Feasibility of a New Wearable Device to Estimate Acute Stress in Novices During High-fidelity Surgical Simulation

Konstantinos E. Georgiou¹, Rossen K. Dimov²,³, Nikola B. Boyanov²,⁴, Konstantinos G. Zografos¹, Andreas V. Larentzakis¹, Blagoi I. Marinov²,⁵

¹ First Department of Propaedeutic Surgery, Hippokration General Hospital of Athens, Athens Medical School, National and Kapodistrian University of Athens, Athens, Greece
² MSTC, Medical University of Plovdiv, Plovdiv, Bulgaria
³ Clinic of General Surgery, Kaspela University Hospital, Plovdiv, Bulgaria
⁴ Clinic of Gastroenterology, Pulmed University Hospital, Plovdiv, Bulgaria
⁵ Department of Pathophysiology, Medical University of Plovdiv, Plovdiv, Bulgaria

Correspondence:
Konstantinos E. Georgiou, First Department of Propaedeutic Surgery, Hippokration General Hospital of Athens, Athens Medical School, National and Kapodistrian University of Athens, 10, 25th Martiou Str., Vyronas, 16233, Athens, Greece
E-mail: kongeorgiou@med.uoa.gr
Tel: +30-6942066216

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INTRODUCTION

It is well known that surgical simulation is a validated standardized training milieu designed to replicate real-life situations, replicating stress, prevent biases and provide objective metrics.¹⁻³

The complexity of stress mechanisms makes acute stress measurement during this learning process is difficult to quantify and interpret.⁴ As there is no reliable method to measure stress, several subjective and/or objective methods have been proposed: among the subjective ones, the State Trait Anxiety Inventory (STAI) is widely validated.⁴ The rationale for the objective methods lays in the fact that acute stress provokes acute autonomic nervous system (ANS) changes. Therefore: a) heart rhythm changes as measured by heart rate (HR) or heart rate variability (HRV) b) electrodermal activity (EDA) levels c) thermal activity, d) blood volume pulse (BVP), and e) saliva stress biomarkers have been suggested.⁵ However, it is important to note that HRV, EDA, and thermal activity all require the use of specific equipment that causes several limitations regarding data collection in the OR or in the simulation setting, by adding discomfort and
thus compromising performance.\textsuperscript{4}

Recently, a couple of more sophisticated wearable devices have been made commercially available, which, besides heart rate (HR) and Inter-Beat Interval (IBI), concomitantly measure several other parameters such as EDA, acceleration and body temperature.\textsuperscript{5}

\textbf{AIM}

Therefore, the first objective of this study was to assess the feasibility of a new watch-sized device to noninvasively measure stress parameters. The second objective was to assess the feasibility of this device to determine the relationship of heart rate and heart rate variability measured with this new device to that of a Holter monitor.

Practically, it might be of value if such an easy-to-wear device might be used to objectively evaluate stress and avoid the use of other motion restricting, uncomfortable devices in our simulation setting as well as it might open a potentially practical window to conveniently train surgeons to manage their stress using a surgical simulation training system.

\textbf{MATERIALS AND METHODS}

The study protocol (ISRCTN No 10985546) was approved by the Institutional Ethical Committee and all participants gave informed consent.

\textbf{SUBJECTS}

Twenty-one male novice trainees aged 23 - 26 years with body mass index (BMI) ranging from 18.5 to 24.9 were included in the study. All of them were medical students in their last year or PGY1 without any previous simulation experience.

\textbf{EXPERIMENTAL PROTOCOL}

Prior to the simulation task, all participants completed a questionnaire regarding age, height, weight, and prior simulation experience. They also completed the short, six-item Spielberger State-Trait Anxiety Inventory (STAI). An orientation phase was then implemented (approximately 15 minutes) during which they were introduced to the simulator and briefed on the tasks to follow. Thereafter they wore the Empatica E4 wristband (E4WB) (Empatica S.r.l, Italy) on their nondominant hand. Additionally, all subjects wore an ambulatory Holter ECG rhythm monitoring (HM) and electrodes were positioned in predetermined thorax positions (ELA Medical - Syneflash MMC-24 hour Rhythm - 3 channel lead - Synescope ELA Medica, France). Throughout the whole experiment, the subjects wore both the E4WB and the HM. An ambient temperature of 27°C was kept in the simulation room in order to avoid any sweating artifacts.

