 Methods

3.1 Overall methodology

The novel optical technology relies on the extraction of physiology-based pulse wave analysis (PWA) features from raw transmission photoplethysmographic signals. These

physiological features are later projected into blood pressure values by means of intermittent oscillometric measurements provided by a brachial cuff (see Figure 2).

3.2 Extraction of PWA features

Raw photo-plethysmographic signals are acquired by a fingertip pulse oximetry probe. While for the current study a commercial transmission probe is used, any other means to acquire a surrogate measure for peripheral arterial pulsatility is adapted for this methodology.

After a pre-processing and denoising procedure, a PWA technique is applied to each arterial pulse [4]. The implemented PWA algorithm extracts features from each pulse based on the wave reflection theory of the arterial system [5]. The algorithm assumes that arterial pulses propagate along the arterial tree being reflected at each arterial branching. The resulting arterial pulses are thus the superposition of forward and backward waves interfering at various locations of the arterial tree.

Given the arterial topology of a particular patient, changes in blood pressure modify the velocity at which arterial pulses propagate, reshaping the individual mixture of incident and reflected waves. These morphological changes are quantified via the implemented PWA algorithm as modifications of the patients' arterial pulsatility patterns. Pulsatility pattern changes are indirect indicators of the underlying changes in propagation characteristics, and thus, of the underlying changes of central blood pressure. Therefore the outcome of the implemented PWA algorithm is a vector of physiologically meaningful

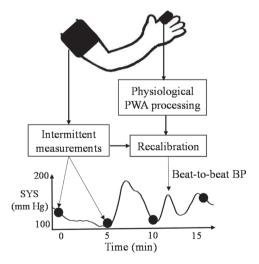


Figure 2: Overall methodology: blood pressure estimates interpolate patient's hemodynamic changes in-between two oscillometric measurement.

features containing information on the patient's central blood pressure status.

3.3 Calibration to brachial cuff values

While containing meaningful physiological information, the feature vector extracted from the PWA algorithm does not yet relate to blood pressure values in mm Hg.

In the context of a methodology to extract beat-to-beat blood pressure estimates in-between two cuff measurements a dedicated (re-)calibration algorithm is thus needed. The aim of this algorithm is to map subject-dependent changes of the PWA feature vector x_i into actual changes of blood pressure. During each

recalibration at instant i, the availability of intermittent cuff-based measurements \mathbf{y}_i is used as a reference to re-estimate the parameters $\hat{\boldsymbol{p}}_i$ of a mapping function f as it is depicted by equation 1. A forgetting factor λ can be used to smooth pressure estimates in time.

$$\hat{p}_{i} = (1 - \lambda) \ \hat{p}_{i-1} + \lambda \ \text{argmin}_{p_{i}} \|y_{i} - f(p_{i}, x_{i})\|^{2}$$
 (1)

4 Results and discussion

Based on the previously described methodology, first experimental evidence on the performance of the novel cuffless technique is provided here. Figures 3–5 illustrate

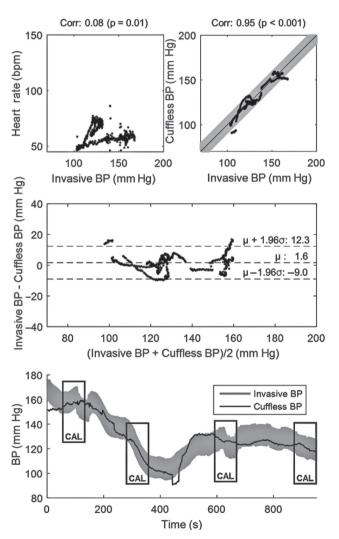


Figure 3: Performance of the cuffless blood pressure estimation technique on a particular study patient during induction of anesthesia. Each data point corresponds a patient's heart beat. Temporal evolution of invasive systolic blood pressure is displayed as $\pm 8\,$ mm Hg range (shaded in grey).

