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A noncontact vital sign sensor demonstrating a strong correlation with an electrocardiogram electrode and a CO_2 sensor

Tatsuya Nagano[1]✉, Nobuyuki Yamamoto[2], Sae Shinomiya[3], Hiroshi Kato[4], Mariko Okamoto[1], Daisuke Hazama[1], Ryosuke Bo[2], Tomohiko Yamamura[2], Takumi Imai[3], Koji Fukuzawa[5], Takuya Funayama[6], Koji Kano[7] & Naoko Katsurada[1]

Accurate assessment of vital signs is important for reducing mortality. The aim of this study was to validate the effectiveness and safety of noncontact vital sign sensors. Interference tests were conducted with a noncontact vital sign sensor and medical devices. Inpatients' heart and respiratory rates were monitored via this sensor, and the measurements of this sensor were compared with those of reference medical equipment. Noncontact vital sign sensors and medical devices did not interfere with each other. A total of 21 patients (10 adults and 11 children, including 1 baby) were analysed. For all patients, the correlation coefficients for the HR and RR were 0.86 and 0.96, respectively. In adult patients, the correlation coefficients for the HR and RR were 0.75 and 0.96, respectively. In paediatric patients, the correlation coefficients for the HR and RR were 0.82 and 0.94, respectively. No effects of noncontact vital sign sensors on patients, surrounding patients or medical equipment were observed. Noncontact vital sign sensors are accurate and safe.

Keywords Noncontact vital sign sensor, Heart rate, Respiratory rate

Accurate assessment of vital signs can reduce mortality by early identification of acute deterioration of a patient's condition and an appropriate response[1]. Indeed, the Acute Physiology and Chronic Health Evaluation (APACHE) score, which includes the respiratory rate (RR), has been proposed as a method for assessing critically ill patients[2]. The CURB-65 score for pneumonia severity also includes an RR ≥ 30 breaths/min as a parameter of severity[3]. The RR is an early indicator of hypoxaemia, hypercarbonaemia, and metabolic and respiratory acidosis and is the first vital sign affected by changes in cardiac and neurological status[4]. Among the four vital signs (pulse, blood pressure, RR and temperature), the RR is often not recorded, even though an abnormal RR has been shown to be an important predictor of serious events such as cardiac arrest and intensive care unit (ICU) admission[4].

Pulse oximetry is simple, is frequently used in daily practice, and provides information on blood oxygenation status[5] but is not a substitute for the RR. This is because when blood oxygen levels decrease, an organism attempts to maintain blood oxygen levels by increasing oxygen uptake through an increased RR, and SpO_2 begins to decrease when it can no longer be compensated for by the increased RR, resulting in a delayed response in SpO_2 compared with the response in the RR. Another reason why the RR is not measured as a vital sign is the lack of measuring equipment. We therefore developed a noncontact vital sign sensor (NCVS) to monitor the respiratory rate together with the heart rate (HR) in a simple and convenient way. Devices that apply short-wavelength

[1]Division of Respiratory Medicine, Department of Internal Medicine, Kobe University Graduate School of Medicine, 7-5-1 Kusunoki-cho, Chuo-ku, Kobe, Hyogo 650-0017, Japan. [2]Department of Pediatrics, Kobe University Graduate School of Medicine, 7-5-1 Kusunoki-cho, Chuo-ku, Kobe, Hyogo 650-0017, Japan. [3]Clinical and Translational Research Center, Kobe University Hospital, 7-5-2 Kusunoki-cho, Chuo-ku, Kobe, Hyogo 650-0017, Japan. [4]Department of Medical Engineering, Kobe University Graduate School of Medicine, 7-5-1 Kusunoki-cho, Chuo-ku, Kobe, Hyogo 650-0017, Japan. [5]Section of Arrhythmia, Division of Cardiovascular Medicine, Department of Internal Medicine, Kobe University Graduate School of Medicine, 7-5-1 Kusunoki-cho, Chuo-ku, Kobe, Hyogo 650-0017, Japan. [6]Startup Promotion Office, Business Creation, Japan Radio Co., Ltd. Advanced Technology Center J20-5F, 834 Inasatomachi, Nagano-shi, Nagano 381-2289, Japan. [7]New Business Development, Nisshinbo Singapore Pte. Ltd., 50 Raffles Place #08-06 Singapore Land Tower, Singapore 048623, Singapore. ✉email: tnagano@med.kobe-u.ac.jp

