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In vitro validation of a non-invasive continuous blood pressure measurement method for the perioperative application

Abstract: Hypotensive periods during surgery lead to an increase in postoperative complications. To further avoid the adverse events associated with the invasive measurement of the blood pressure, a perioperative, continuous, non-invasive blood pressure measurement method was developed. The precision of the method was tested for different mean pressure values and different thicknesses of the tissue model using a specifically designed and validated simulator that has the characteristics of the lower arm. The mean pressure difference between the pressure determined by the proposed method and simulated blood pressure from the simulator was 3.93 mmHg (± 4.75 mmHg) for the systole and 4.89 mmHg (± 6.10 mmHg) for the diastole. The results showed that the method can be a promising alternative to invasive blood pressure measurement methods.

Keywords: Blood Pressure Measurement, Perioperative, Non-invasive, Iterative Learning Control

<https://doi.org/10.1515/cdbme-2021-2219>

1 Introduction

Worldwide, 234 million major surgical procedures are undertaken every year [1]. In most of these surgeries, the blood

pressure (BP) is determined non-invasively and intermittently with the upper arm cuff, where the standard measurement frequency is once per five minutes [2]. This can lead to undetected cumulated periods of hypotension of 7 min / h of surgery [3]. It has been shown that hypotensive periods lead to an increased risk of acute kidney injury, myocardial injury, and stroke [4]. Further, Pietropaoli et al. analysed severe head injury patients and found that mortality was twice as likely if these patients went into a hypotensive state during surgery [5].

Due to their imprecision, previously developed continuous non-invasive measurement methods that have been tested during surgery cannot be considered interchangeable with invasive methods for critically ill patients [6]. However, measuring the blood pressure invasively is not only more expensive, compared to non-invasive methods, but it can also lead to more complications. These can include hematoma (in 14.4% of applications), temporary occlusion (19.7%), sepsis (0.13%) or local infection (0.72%) [7].

Therefore, a continuous non-invasive BP measurement method at the radial artery was proposed for the perioperative application [8]. The precision of this method is now validated using a specifically designed and validated simulator.

2 Material and methods

The setup of the proposed method consists of a small balloon, positioned on top of the radial artery, a downstream-positioned custom-designed Doppler ultrasound sensor (GAMPT mbH, 8MHz), a control unit (STM32), and a pneumatic unit. The blood pressure is determined via the control system by reducing the flow in the radial artery to a constant near-zero target value. The flow is reduced by pneumatically adjusting the pressure of the balloon, positioned on top of the radial artery. This is performed by a voice coil actuator (GVCM-051-025-01, Moticon) that presses down on a small balloon that is connected to a pressure pad positioned on top of the radial artery. Hence, the movement of the actuator influences the flow in the radial artery. When the flow in the radial artery is

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reduced to a constant target value, the pressure in the pressure pad (called balloon pressure) can then be correlated to the blood pressure.

2.1 Simulator

To develop and validate the proposed method, a simulator based on the properties of the lower arm was constructed.

A model of the artery and its surrounding tissue create anatomical conditions. With a peristaltic pump, a linear motor, a variable resistance, and a water column, the simulator can create arbitrary physiological and pathological volumetric flow and pressure curves. The simulator set-up, based on [9], can be seen in Figure 1.

Figure 1: Schematic diagram of the simulator with the physiological and anatomical characteristics of the lower arm. (1) fluid reservoir, (2) peristaltic pump, (3) water column, (4) piston, (5) linear motor, (6) pressure sensor, (7) overflow basin, (8) radial artery model, (9) bone model, (10) bone mat, (11) skin mat, (12) plexiglass, (13) pressure pad, (14) doppler ultrasound sensor (US), (15) time-of-flight US, (16) adjustable resistance

The peristaltic pump (2) (PERIMAX 12, SpecTec GmbH) pumps the ultrasound fluid (GAMPT mbh) with a constant volumetric flow rate from the reservoir (1) into the water column (3). The mean volumetric flow rate can be set arbitrarily between 60 – 100 mL/min. This corresponds to the mean flow rates for the radial artery during surgery with anaesthesia [11]. The linear motor (5) (LinMot K05-D/P-4 by NTI AG), with the piston (4), is connected to the air-filled part of the water column. The motion of the linear motor is defined in a LabView (National Instruments) script. Hence, physiological and pathological pressure curves can be recreated with arbitrary frequencies. The piston compresses and decompresses the air in the water column and therefore applies a pulsatility to the flow. Based on the fluid level within the water column, the pulsatility of the flow can be damped or amplified. Then, the fluid flows past a pressure sensor (6) (26PCAF6D (1psi), Honeywell GmbH) and splits into an overflow basin (7) and into the measurement area. The overflow basin prevents an increase in system pressure even if the pressure pad is inflated and the flow through the

