PPG in the OR and ICU

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40811

Source
ToetsingOnline

Brief title
PPG@OR&ICU

Condition

- Other condition

Synonym
vitale parameter monitoring

Health condition

monitoring van vitale parameters tijdens heelkundige ingrepen (mn die van de buik)

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Sponsor: Philips Research

Intervention

Keyword: correlation, Physiological patient state, PPG sensors, Pulsoximetry

Outcome measures

Primary outcome

The primary endpoint of the study is the correlation of the effects of blood transfusion, fluid therapy, and vasoactive medication during surgery, recovery, and intensive care with and without mechanical ventilation on the invasively measured arterial blood pressure waveforms and the PPG waveforms non-invasively measured at the finger, ear, and forehead. The secondary endpoint of the study is the assessment of the PPG signal quality from different sensors in terms of information on heart rate, arterial blood saturation, volume status, blood pressure, and early warning for hemodynamic crisis.

Secondary outcome

Not applicable

Study description

Background summary

Photoplethysmography (PPG), often performed with a pulse oximeter, is an optical method providing a measurement of the changes in blood volume in the measurement site (e.g., the finger tip) as a result of cardiac output-induced blood pressure pulses [WebsterJG1997-Book-a]. With each cardiac cycle the heart pumps blood around in the body and the pressure wave induced by heart contraction results in a transient increase in vascular diameter, which is shown in the PPG signal as a transient decrease in the light transmission through e.g. the finger. Since the late 1980's, pulse oximeters are widely used to measure SpO2 and pulse rate.

Various reviews in the last decade advocate to investigate novel advanced PPG-derived hemodynamic parameters beyond pulse rate and SpO2 [ShelleyKH2007a,

AllenJ2008a, SahniR2012a]. Some recent PPG-derived parameters under investigation are predictors of fluid responsiveness [CannessonM2007a, MonnetX2012a], respiration frequency [AddisonPS2012a], detection of congenital heart disease in newborn infants [EwerAK2012a], blood pressure [SolaJ2013a], cardiac output [IshiharaH2004a,IshiharaH2012a], and detection of return of spontaneous circulations in patients with cardiac arrest [WijshoffRWCGR2013a]. However, little is known about the performance of these advanced PPG-derived parameters in clinical practice, and these new parameters may put more stringent requirements on the PPG signal than before [MonnetX2013a]. There are two aspects of the PPG signal that require deeper understanding.

The first aspect is the reliability and quality of the PPG signal. The performance of pulse oximeters can be severely compromised under low-perfusion conditions, motion, and arrhythmias [WebbRK1991a, ReichDL1996a, BransonRD2004a, BatchelderBP2007a, HummlerHD2006a]. The performance of pulse oximeters is traditionally measured in terms of the precision, bias, and accuracy of the SpO2 reading [ISO9919:2005, VanDeLouwA2001a, SeguinP2000a], but drop-out rates, frozen readings, and fall-off events are also common problems of pulse oximeters [ReichDL1996a, BatchelderBP2007a]. Some studies have dealt with SpO2 in low-perfusion conditions and motion [ShahN2012a, GehringH2002a]. These investigations, however, have been done in laboratory settings and the studies intrinsically depend on undisclosed algorithms for the computation of the SpO2 value.

The second aspect refers to the characteristics of the raw PPG signal depending on the type of PPG sensor and sensor location. Due to the complex origin of the photoplethysmography signal, a deep understanding of the PPG signal in relation to various physiological conditions and sensor location/geometry is still lacking [SinexJE1999a, ShelleyKH2007a, ReisnerA2008a]. A certain change in the hemodynamic state will almost certainly manifest itself differently in the PPG signals measured at different sites on the body.

There is no literature specifically targeting the quality of and information contained in the raw PPG signals measured at different body sites during surgery and recovery. The PPG-derived hemodynamic parameters (beyond heart rate and SpO2) should reflect established methods based on the arterial blood pressure (ABP) waveform. For example, the PPG-derived measure for the fluid responsiveness corresponds to the ventilation-induced modulation of the pulse pressure, commonly known as the pulse pressure variability (PPV). Therefore, investigating the quality of and information in the raw PPG signals from different body sites can best be done by correlating the raw PPG signal from different sites with the intra-arterial blood pressure, fluid status changes, and vasoactive medication.We aim to investigate (1) whether features in the PPG signal correlate with features in the ABP signal and (2) whether this correlation is affected by specific clinical conditions encountered during surgery (i.e. mechanical ventilation, anesthesia, blood loss, and blood transfusion), intensive care (i.e. mechanical ventilation, anesthesia, fluid

therapy, and vasopressor administration), and less intensive care (i.e. spontaneously breathing, no anesthesia, less medication).

Study objective

The primary objective of the study is to correlate the effects of blood transfusion, fluid therapy, and vasoactive medication during surgery, recovery, and intensive care with and without mechanical ventilation on the invasively measured arterial blood pressure waveforms and the PPG waveforms non-invasively measured using commercial PPG sensors at the finger, ear, and forehead.This clinical investigation is needed, because there is not sufficient knowledge available on the clinical use of PPG for non-invasive hemodynamic monitoring other than its use for heart rate and SpO2 assessment.

Study design

Observational study, compliant with ISO 14155.

Study burden and risks

Not applicable

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria are: adult (>=18 years) patients planned to undergo major abdominal surgery followed by recovery and/or intensive care. These patients are routinely equipped with an iinvasieve arterial blood pressure line and ECG lines.

Exclusion criteria

Exclusion criteria are: neuro-trauma, pregnancy, prone position during surgery or intensive care, obesity (BMI>40), and a significant language barrier that prevents the patient from understanding the Informed Consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	40

Type:	Anticipated

Ethics review

Approved WMO Date:	24-04-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48421.028.14