microwaves to the human body to measure the HR and RR have been used in many studies and according to a systematic review in 2024 by Liebetruth et al.[6] there were 114 papers on NCVS of HR and RR using radar technology. Seventy-four studies measured both HR and RR; 14 studies examined only RR and 26 examined only HR. The radars addressed in this review are classified as continuous wave (CW) radar (N = 58), frequency-modulated continuous wave (FMCW) radar (N = 24), and ultra-wideband (UWB) radar (N = 34). Based on the findings from this review, Liebetruth et al., noted three challenges in the use of NCVSs: (1) the frequency is not expressed in real time; (2) the HR and RR of those around it are picked up; and (3) the measurements are affected by body movements. The NCVS used in this study has a trade-off between accuracy and time delay and automatically adjusts to the optimum state depending on body movements, disturbances and other conditions. In addition, the antenna design is optimized to ensure that radio waves are emitted only over the bed range. Furthermore, the system was designed to not be affected by momentary body movements; however, when body movements continue over a long period of time, the data are considered invalid. In these three points, this NSVS differs from conventional products. The aim of this study was to assess the correlation between measurements taken by this NCVS and reference equipment with quality that can be scientifically proven to be clinically applicable.

Methods

NCVS

The NCVS used in this study was developed by Nisshinbo Singapore Pte. Ltd. (Singapore). Modulated 24 GHz radio waves (microwaves) are transmitted to the monitored person, and reflected waves from the monitored person are received. The received wave is amplified, mixed with the transmitted wave and converted into an intermediate frequency (IF) signal. This IF signal is filtered and then digitized for signal processing. The processed signal data are transmitted via Wi-Fi communication to a cloud server, where the HR and RR are calculated via signal processing. The HR and RR can be monitored via an optional tablet browser. This NCVS is categorized in FMCW radar. Since specific absorption rate (SAR) level is sufficiently small, about 1/10,000 of the ICNIRP GUIDELINE equivalent plane wave power density (Sab) reference value (reference value: 20 [W/m^2], calculated value: 0.0022 [W/m^2]), we have no measured values. FMCW radar transmits a frequency-modulated continuous wave and measures the distance to the target by calculating the frequency difference between the transmitted wave and the reflected wave. Additionally, by analysing the Doppler shift component contained in the reflected waves from moving objects, it is possible to simultaneously estimate the relative velocity of the target object. By applying this characteristic to vital sensing, it is possible to detect movements and micro-vibrations on the body surface, separate the speed differences between heartbeat and respiration, and measure HR and RR. Motion artifacts and activities of nurses around the bed are disturbances for vital sensing. HR and RR output values are calculated based on measurement data over a specified period. By invalidating data from periods where disturbances occur and calculating using the remaining data, the influence of disturbances on the output values is suppressed. The results of an internal pseudo-clinical trial conducted to evaluate this NCVS confirm that it has the same accuracy as the measurement performance described in the FDA 510(k) Summary, #K212143, for the similar device Neteera 130H/131H. In the valid measurement data for HR, the percentage of data with errors within ± 10% of the reference device was 97.3% for NCVS and 96.4% for Neteera 130H/131H. In the valid measurement data for RR, the percentage of data with errors within ± 10% or ± 2 bpm of the reference device was 97.7% for NCVS and Neteera130H/131H was 93.1%.