A baseline recording phase of 10 minutes was initiated with the subjects engaged in leisurely reading (BL phase). Immediately after, the simulation exercise started (E phase) in which the subjects were trained on a basic skills module (Lap mentor, 3D Systems) for 9 minutes followed by a 6 minutes recovery period (R phase). During this phase all subjects repeated the short, six-item STAI. Each phase was tagged by triggering concomitantly the markers on both devices.

E4WB recorded photoplethysmography (PPG) BVP data were used to estimate HR and inter-beat interval duration (IBI). Additionally, EDA, 3-axis hand motion activity (Acc), and skin temperature (ST) data were recorded from the E4WB. Furthermore, R-R interval data obtained from the Holter monitor were extracted in order to measure HR and calculate HRV indices.

\textbf{DATA ANALYSIS}

When each session ended, the E4WB was connected to a PC and its internal storage data were uploaded to a secure cloud web site. Through this site the sessions’ data can be visualized and exported as CSV files for each one of the parameters recorded.

In order to compare the R-R with the IBI data derived respectively from the two devices, some pre-processing was necessary before any further analysis takes place. This was necessary due to two reasons: a) the E4WB starts recording automatically 40 sec after pushing the mark button, while the Holter starts to record immediately after pressing the mark, and b) E4WB heart beats are recorded in respect to initial time which in turn is expressed in UTC time. Therefore, all the time points had to be converted to absolute local time. Additionally, since both devices did not share the same time settings from a reliable third-party source, their recorded data needed synchronization.

In order to avoid multifactorial external stress bias, the percentage differences between base line and exercise of all parameters measured were derived for each subject. Additionally, pre- and post-exercise STAI scoring as well as their differences was calculated.

The Bland-Altman method was used to plot the difference for each subject against HRV and IBI values in order to compare Holter derived HRV...
versus PPG derived IBI.

All sets of synchronized intervals data extracted from both Holter and E4WB were analyzed by using the Kubios HRV® software.\textsuperscript{6} Indices of HRV were computed in the frequency domain (high frequency [HF]; low frequency [LF] and LF/HF ratio) for all phases of the study.

RESULTS

None of the subjects reported any problems / discomfort related to the wearing equipment.

A) Exploiting the best stress detector among the E4WB parameters.

A1. Descriptive observation

A representative output of the E4WB parameters of one subject is shown in Fig. 1. As it can be seen, EDA started to increase as soon as the E phase starts and remained elevated even during the R phase while BVP did not seem to have a trend during the E phase. Acc and HR increased during E phase but with many fluctuations, while ST remained almost stable during the whole experiment.

A2. E4WB parameters response during E phase

Of all parameters studied, only the mean EDA levels for all subjects combined, significantly increased from BL phase to the E phase (from 1.47 to 3.00 μS; \( p<0.001 \)), and further increased during the R phase as compared with BL levels (from 1.47 to 5.62 μS; \( p<0.001 \)). Fig. 2 shows the percentage increase of the mean value of EDA during E phase to the one during BL phase for each individual. It can be noticed that stress during E phase provoked about 105% increase in the EDA values.

IBI change was smaller as it changed from 730 ms during BL phase to 607 ms during E phase (16% decline) and finally to 716 ms during R phase (\( p<0.001 \)). Similar nonsignificant variations were observed in HR irrespective if it was derived from Holter or E4WB. In all cases during the E phase, the Acc values where within the measurement limits since none exerted the force of 2 g. Temperature data didn’t change significantly in all subjects at any phase (\( p<0.001 \)).

A3. Correlation of E4WB parameters with STAI

A positive post- to pre-exercise STAI scoring difference (STAIdif%) was seen in 15 (71\%) subjects while in the remaining 6 (29\%) it was negative.

Percentage differences of the average values of EDA (EDAdif%), IBI (IBIdif%), Holter R-R (HolterRRdif%) during exercise and baseline phase as well as STAI (STAIdif%) differences between post- and pre-exercise phase were calculated. Table 1 summarizes the correlation coefficient \( r \) between all the above parameters.

As can be seen from this table, the EDA difference exhibited the best correlation with STAI difference, while IBI and Holter ones showed similar \( r \) values.

The sensitivity and specificity of Holter’s R-R, IBI and EDA are seen in Table 2. As can be seen from this table, the EDA difference exhibited the best sensitivity (equal to Holter R-R differences) and the best specificity.

B) Ambulatory Holter versus E4WB wristband HR detection.

