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The accuracy of heartbeat detection using photoplethysmography technology in cardiac patients

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A R T I C L E I N F O

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Continuous monitoring
Wearable diagnostics

A B S T R A C T

Introduction: Photoplethysmography (PPG) in wearable sensors potentially plays an important role in accessible heart rhythm monitoring. We investigated the accuracy of a state-of-the-art bracelet (Corsano 287) for heartbeat detection in cardiac patients and evaluated the efficacy of a signal qualifier in identifying medically useful signals.
Methods: Patients from an outpatient cardiology clinic underwent a simultaneous resting ECG and PPG recording, which we compared to determine accuracy of the PPG sensor for detecting heartbeats within 100 and 50 ms of the ECG-detected heart beats and correlation and Limits of Agreement for heartrate (HR) and RR-intervals. We defined subgroups for skin type, hair density, age, BMI and gender and applied a previously described signal qualifier.
Results: In 180 patients 7914 ECG-, and 7880 (99%) PPG-heartbeats were recorded. The PPG-accuracy within 100 ms was 94.6% (95% CI 94.1–95.1) and 89.2% (95% CI 88.5–89.9) within 50 ms. Correlation was high for HR ($R = 0.991$ (95% CI 0.988–0.993), $n = 180$) and RR-intervals ($R = 0.891$ (95% CI 0.886–0.895), $n = 7880$). The 95% Limits of Agreement (LoA) were −3.89 to 3.77 (mean bias 0.06) beats per minute for HR and −173 to 171 (mean bias −1) for RR-intervals. Results were comparable across all subgroups. The signal qualifier led to a higher accuracy in a 100 ms range (98.2% (95% CI 97.9–98.5)) ($n = 143$).
Conclusion: We showed that the Corsano 287 Bracelet with PPG-technology can determine HR and RR-intervals with high accuracy in cardiovascular at-risk patient population among different subgroups, especially with a signal quality indicator.

Introduction

Cardiovascular disease (CVD) is among the leading causes of mortality globally with approximately 17 million deaths annually, a number growing to up to 23 million by 2030 [1]. To minimize complications of CVD, early detection of cardiac disorders, such as arrhythmias, is critical. The electrocardiogram (ECG) is considered the golden standard for arrhythmia detection, but its application is limited to the clinical setting, making concurrent recording with an episode of symptoms challenging [2]. Additionally, arrhythmias such as atrial fibrillation (AF) are often asymptomatic and potentially remain undetected until complications, such as thromboembolic events, occur [3].

Therefore, continuous heart rhythm monitoring is beneficial, especially in at-risk cardiac patients [4]. Current devices for continuous monitoring, such as ambulatory ECG (AECG) recorders and implantable loop recorders (ILR), have their limitations, as AECG recorders are burdensome to wear and provide only limited recording time (24–72 h), while ILRs are invasive and costly [4,5].

As an alternative, the use of wearable devices for recording vital parameters through sensors enables mobile diagnostics by supplying data on the cardiovascular status of a patient at home. These smartphone-based solutions enable efficient and easy screening, and may reduce complications of cardiovascular disease through early detection of anomalies and appropriate therapeutic intervention [6]. Recent advances in photoplethysmography (PPG) have produced a new class of wearable devices for continuous and long-term health data acquisition and monitoring [7,8].

Previous research on the application of smart devices with sensor technology either focused on large consumer populations without selection for at-risk participants [9] or is applied on a limited number of patients at risk of cardiac arrhythmias [3,10]. Additionally, there has been limited attention on the impact of subject characteristics, such as skin type, hair density and body mass index, on PPG accuracy and of external disturbances such as ambient light or movement on PPG signal quality [11–15]. Because of the variance in signal quality, a signal qualifier can be applied to remove low quality parts of PPG recordings, with the aim of producing data with medical precision that is usable in clinical practice [15].

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In this study, we aimed to evaluate the accuracy of a wrist-worn PPG device (Corsano CardioWatch/Bracelet 287) for pulse detection in a varied group of cardiovascular patients in a real-life outpatient setting, taking subject characteristics into account. Furthermore, we evaluated the efficacy of a signal qualifier for identifying medically useful signals.

Methods

Study design and patient selection

In this single-centre prospective study, we assessed the accuracy of pulse detection using Corsano CardioWatch 287 (the Corsano Watch 287 or the Corsano Bracelet 287, Corsano Health B.V. Bussum, The Netherlands), determined its accuracy among pre-specified subgroups and applied a signal qualifier to determine its added value. The study population consisted of cardiac patients referred by their general practitioners to one of the outpatient clinics of Cardiology Centers of the Netherlands. All patients scheduled for a resting-ECG were included consecutively based on the inclusion- and exclusion criteria. Patients <18 years or with pacemaker dependent rhythm were excluded from the study.