Participants and ethical issues

Hospitalized patients not requiring the use of life-sustaining medical devices, such as ventilators or pacemakers, were invited to participate in the study, with separate cohorts of adults and children. This prospective observational study was approved by the Ethics Committee at Kobe University Graduate School of Medicine (reference number: B240049). Informed consent was obtained from all participants or legal representatives included in the study. All procedures were performed in accordance with the ethical standards of the institutional and national research committees and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Protocol

Study 1. Medical equipment interference tests

The medical equipment included a remote monitoring station (WEP5204, Nihon Kohden, Japan), a telemetric monitor (ZS-630P, Nihon Kohden), a bedside monitor (BSM-2301, Nihon Kohden), a ventilator system (HAMILTON-C1, Nihon Kohden), a Terufusion™ Infusion Pump (TE-352Q, and TE-261, Terumo, Japan) and a pacemaker (3077, Abbott Medical, Japan). The NCVS and medical equipment were progressively brought closer to each other from a position of 2 m to test whether they affected each other.

Study 2. A study to assess the effectiveness and safety of the NCVS

The patient was placed in the supine position, and the NCVS was positioned 1.7 m away from the patient on the lateral side of the patient's head to determine the HR and RR. An ECG monitor and a capnometer were used as reference sensors to measure the HR and RR. One subject was observed for a certain period of time and HR and RR were measured during that time. Unless the data were clearly inconsistent due to the subject's own body movements or intervention by others, we generally used all the obtained data without exclusion.

Statistical analysis

Two statisticians, independent of the researcher who collected the data, performed the analyses. These analyses were performed for all patients and separately for the adult and child subgroups. Patient characteristics were summarized via basic descriptive statistics. Summary statistics for the HR and RR were calculated for

each device, and correlations between devices were assessed via correlation plots and Pearson's correlation coefficients. To quantify the differences between the devices, Bland–Altman analyses were performed for the HR and RR. To account for the correlation among repeated measurements from a patient, linear mixed-effects models with patients as random effects were fitted to estimate the differences between devices, with deviance parameters calculated from the model's variance estimates. Mean absolute error (MAE) and mean relative error (MRE) for HR and RR were calculated based on the following formulae: formulas: MAE = mean(|NCVS − Ref|), MRE = mean(|NCVS / Ref − 1|) × 100. Their 95% confidence intervals were estimated using the simple bootstrap method. The analyses were performed with R software, version 4.3.3 (R Foundation for Statistical Computing).

Sample size consideration

The sample size was planned for Study 2, A study to assess the effectiveness and safety of the NCVS. In the Bland–Altman analyses, it is necessary to evaluate the variance of the differences in measurements between the devices, particularly the between-subject variance. Based on the conventional formula for the standard error of a variance estimate, we planned to include 10 participants each from the adult, children, and baby populations to ensure a certain level of reliability in this estimation.

Results

Medical equipment interference tests

Medical devices that are expected to be near patients were tested for interference with the NCVS. Direct contact between the NCVS and the medical device did not cause interference.

Patient characteristics

Twenty-three hospitalized patients were enrolled. We excluded one child who did not breathe well on the reference capnometer and one baby whose respiratory rate was not well picked up due to body movement. Therefore, we analysed a total of 21 patients, including 10 adults and 11 children, including 1 baby. We planned to enrol 10 babies but were unable to enrol them during the study period. The patients' characteristics are summarized in Table 1. In the present study, because patients with respiratory diseases were included, many of the patients in the adult group were elderly. In addition, in the children's group, the range of body sizes was greater because the group included low birthweight babies.

Correlation between NCVS and reference device measurements

Summary statistics are listed in Table 2. Correlation plots of the HR and RR measurements from the NCVS and reference sensor, along with correlation coefficients for all patients, as well as for the adult and child subgroups, are shown in Fig. 1. For all patients, the correlation coefficients for the HR and RR were 0.86 and 0.96, respectively. For adults, the correlation coefficients for the HR and RR were 0.75 and 0.96, respectively. For children including 1 baby, the correlation coefficients for the HR and RR were 0.82 and 0.94, respectively. For children excluding 1 baby, the correlation coefficients for the HR and RR were 0.34 and 0.89, respectively. The degree of agreement between the paired HR and RR data from the two devices was visualized in Bland–Altman plots for all patients, as well as for the adult and child subgroups, and is shown in Fig. 2. The mean values and deviations of the differences between devices in terms of the measured values are summarized in Table 3. The MAE and MRE of HR and RR are summarized in Table 4.