1. Descriptive comparison

A comparison was made to get an understanding of how well the E4WB sensor performs compared to Holter’s HR. Therefore, in a representative subject the synchronized signals from the E4WB and Holter were superimposed and compared (Fig. 3).

2. Statistical analysis

The whole session of each subject provided a range of 3625-3830 data points for R-R and IBI estimation (1500-1690 for BL, 1210-1400 for E, 740-920 for R respectively).

Correlation coefficient \( r \) was used to quantify the correlation between R-R and IBI data for each individual during the entire experiment as well as during each phase. Their mean values and range are presented in Table 3. It can be seen that the mean value of \( r \) during all sessions shows a high agreement between the two methods \( (r=0.938; \ p<0.001) \) reaching its maximum at BL phase \( (r=0.947, \ p<.001) \) and being minimized at E phase \( (r=0.749, \ p<.001) \).

Bland-Altman analysis was also used to compare the two methods. For each subject, percentage differences of the mean values \( [(\text{Holter-E4WB})/\text{Holter}] \) were calculated for each phase as well as for the whole experiment. The descriptive statistics are presented in Table 4. As can be seen from this table, the mean value of the difference is +0.419\% during all phases suggesting a close agreement between these two methods. The mean bias is minimum during BL phase (-0.013\%) and maximum during the E phase (+1.07\%).

Fig. 4 presents the Bland-Altman plots (for each phase and for the whole experiment) of the collected data from the 21 subjects. Y axis represents the percentage difference and X axis represents the value of the HM (as it is the reference method). Moreover, mean values and levels of agreement (upper and lower LoA) are presented for each plot. It is obvious that the two methods are in close agreement as the vast majority of the 21 subject
points are within the lower and upper LoA.

The HRV results from the Kubios derived analysis of the synchronized data extracted from both Holter and E4WB are presented in Table 5. As can be seen, the agreement between the RR series obtained from both devices is high (p>.05) for the most part of the whole experiment as both methods were interchangeable when comparing all parameters studied at BL and R phases.

During E phase, while HR and HF still showed close agreement (p>.05), LF and consequently LF/HF, did not (p<.001) as the E4WB derived LF was almost 1.5 times greater than the one derived from HM.

DISCUSSION

It is well known that stress associated with learning a psychomotor task can influence the ability of the trainee to learn.

HR and HRV have been extensively used either alone or in combination with subjective tests to indirectly measure the surgeons’ cognitive load and mental strain in a simulated or actual OR setting.4

Except HR, several HRV parameters are computed using time-domain, frequency-domain, and nonlinear methods.7 In the frequency domain evaluation, the high frequency (HF) component represents the parasympathetic activity while the low frequency / HF ratio represents the sympathetic activity.8

Apart the cardiovascular system, ANS stimulation increases the sweat production from the eccrine glands of the skin and therefore it causes fluctuations in electrical conductivity, enabling measurement of EDA or galvanic skin response (GSR) or skin conductance.9

Recently, several wearable HR monitors using photoplethysmography (PPG) became widely available. PPG is a simple and low-cost method to detect blood volume changes in the peripheral circulation at the skin surface.10 Usually, placed on the wrist, these user-friendly devices detect the underlying pulse rate by means of sensors, which reliably monitor minor changes in the intensity of light emitted from light emitting diodes (LEDs) that is transmitted through or reflected from the human tissues. Although they have obvious advantages over the classical ambulatory ECG recording, the fact that they use PPG, i.e. a different detecting approach, raises the question of how much accurate and reliable their results are when compared to the gold standard HM.5 The main difference between PPG and ECG is that the latter depicts heart’s electrical activity whereas the PPG

![Figure 1](image-url)
is a mechanical signal measuring the propagation of the peripheral pulse wave.\textsuperscript{11}

The use of BVP as a surrogate measurement of HRV has been assessed in resting conditions where a strong correlation is observed; however, a moderate or no agreement was observed during physical exercise or mental stress, with diminishing correlation as the stress and / or exercise intensity were increasing.\textsuperscript{5}

We therefore thought that it is worthwhile to assess the feasibility of a new watch-sized device to a) noninvasively measure stress parameters in

**Figure 2.** Percentage increase of the mean value of EDA (Y axis) during Exercise phase to the one during Base Line phase (X axis) for each individual.