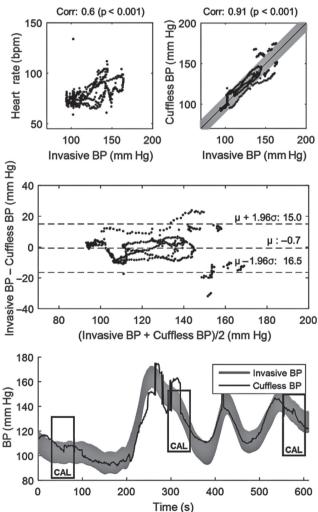


Figure 4: Performance of the cuffless blood pressure estimation technique on a particular study patient during induction of anesthesia. Each data point corresponds a patient's heart beat. Temporal evolution of invasive systolic blood pressure is displayed as $\pm 8\,$ mm Hg range (shaded in grey).

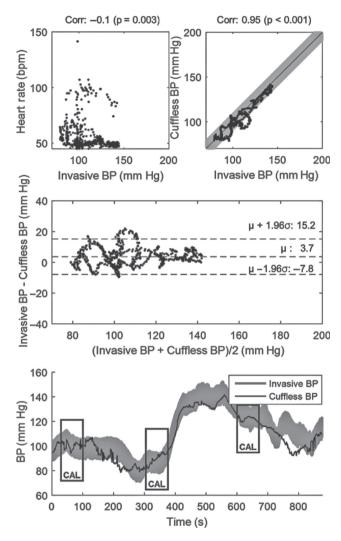


Figure 5: Performance of the cuffless blood pressure estimation technique on a particular study patient during induction of anesthesia. Each data point corresponds a patient's heart beat. Temporal evolution of invasive systolic blood pressure is displayed as $\pm 8\,$ mm Hg range (shaded in grey).

the results of cuffless systolic blood pressure estimations compared to invasive reference measurements. Each figure corresponds to data recorded during induction of anaesthesia on one patient. Each data point in these figures corresponds to a single heartbeat. Calibration with reference measurement was performed every 5 min.

The first row in each figure depicts correlation plots between invasive systolic blood pressure values and heart rate estimates (left plot) or cuffless blood pressure estimates (right plot), respectively. Note that in current clinical practice, when only intermittent blood pressure measurements are available, anaesthetists fully rely on heart rate measurements to infer blood pressure changes.

The second row in each figure depicts Bland-Altman plots when comparing invasive systolic blood pressure values against cuffless blood pressure estimates. Due to the re-calibration procedures, overall bias are within a reasonable range ($|\mu| < 4$ mm Hg). Standard errors of the estimates σ are all smaller than 8 mm Hg, and thus comply with the specifications of the AAMI standard [6].

The third row in each figure depicts the temporal evolution of invasive systolic blood pressure during anesthesia induction (± 8 mm Hg range shaded in grey), and simultaneous cuffless estimates. Note that calibration periods are illustrated by black boxes marked as "CAL". It is important to note that the novel cuffless method was able to detect blood pressure changes in between calibration periods for all the three patients analyzed.

5 Conclusion

This manuscript presented first experimental evidence for the feasibility of estimating blood pressure changes in the operating room by means of a simple optical probe at the fingertip, which is routinely applied to every patient.

During all anaesthetic procedures and surgeries, the patient's oxygenation, ventilation, circulation and temperature must be continuously monitored. To cope with these requirements, and in order to increase patients' safety, international standards for safe practice of anaesthesia have been implemented and consist of cumbersome equipment.

While comprehensive statistical analysis of the performances of the novel approach will be presented at finalisation of the ongoing clinical study, these preliminary results support the hypothesis that physiology-based PWA algorithms applied to standard photo-plethysmographic signals might contain sufficient information to deduce blood pressure changes during general anaesthesia, without the need of additional monitoring equipment.

Technological advances such as the one herein presented appear as an interesting alternative, aiming at simplifying patient access, and potentially decreasing morbidity associated to invasive monitoring in the operating room.

Authors' Statement

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