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Can a wristband wearable device accurately measure acute stress of novice surgeons during a high-fidelity surgical simulation?

Submission date
20/02/2018

Recruitment status
No longer recruiting

Registration date
24/02/2018

Overall study status
Completed

Last Edited
23/02/2018

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is known that acute stress has a direct impact on surgical performance and patient safety as well. As it is rather unfeasible to measure surgeon's stress in the operating room, surgical simulation has been proposed as the best alternative, since it is establish way of training that is designed to replicate real-life situations replicating stress, prevent biases and provide objective metrics. As there is no gold standard method to measure stress, several subjective and/or objective methods have been proposed. The rationale for the objective methods lies in the fact that acute stress provokes changes. Therefore changes that are looked at are: Heart rhythm changes as measured by heart rate (HR) or heart rate variability (HRV), electrodermal activity (EDA) levels , thermal activity, blood pressure variability (BVP), and saliva stress biomarkers have been suggested as markers. Using a wearable device that simultaneously captures HR/HRV, BVP, and EDA, in order to evaluate the accuracy of these parameters on stress detection, as well as, to compare them against the most widely method used, the Holter derived HRV could be helpful for measuring stress levels. The aim of this study is to assess the feasibility of a new watch-sized device to noninvasively measure stress parameters in novices during a simulation task in a high fidelity simulator as well as to explore the best stress detector among the recorded parameters. This study also aims to detect if HR and HRV derived parameters when calculated from this wearable device can substitute reciprocal Holter measurements in our simulation environment.

Who can participate?
Male medical school trainees aged 23 to 26 years old

What does the study involve?
Participants are introduced to the simulator, briefed of the tasks to follow and given detailed information about the data recording equipment and the video-evaluation of their performance. HTye are given the Empatica E4 wristband (E4WB) in their non-dominant hand to wear. Additionally, all participants wear an Holter ECG rhythm monitoring and electrodes positioned in certain positions. A baseline recording phase of 10 minutes is initiated with the subjects

engaged in leisurely reading (BL phase). Immediately after the simulation exercise starts, the participants are trained on a basic skills module for 9 minutes and are videotaped for later visual analysis of any major errors (failures) detection followed by a 6 minutes recovery period.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
Athens University Medical school

When is the study starting and how long is it expected to run for?
March 2015 to March 2018

Who is funding the study?
National and Kapodistrian University of Athens (Greece)

Who is the main contact?
Mr Konstantinos Georgiou (Scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7276

Study information

Scientific Title
Feasibility of a new wearable device to estimate acute stress in novices during high-fidelity surgical simulation

Study objectives
1. The first objective of this study is to assess the feasibility of a new watch-sized device to noninvasively measure stress parameters in novices during a simulation task in a high fidelity simulator as well as to explore the best stress detector among the recorded parameters.
2. The second objective is to detect if HR and HRV derived parameters when calculated from this wearable device can substitute reciprocal Holter measurements in our simulation environment. .

Ethics approval required
Old ethics approval format

Ethics approval(s)
Athens Medical School Ethics Committee, 19/04/201, ref:1516023954

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available in English. Please use the contact details below to request a patient information sheet in Greek.

Health condition(s) or problem(s) studied
Healthy participants

Interventions
Prior to the simulation task, all participants complete a questionnaire regarding age, height, weight, and prior simulation experience. An orientation phase is then implemented (approximately 15 minutes) during which the participants are introduced to the simulator, briefed of the tasks to follow and given detailed information about the data recording equipment and the video-evaluation of their performance. Thereafter they wear the wristband (E4WB) in their non dominant hand. Additionally, all participants wear an ambulatory Holter ECG rhythm monitoring and electrodes were positioned in predetermined thorax positions. Throughout the whole experiment, the subjects wear both the E4WB and the Holter rhythm

monitor and an ambient temperature was kept in the simulation room in order to avoid any sweating artifacts.

A baseline recording phase of 10 minutes is initiated with the subjects engaged in leisurely reading (BL phase). Immediately after the simulation exercise started (T phase) where the subjects were trained on a basic skills module (Lap mentor, 3D Systems) for 9 minutes and were videotaped for later visual analysis of any major errors (failures) detection (F) followed by a 6 minutes recovery period (R phase). Each phase was tagged by triggering concomitantly the markers on both devices.

Heart Rate (HR), inter-beat interval duration (IBI), electrodermal activity (EDA), 3-axis hand motion activity (Acc), and skin temperature (ST) data were recorded from the E4WB. Furthermore, HR and heart rate variability (HRV) data were obtained from the Holter device.

Intervention Type

Primary outcome measure
Stress is detected using the EDA at baseline and after the stimulation.

Secondary outcome measures
1. Heart Rate (HR) is recorded using the E4WB at baseline and after the stimulation
2. Inter-beat interval duration (IBI) is recorded using the E4WB at baseline and after the stimulation
3. Electrodermal activity (EDA) is recorded using the E4WB at baseline and after the stimulation
4. 3-axis hand motion activity (Acc) is recorded using the E4WB at baseline and after the stimulation
5. Skin temperature (ST) data is recorded from the E4WB at baseline and after the stimulation
6. HR and heart rate variability (HRV) data is recorded from the Holter device at baseline and after the stimulation

Overall study start date
01/03/2015

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Male novice trainees aged 23 to 26 years old
2. Body mass index (BMI) from 18.5 to 24.9
3. Medical students or PHY1
4. No simulation experience prior

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit

18 Years

Sex
Male

Target number of participants
27

Key exclusion criteria
if experienced surgeons in simulation

Date of first enrolment
12/12/2016

Date of final enrolment
20/12/2017

Locations

Countries of recruitment
Greece

Study participating centre
Athens University Medical school
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Sponsor information

Organisation
National and Kapodistrian University of Athens, Greece

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Sponsor type
University/education

ROR
https://ror.org/04gnjpq42

Funder(s)

Funder type
University/education

Funder Name
National and Kapodistrian University of Athens, Greece

Results and Publications

Publication and dissemination plan
Plans to submit for publication in a high-impact peer reviewed journal.

Intention to publish date
03/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Konstantinos Georgiou MD at kongeeorgiou@med.uoa.gr

IPD sharing plan summary
Available on request