**Figure 3.** Synchronized signals from the rhythm Holter (R-R, solid line) and from the E4 wristband (IBI/2, dashed line). IBI values were divided by 2 to avoid the graphs superimposition and better graph presentation.
Figure 4 A. Bland-Altman plots of the collected data recorded during: Base Line phase.

Figure 4 B. Bland-Altman plots of the collected data recorded during: Exercise phase.
**Figure 4 C.** Bland-Altman plots of the collected data recorded during: Recovery phase.

**Figure 4 D.** Bland-Altman plots of the collected data recorded during: All sessions.
Table 1. Correlation coefficient r between EDAdif%, IBldif%, HolterRRdif% and STAIdif%

|                | HolterRRdif% | IBldif% | EDAdif% |
|----------------|--------------|---------|---------|
| STAIdif%       | -0.78        | -0.74   | 0.83    |
| HolterRRdif%   | 0.87         | -0.71   |         |
| IBldif%        |              | -0.67   |         |

Table 2. Sensitivity and specificity of Holter’s R-R, IBI and EDA to identify STAI derived stress estimation

|                | Sensitivity | Specificity |
|----------------|-------------|-------------|
| HOLTER R-R     | 67%         | 93%         |
| IBI            | 67%         | 87%         |
| EDA            | 83%         | 93%         |

IBI: inter-beat interval; EDA: electrodermal activity.

Table 3. Mean values and range of the correlation coefficient (r) between R-R and IBI during the whole experiment as well as during each one of the three phases

|                  | Correlation (r) Mean value | Range          |
|------------------|-----------------------------|----------------|
| All sessions     | 0.938                       | 0.926-0.950    |
| Base Line (BL)   | 0.947                       | 0.921-0.963    |
| Exercise (E)     | 0.749                       | 0.671-0.808    |
| Recovery (R)     | 0.900                       | 0.803-0.955    |

Table 4. Descriptive statistics based on the Bland-Altman analysis

|                  | All sessions | Base Line (BL) | Exercise (E) | Recovery (R) |
|------------------|--------------|----------------|--------------|--------------|
| Sample size      | 21           | 21             | 21           | 21           |
| Arithmetic mean (%) | 0.419       | -0.013         | 1.070        | 0.276        |
| Standard deviation | 0.251       | 0.301          | 0.547        | 0.473        |
| 95% CI for the mean | 0.311 - 0.526 | -0.141 - 0.116 | 0.836 - 1.304 | -0.074 - 0.479 |
| LoA (lower)      | -0.073       | -0.603         | -0.002       | -0.651       |
| LoA (upper)      | 0.910        | 0.578          | 2.143        | 1.204        |

CI: confidence level; LoA: level of agreement.
Table 5. Heart rate variability parameters at rest, exercise and recovery phase by means of ambulatory Holter and E4WB

|            | Rest               | Exercise           | Recovery            |
|------------|--------------------|--------------------|---------------------|
|            | Holter mean±SD     | E4WB mean±SD       | p value             | Holter mean±SD     | E4WB mean±SD       | p value             | Holter mean±SD     | E4WB mean±SD       | p value             |
| HR         | 83.33±3.33         | 82.15±4.23         | 0.061               | 97.83±2.32         | 98.88±3.80         | 0.068               | 83.33±0.83         | 83.33±0.83         | 0.17               |
| LF         | 24.57±23.93        | 32.97±30.10        | 0.063               | 30.86±16.74        | 48.77±22.78        | <0.001              | 23.12±8.06         | 24.57±10.73        | 0.50               |
| HF         | 67.98±38.25        | 55.95±42.25        | 0.072               | 48.36±19.47        | 41.35±24.27        | 0.081               | 69.61±7.64         | 67.98±11.25        | 0.46               |
| LF/HF      | 0.40±0.54          | 0.62±0.84          | 0.057               | 0.67±0.51          | 1.33±1.00          | <0.001              | 0.35±0.14          | 0.40±0.24           | 0.25               |

In our data, the Bland-Altman showed that E4WB derived IBI was in high agreement with Holter RR and therefore E4WB derived heart rate parameters can be used instead of those derived from Holter.

In our setting, we found that BVP was in agreement with HRV not only during the baseline and recovery phases, but also during the exercise phase. According to this finding, E4WB derived BVP can be used as a reliable surrogate of Holter derived HRV.