measurement area (8-14) is stopped or decreased. The measurement area is based on the anatomical characteristics of the lower arm. It consists of two silicone mats that represent the tissue from bone to artery (bone mat (10)) and artery to skin (skin mat (11)), a model of the radial artery (8), a pressure pad (13) (50 x 25mm) and a Doppler US (14). The pneumatic unit that is connected to the pressure pad is not visualized in Figure 1. The bone is modelled as a flat surface, made from PLA (3DXTech™) (9). The tissue models and artery model are interchangeable to test and develop the method on different anatomies. The tissue model is made from Exoflex® 0030 (Smooth-On) that has a similar elastic modulus to the tissue surrounding the artery at the wrist [11]. The size of the pressure pad was determined through experiments with a plastered wrist where different pressure pads were evaluated. The plastered wrist was used for an optimal and reproducible counter bearing to the pressure pad. The aim was to find the minimum required volume for a pressure increase of 200 mmHg in the balloon, while fully compressing the radial artery and stopping the flow (measured with an US). In the simulator, the counter bearing to the pressure pad is a plexiglass disc (12). The simplified radial artery model has a lumen area of 5.4 mm², which is based on [12], [13], [14]. It is made out of polyurethane foil (U04/PE), with a thickness of 200 µm and an elasticity of 6 – 7 MPa, which is in the range of literature values for the arterial elasticity and thickness [15], [16]. The fluid then flows through a time-of-flight US (15) (SONOFLOW IL52.0 V2.0, 50Hz Frequency), past an adjustable resistance (16), and into the fluid reservoir. The time-of-flight sensor is used for a reference flow measurement.

2.2 Control System

The overall control system is depicted in Figure 2 and described in [8] and [17] in more detail. It consists of an inner loop to control the balloon pressure as well as an outer loop to obtain a low and constant flow through the radial artery. The control system is implemented in Matlab/Simulink (version 2017b) and integrated into the control unit firmware using automatic C code generation.

Figure 2: Structure of the control system to achieve a low and constant artery flow. An iterative learning controller determines the required reference pattern for the self-tuning pressure controller

The balloon pressure is controlled with a PI controller that outputs a pulse-width modulation (PWM) signal to the voice coil actuator. The corresponding controller parameters are determined during an auto-calibration procedure before starting the actual blood pressure measurement. This ensures consistent controller performance even with changing system dynamics, e.g., when the tube length between voice coil actuator and balloon or the attachment of the device to the patient's forearm changes. The pressure dynamics are modelled by a second-order transfer function in z-domain with dead time, and the corresponding parameters are identified using a recursive least squares algorithm. The digital magnitude optimum method is subsequently used to calculate optimal controller parameters for the identified model.

The outer control loop consists of an iterative learning controller (ILC), which exploits the periodic pulsatility of the blood flow in human arteries. The ILC determines a reference pattern for the balloon pressure over several iterations. It exhibits a P-type structure with a fixed learning rate and a Butterworth robustness lowpass filter. A pulse detection algorithm determines peaks in the artery flow signal to identify the iteration periods needed by the ILC. To increase the blood perfusion of the hand, the ILC is only active for two iterations and subsequently inactive for three iterations. Furthermore, a time-scale transformation approach is used to increase the robustness against physiologically time-varying heart rates.

2.3 Validation Experiments

To evaluate the overall precision of the proposed measurement method, tests were performed with a mean pressure (2/3 diastole + 1/3 systole) of 68 mmHg - 105 mmHg. To analyse how susceptible the method is to the characteristics of the tissue, three different thicknesses of the skin mats were used: 2.1 mm, 2.8 mm, and 3.5 mm, based on [14] and [16].

3 Results

3.1 Validation of the Simulator

For the development of the method, it was important that the simulator can create stable pressure and flow curves for at least 5 minutes. Figure 3 shows these pressure and flow curves created by the simulator in blue and red, respectively, as well as an idealized reference invasive pressure curve in green.

Over a 5-minute period, the system pressure was determined using the pressure sensor (6), see Figure 1. When comparing each systolic and diastolic pressure value from the

simulator with the invasively measured pressure curves, the values are in good agreement (mean deviation of less than 5%). It can also be seen that the frequency is constant and that the flow curve correctly follows the pressure curve with a small time offset. The mean volumetric flow rate in the simulator, shows a good agreement to the literature data [10].

Figure 3: Flow and pressure curves of the simulator and a reference invasive blood pressure measurement

3.2 Validation of the measurement method with stress tests

In total, 67 stress tests were performed with the three different skin mats. The combined measurements are shown in the Bland-Altman plot, in Figure 4. The term system pressure refers to the pressure in the simulator, measured just before the measurement area. The term balloon pressure refers to the pressure determined through the proposed method. The balloon pressure values are shown following a linear regression analysis with $R^2 = 0.90$ and $R^2 = 0.86$ for systolic and diastolic values, respectively. The mean pressure difference between balloon pressure and system pressure was

Figure 4: Bland-Altman plot comparison of system pressure to balloon pressure. Top: Systole, bottom: Diastole

3.93 mmHg (± 4.75 mmHg) for the systole and 4.89 mmHg (± 6.10 mmHg) for the diastole.

4 Discussion

The precision of the proposed method, as shown in Figure 4, is considered acceptable since the probability of a tolerable error (≤ 10 mmHg) is higher than 85 %, as required by the Universal Standard for the Validation of Blood Pressure Measuring Devices [19]. The results show that the method is not susceptible to different thicknesses of the skin mats. However, during the measurements, the measured flow signal and thus the controller performance were found to be susceptible to small movements of the US. This needs to be resolved before the system can be tested on patients.

Further stress tests should be performed to evaluate how the system reacts towards pathological behaviour. Tests on varying heart rates have been successfully performed with the proposed system [9] using the time-of-flight US and must now be repeated with the Doppler US.

In summary, it can be said that the proposed method is a promising alternative to invasive measurement methods for a continuous monitoring of the blood pressure during surgery.

Author Statement

Research funding: The project RadialisPeriOP (FKZ 13GW0190F) is supported by the German Federal Ministry of Education and Research

Conflict of interest: Authors state no conflict of interest.

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