Safety of the NCVS

No effects of the NCVS on patients, surrounding patients or medical equipment were observed.

Discussion

The study is unique in that (1) it was a well-designed clinical study, (2) it is one of the few studies conducted with patients, (3) it is one of the few studies with a mix of men and women of all ages, and (4) it had a relatively large number of participants. The study also revealed that patients with several respiratory diseases, including chronic obstructive pulmonary disease or interstitial pneumonia, could be assessed without problems. Interference

	Adults (N = 10)	**Children (N = 11)**
Age, median, range, years	73 (52–82)	10 (0–15)
Gender, Male/Female	7/3	5/6
Height, median, range, m	1.64 (1.46–1.72)	1.4 (0.45–1.57)
Body weight, median, range, kg	61 (50–77)	31 (2–42)
Body mass index, median, range, kg/m^2	23 (19–35)	15 (10–20)
Disease	Lung cancer 4 Lung cancer with COPD 3 Interstitial pneumonia 2 CPFEE 1	No respiratory cardiovascular disease

Table 1. Patient characteristics. COPD, chronic obstructive pulmonary disease; CPFEE, combined pulmonary fibrosis and emphysema.

	Data	Mean	SD	Min	25%	Median	75%	Max
All patients								
NCVS. HR	883	79.2	21.5	57.0	67.0	75.0	81.5	164.0
NCVS. RR	883	17.7	9.2	5.0	11.0	15.0	21.0	51.0
Ref. HR	883	80.9	22.8	57.0	69.0	78.0	82.0	167.0
Ref. RR	883	18.5	9.7	8.0	12.0	15.0	23.0	59.0
Adults								
NCVS. HR	442	68.5	7.8	57.0	61.0	69.0	75.0	89.0
NCVS. RR	442	12.4	3.6	8.0	9.0	12.0	15.0	21.0
Ref. HR	442	69.2	9.1	57.0	60.0	69.0	77.0	96.0
Ref. RR	442	13.1	3.2	8.0	10.0	13.0	15.0	21.0
Children								
NCVS. HR	441	89.9	25.2	61.0	77.0	80.0	91.0	164.0
NCVS. RR	441	23.0	10.0	5.0	15.0	21.0	28.0	51.0
Ref. HR	441	92.5	26.1	68.0	79.0	82.0	97.0	167.0
Ref. RR	441	24.0	10.8	9.0	16.0	23.0	29.0	59.0

Table 2. Summary statistics. SD, standard deviation; Min, minimum; Max, maximum; NCVS, noncontact vital sign sensor; HR, heart rate; RR, respiratory rate; Ref, reference sensor.

tests with medical devices also revealed no interference of the NCVS with pacemakers. These advantages are significant for the introduction of the NCVS into daily practice.

Remote vital sign monitoring can be done by sensing changes in skin temperature or color, by Doppler radar technology, by ultrasound, or by Wi-Fi[7]. However, devices that use cameras or Wi-Fi have privacy issues. Radar vital sign monitoring has a long history, dating back to the Doppler radar sensing technique by G Matthews et al. in 2000 and B Lohman et al. in 2002[8,9]. The latter reported that HR matched references 88% of the time overall. The Pearson's correlation coefficient (r) between the NCVS measurements and reference measurements was shown in 2 studies. Lee et al. assessed the efficacy of the NCVS in 34 babies and reported that the r value was 0.97 for the HR and 0.95 for the RR[10]. Park et al. also assessed the efficacy of the NCVS in 50 subjects and reported that the r value was 0.749 for the HR and 0.925 for the RR[11]. In the aforementioned review, the MAE for HR was around 0.5–9 bpm and MRE around 1–10%, whereas in the present data, MAE was 3.76 bpm and MRE 4.36% for All patients[7]. Therefore, the NCVS used in this study is considered comparable to previously reported devices. However, we have improved them to overcome some issues for clinical application as described in the Introduction.