**Limitations**

A limitation of our study is that it focused on just one basic training skills simulated scenario and therefore our findings cannot be extrapolated into the real OR practice. Furthermore, the number of subjects was rather small and although we collected a large amount of data it is obvious that more studies with large numbers of subjects is needed, before arriving to a clinically relevant conclusion. Additionally, other stress parameters measuring stress such as saliva biochemical indices, for example cortisol, a-amylase, immunoglobulin A or chromogranin levels, were not included in our study.

**Future Actions**

It has been shown that exposure to moderate stress on task trainers may have a beneficial effect and improve performance while excessive stress may have detrimental effects.29-30

Therefore, further research is required in order to establish a normative threshold beyond which the stress is detrimental and counterproductive. On the other hand, using each individual’s results could be used to effectively formulate individual improvement plans.

**Conclusions**

This study has demonstrated that a wrist wearable device is an easy-to-use non-invasive tool capable...
to noninvasively measure several stress parameters before, during, and after a simulation task in novices. Among them, electrodermal activity was the best stress detector. E4WB derived heart rate and heart rate variability derived from this device highly correlated with the reciprocal values as measured from an ambulatory Holter monitor and therefore they can be used instead of those derived from the Holter in our simulation setting.

Therefore, this device may open a practical window to conveniently train surgeons to manage their stress using a surgical simulation training system.

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Приемлемость нового переносного устройства для измерения острого стресса у студентов во время хирургической симуляции высокой точности

Константинос Е. Георгиу1, Росен К. Димов2,3, Никола Б. Боянов2,4, Константинос Г. Зографос1, Андреас В. Ларенцакис1, Благой И. Маринов2,5

1 Первая кафедра пропедевтики хирургических болезней, Многопрофильная больница Гиппократа - Афины, Афинский медицинский факультет, Афинский национальный университет имени Каподистрии, Афины, Греция
2 Симуляционный центр, Медицинский университет - Пловдив, Пловдив, Болгария
3 Клиника общей хирургии, УМБАЛ „Каспела”, Пловдив, Болгария
4 Клиника гастроэнтерологии, УМБАЛ „Палмед”, Пловдив, Болгария
5 Кафедра патофизиологии, Медицинский университет - Пловдив, Пловдив, Болгария

Адрес для корреспонденции:
Константинос Е. Георгиу,
Кафедра пропедевтики хирургических болезней, Многопрофильная больница Гиппократа - Афины, Афинский медицинский факультет, Афинский национальный университет имени Каподистрии, ул. “25-ое марта” № 10, Виронас, 16233, Афины, Греция
E-mail: kongeorgiou@med.uoa.gr
Tel: +30-6942066216

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Ключевые слова: wearable device, electrodermal activity, acute stress, surgical simulation, stress estimation

Введение: Стресс, связанный с усвоением психомоторного задания, может повлиять на способность обучаемого к обучению. Хирургическая симуляция является валидированной средой обучения, которая создана с целью моделирования ситуаций из реальной жизни, предотвращения пристрастности и обеспечения объективной метрики. Однако сложность механизмов стресса и отсутствие надёжного метода идентификации затрудняют оценку и интерпретацию оценки стресса.

Цель: а) Оценить приемлемость нового устройства размером с наручные часы для измерения неинвазивных параметров стресса для начинающих во время симуляционной задачи и б) Сравнить полученные параметры сердечного ритма с данными, полученными с помощью холтеровского амбулаторного монитора.

Материалы и методы: Двадцать один студент прошёл обучение по модулю базовых умений. На начальном этапе, на этапах нагрузки и восстановления у всех участников были переносные устройства и были записаны такие данные, как кровяное давление, частота сердечных сокращений, частота пульса, электродермальная активность и температура кожи. Параллельно с этим, холтеровский монитор использовался одновременно для измерения частоты сердечного ритма, интервалов R-R и вариабельности сердечного ритма. До и после каждого эксперимента все испытуемые заполняли краткую шкалу STAI с шестью пунктами.

Результаты: Анализ данных показал: а) по сравнению со STAI, электродермальная активность показала лучшую корреляцию, чувствительность и специфичность, и б) устройство установило параметры сердца, которые имеют высокую корреляцию с реципрочными значениями Холтера на всех этапах эксперимента.
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Выводы: Данное переносное устройство является неинвазивным инструментом, который прост в использовании, хорошо принимается участниками, и который может обеспечить точную оценку стресса в нашей симуляционной среде. Кроме того, он может повторять параметры сердца, связанные со стрессом, и установленные с помощью Холтера, что исключает необходимость носить довольно неудобное устройство.