Exploring the validity of a contactless monitor used to measure vital parameters during sleep: A pilot study

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Abstract

Study investigating the validity of a contactless monitor during sleep. Overall, the contactless monitor seems to be a valid method for monitoring vital parameters, even though parameters such as position and number of people in bed might have implications for monitoring.

Keywords

Type 1 diabetes - Nocturnal Hypoglycemia - Contactless Monitor - Validation - Vital parameters

1 INTRODUCTION

Diabetes mellitus (DM) is a major global challenge [1]. DM causes a chronic condition of hyperglycemia, which can lead to various health complications [2]. In type 1 diabetes (T1D), insulin treatment is required. However, insulin treatment induces a risk of hypoglycemia, which can be life-threatening [3]. The risk of hypoglycemia increases at night, leading to fear and reduced quality of life among people with T1D [4]. To prevent hypoglycemia, people with T1D frequently measure glucose at night [5]. Self-monitoring of blood glucose (SMBG) is a major negative burden for people with T1D [6]. Some people with T1D use a continuous glucose monitor (CGM) as an alternative to SMBG. However, CGMs also have disadvantages such as a discrepancy between glucose values measured with CGM and venous blood glucose values [7], and skin irritation [8]. Currently, there are no acceptable alternatives to CGM and SMBG for measuring blood glucose levels. However, there is a significant interest in developing new methods based on hypoglycemia induced changes in vital parameters [9]. A new contactless monitor (Sleepiz One, Sleepiz AG, Switzerland) may be able to predict hypoglycemia as it, based on radar technology, measures vital parameters that are affected hereby. However, there is no available documentation for the validity of the contactless monitor. Therefore, the aim of the present study was to investigate the validity of the contactless monitor during sleep.

2 METHODS

The study examined the contactless monitor's ability to monitor heart rate (HR) and respiration rate (RR). Furthermore, the sensitivity of the monitor related to the participants' position and the number of people in bed were assessed. Inclusion criteria were Danish or English-speaking healthy individuals aged ≥ 18 years. Exclusion criteria were pregnancy, tendonitis, carpal tunnel syndrome, implanted electronic devices, reduced circulation, epilepsy, and taking photosensitive medicine. Three women aged 25-31 years participated in the study. Study duration was two nights, where the participant slept one night alone and one night with a partner.

HR and RR from the monitor were compared with HR from a smartwatch (Fitbit Charge 2) and manual RR counts (Figure 1).
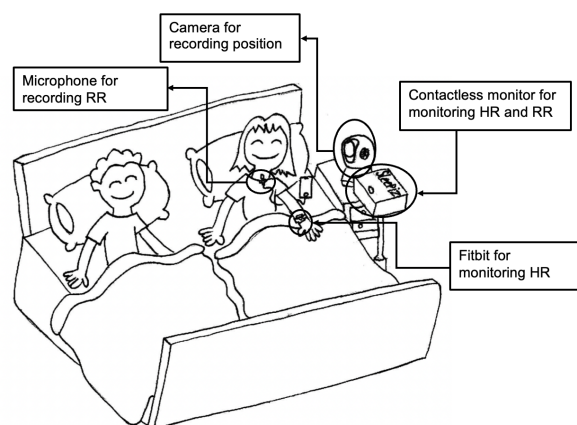

Figure 1. Illustration of experimental setup.

A correlation analysis was performed to examine the correlation between data from the contactless monitor and reference measurements for each participant. In addition, Root Mean Square Error (RMSE), Pearson's correlation coefficient (r), and 95% confidence interval (95% CI for r) were calculated.

3 RESULTS

For both HR and RR, a statistically significant correlation was found between data from the contactless monitor and reference measurements, except for one test. Correlation of HR from the monitor and smartwatch was R^2 (0.0183 - 0.6948), RMSE (1.65 - 3.87), and r (0.1354 - 0.8336). Correlation of RR from the monitor and manual RR counts was R^2 (0.5551 - 0.895),

RMSE (0.22 - 0.73), and r (0.7451 - 0.9460). In the absence of missing data, supine was the dominant position (Figure 2A and 2B). According to the number of people in bed, no unambiguous results were found (Figure 2C and 2D).

Participant	p-value			
	HR Alone	HR > one	RR alone	RR > one
P1	0.630	0.001	0.000	0.000
P2	0.009	0.027	0.000	0.000
P3	0.000	0.011	0.001	0.000

Table 2 *P*-value from correlation between reference measurements and the contactless monitor for HR and RR, related to participants (P) and number of people in bed. Alone in bed (alone), more than one in bed (> one).
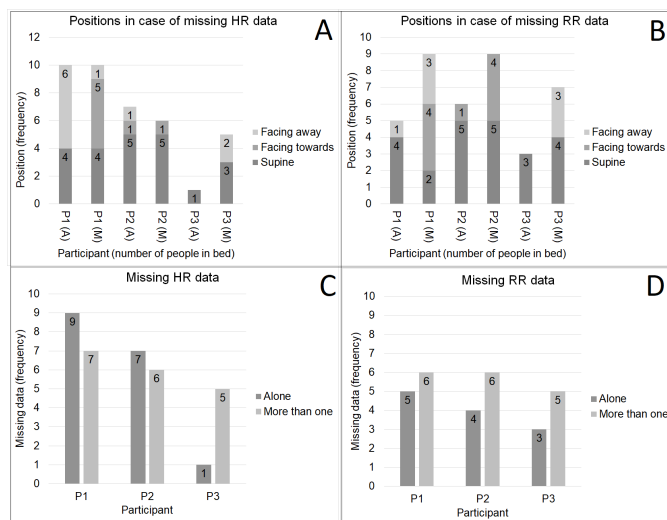
Figure 2. Sensitivity of the contactless monitor related to position and number of people in bed. Participant (P), sleeping alone (A), sleeping more than one in bed (M). Figure A,B) illustrates whether the participant is facing away from the monitor, is facing towards the monitor or is in supine position in case of missing HR and RR data registration > 2 min. Figure C,D) illustrates the frequency of missing data registration > 2 min. depending on whether the participant slept alone or more than one in bed.

4 DISCUSSION

The aim of the present study was to investigate the validity of the contactless monitor during sleep. HR and RR data measured with the contactless monitor correlated with data from the reference measurements. Turppa et al. found a statistically significant correlation for HR and RR measured with radar technology and reference technology, respectively (p <0.01) [10]. This corresponds to the results of the present study. Turppa et al. assessed that radar technology could be used to accurately monitor vital parameters during sleep [10]. It is assessed that the contactless monitor in the present study has the same potential for monitoring vital parameters during sleep.

In conclusion, the contactless monitor seems to be a valid method for monitoring vital parameters during sleep. However,

the present study suggests that the user's position in bed may have implications for monitoring. It is not possible to determine the significance of the number of people in the bed as there are no unambiguous results.

5 LIMITATIONS

A limitation of the present study is the small and homogenous sample size of three women, which make the results less generalizable. Furthermore, the short duration of the study. Therefore, increased sample size, inclusion of both genders, and a longer study duration is recommended for future studies. Another limitation is that the missing data, may be caused by other reasons than position and number of people in bed. Therefore, future research is needed to evaluate the sensitivity of the monitor related to the position and the number of people in bed during sleep.

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