One of the limitations of the present study is that the NCVS itself is not very new. In fact, several reviews other than the review mentioned in the Background section[12,13] exist. Notably, as Choo et al. noted in their review article, monitoring vitals at home is receiving increasing attention because of the ageing of the population and the prevalence of COVID-19[12]. They also noted that wearable devices are uncomfortable for patients and require them to keep their own records[12]. The NCVS used in this study is not a wearable device, and data are remotely observable. This NCVS is being refined and improved for practical use in clinical practice and at home. Another limitation is that we were not able to obtain data from one baby because of her own movement. Thus, correct data cannot be obtained if signals other than respiration and heart rates are obtained due to disturbances caused by a subject's own body movements or by doctors and nurses approaching the irradiation area. This NCVS calculates HR and RR based on measurement data collected over a specified period. To reduce the impact of motion artefacts, data deemed to contain motion artefacts are invalidated, and only the remaining valid data are used for calculating HR and RR. This measure is effective for measurements of subjects in the resting state assumed by this NCVS; however, it has been confirmed that measurements are not possible for infants who continue to move, as sufficient valid data required for calculation cannot be obtained. The development of a motion artifact removal algorithm is an important challenge for expanding the scope of application of this NCVS. Disturbance compensation and the removal of invalid data have been implemented to address this limitation, but further improvement of tolerance is aimed at enabling the system to be used in a wider range of situations.

Conclusion

The NCVS used in this study was accurate and safe. It is hoped that one day in the near future, this sensor will be applied in clinical practice.

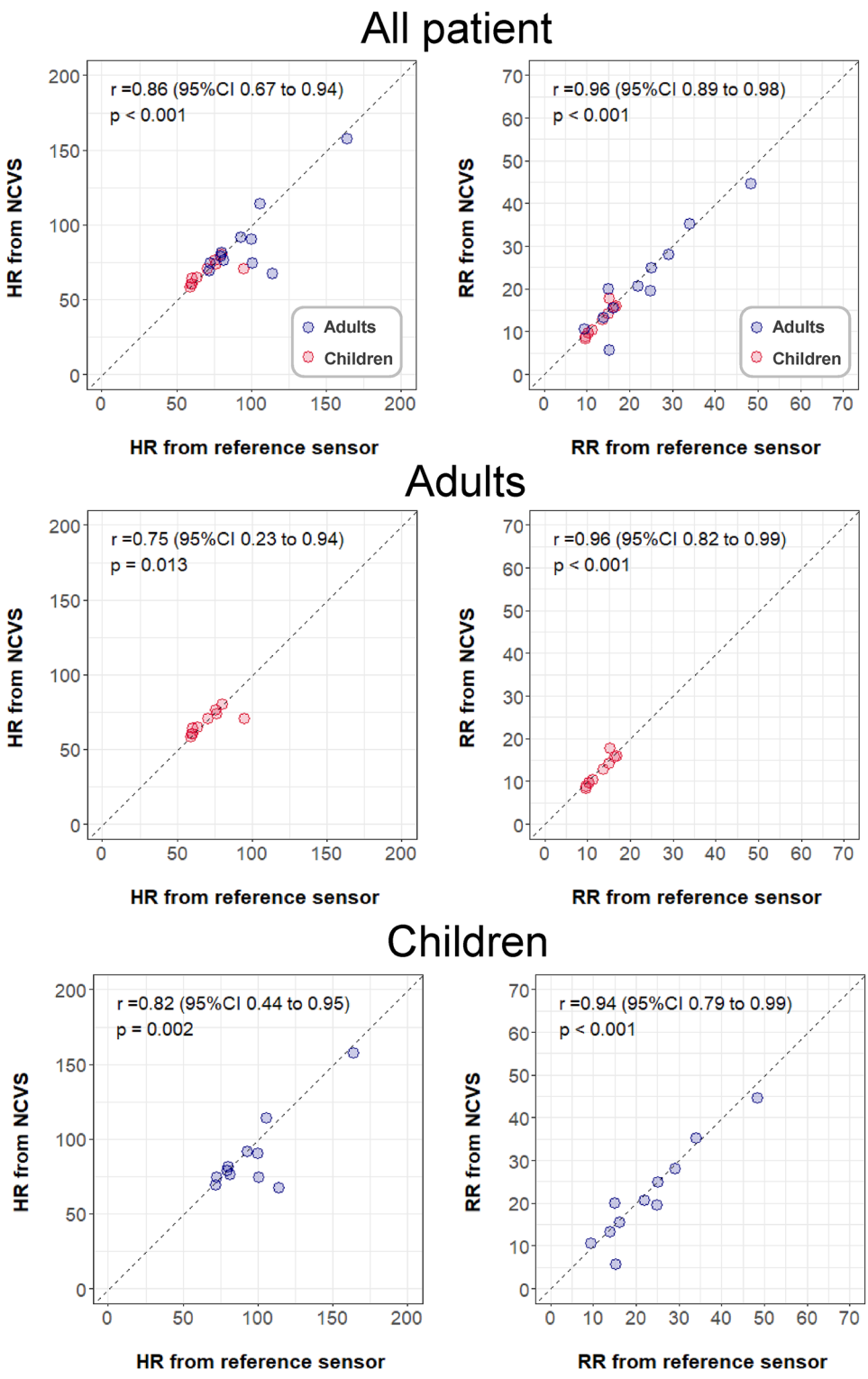

Fig. 1. The correlation coefficients of the NCVS and Ref. for the HR and RR in all patients, as well as in the adult and child subgroups, are shown. Each point represents the average value for each patient. NCVS, noncontact vital sign sensor; Ref, reference sensor; HR, heart rate; RR, respiratory rate; r, correlation coefficient; p, p value.

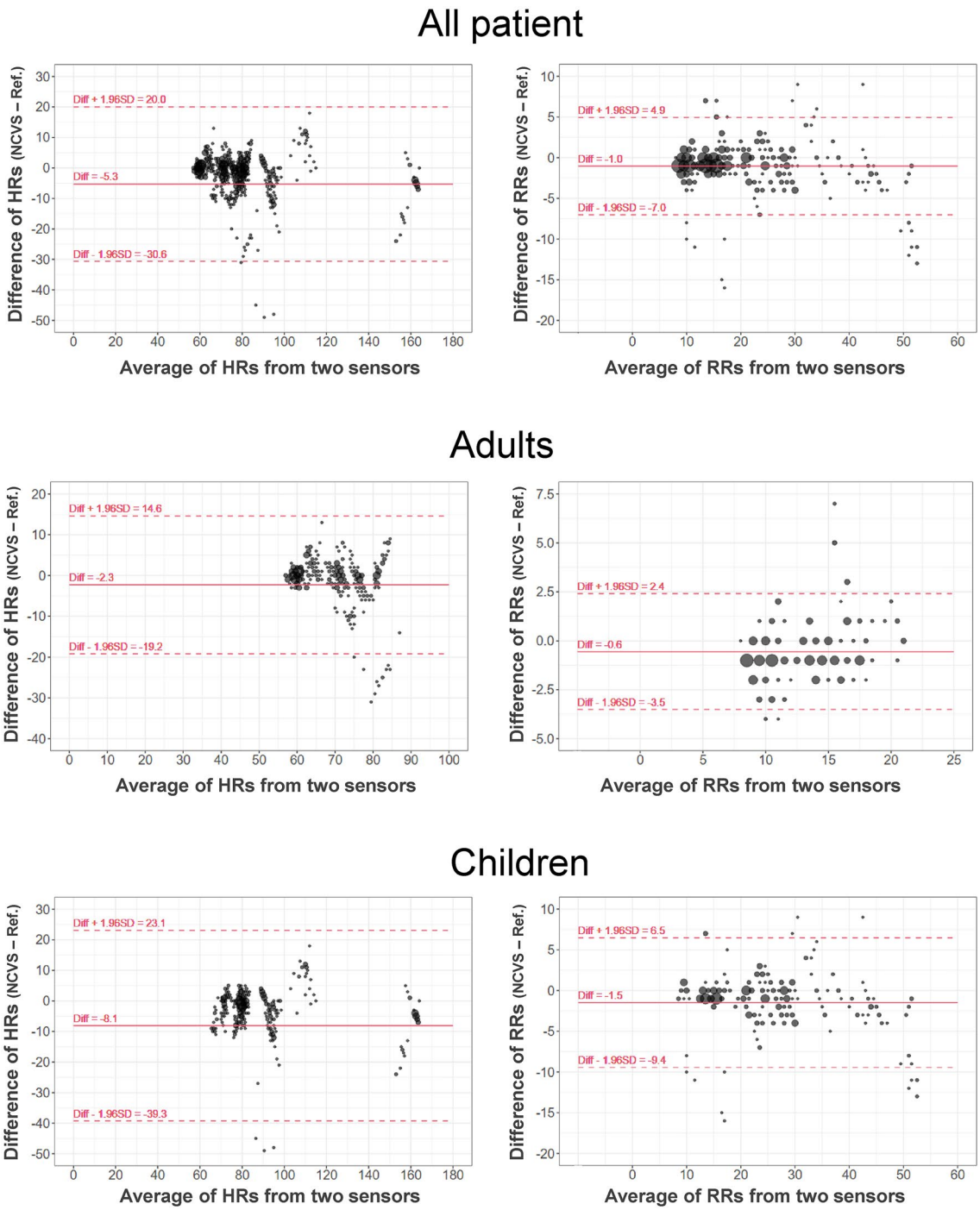

Fig. 2. Bland–Altman plots of the NCVS and Ref. for the HR and RR in all patients, as well as in the adult and child subgroups, are shown. NCVS, noncontact vital sign sensor; Ref, reference sensor; HR, heart rate; RR, respiratory rate.

	Mean differences between the NCVS and Ref.	Deviation
All patients		
HR	− 5.3 bpm	12.9 bpm
RR	− 1.0 breaths/min	3.1 breaths/min
Adults		
HR	− 2.3 bpm	8.6 bpm
RR	− 0.6 breaths/min	1.5 breaths/min
Children		
HR	− 8.1 bpm	15.9 bpm
RR	− 1.5 breaths/min	4.1 breaths/min

Table 3. Mean values and deviations of differences in measured values between the NCVS and Ref. NCVS, noncontact vital sign sensor; Ref, reference sensor; HR, heart rate; RR, respiratory rate.

	HR		RR	
	MAE (bpm)	MRE (%)	MAE (breaths/min)	MRE (%)
All patient	3.76 (95%CI 3.43 to 4.11)	4.36 (95%CI 4.03 to 4.69)	1.49 (95%CI 1.38 to 1.62)	8.46 (95%CI 7.90 to 9.06)
All patient (Excluding infant)	3.57 (95%CI 3.24 to 3.91)	4.36 (95%CI 4.00 to 4.71)	1.35 (95%CI 1.25 to 1.46)	8.48 (95%CI 7.89 to 9.12)
Adults	2.93 (95%CI 2.53 to 3.40)	3.94 (95%CI 3.49 to 4.42)	1.14 (95%CI 1.06 to 1.24)	9.19 (95%CI 8.50 to 10.00)
Children	4.59 (95%CI 4.11 to 5.12)	4.79 (95%CI 4.31 to 5.25)	1.85 (95%CI 1.63 to 2.07)	7.73 (95%CI 6.80 to 8.78)
Children (Excluding infant)	4.29 (95%CI 3.78 to 4.85)	4.83 (95%CI 4.32 to 5.34)	1.58 (95%CI 1.39 to 1.79)	7.67 (95%CI 6.63 to 8.73)

Table 4. The mean absolute error and mean relative error for heart rate and respiratory rate. HR, heart rate; RR, respiratory rate; MAE, mean absolute error; MRE, mean relative error; CI, confidence interval.

Data availability

If someone wants to request the data from this study, T.N., the corresponding author, will respond and provide the data.

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Author contributions

T.N. wrote the main manuscript text and S.S. and T.I. prepared figures. T.N., H.K., T.F., and K.K. engaged study 1. T. N., N.Y., S.S., M.O., D.H., R.B., K.F., T.F., K.K., and N.K. engaged study 2. All authors reviewed the manuscript.

Competing interests

The authors declare no competing interests.

Additional information

Correspondence and requests for materials should be addressed to T.N.

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