The primary outcome of the study was the accuracy of the PPG-signal compared to a 12-lead resting ECG, defined as the proportion of correctly detected heartbeats by PPG within 100 ms and within 50 ms of the ECG registration. In addition, we determined the correlation (r) and the 95% Limits of Agreement (LoA) between ECG and PPG for HR and RR-intervals. We determined accuracy of the PPG-signal among subgroups separately and constructed a linear regression model to evaluate the influence of patient characteristics on the accuracy of RR-intervals. The absolute difference of RR-intervals in milliseconds between PPG and ECG was defined as the dependent variable.

RR-interval determination is sensitive to signal quality fluctuations. Therefore, besides analysing RR-interval accuracy for the whole study population, we also analysed RR-interval accuracy for a subgroup of patients whose measurements scored no less than 80% on the index. Since the determination of HR is based on the total number of detected heartbeats and is to a much lesser extent dependent on high RR-interval determination accuracy, we considered applying the signal qualifier to the analysis of HR accuracy as clinically irrelevant.

Cardiovascular history, and body height and weight were registered. Skin type was determined for each patient according to the Fitzpatrick classification, ranging from skin type I (pale white skin) to type VI (dark brown or black skin) [16]. Hair density was graded into four categories by comparing the forearm of the participant to a set of previously described set of photographs, ranging from nil to dense [17]. Subgroups were defined by gender, age, BMI, skin colour, hair density and atrial fibrillation (AF). Age was segmented into cohorts of 10 years. BMI > 25 was defined as overweight. Skin levels IV, V and VI were considered dark. Hair density 'moderate' and 'dense' were considered increased.

To determine the quality of the recordings, we applied a signal qualifier that has been described in previous research [15]. This method calculates the normalized cross-correlation coefficient of each signal segment with a reference signal. Then, it non-linearly scales the coefficient to a signal quality index (SQI) ranging from 0 to 100%, where 0% indicates the poorest, and 100% the highest signal quality. For each recording, the mean SQI was calculated.

Participants agreed to participate in the study by signing written informed consent before inclusion. The study was approved by the institutional ethics committee of Amsterdam University Medical Centre. The trial was registered at www.trialregister.nl under reference number NL8866.

Data acquisition

For each participant, measurements of PPG and ECG were simultaneously recorded for 45 s. The PPG-device was started several seconds before and ended after several seconds the ECG-device registration. Participants were at rest and supine on an exam table with their arms resting on a steady surface and were instructed not to move or speak during the measurements for quality optimisation of the recordings.

The PPG-wearables were wirelessly connected to an Android smartphone running dedicated software. The data was transmitted from the bracelet to the smartphone via a Bluetooth Low Energy (BLE) connection. From the smartphone the raw PPG data were transferred to a cloud server and forwarded to the cloud-based application for analysis.

The 12-lead ECGs were acquired by a Welch Allyn Pro resting ECG Recorder (Skaneateles Falls, New York, USA). Raw ECG data were exported to a cloud server.

Data processing

RR-intervals from both the PPG signal and the ECG signal were determined by an algorithm implemented in MATLAB version R2020b (MathWorks, Massachusetts USA). The PPG-signal was denoised by applying a 0.6–5.0 Hz band-pass filter. The individual heartbeats were detected by automated peak detection. R-peaks were determined from the ECG signal by automated peak detection. For both the PPG and ECG signal, the RR-intervals were subsequently calculated and stored in an array, with one array for each signal. The signals were then synchronized by determining the time lag with the least error between both arrays, enabling the matching of every PPG heartbeat to an ECG heartbeat. Non-matching PPG heartbeats were automatically matched to the closest ECG heartbeat. Fig. 1 shows a typical synchronized PPG and ECG measurement.

Sample size

We performed a sample size calculation to guarantee sufficient power for establishing accuracy in terms of the proportion PPG heartbeats within 100 ms of ECG heartbeats. The calculation was done with PASS (version 15.0.2) for two-sided exact Clopper-Pearson 95% confidence intervals for one proportion. Recording in 150 patients with an average heart rate of 60 bpm for 45 s, yielding 6750 heartbeats, produces a two-sided 95% confidence interval with a width equal to 0.015 and a lower limit of the 95% confidence interval of 0.893 when the sample proportion is 0.900. We added 20% as a buffer and aimed for a study population of 180 participants.

Statistical analysis

The HR metrics and the beat-to-beat intervals derived from the PPG-signal were compared with the HR and RR length of corresponding windows of the ECG signal. The accuracy was assessed by a Pearson's correlation and Bland Altman plots with multiple observations correction for Limits of Agreement, and measurements of the proportion of accurately detected measurements. We determined the proportion of PPG detected heartbeats within 100 ms of ECG measurements as primary outcome. We additionally established the proportion of PPG measurements within 50 ms of ECG measurements, the Pearson correlation between PPG and ECG HR and RR-intervals, and 95% (LoA) between PPG and ECG HR and RR-intervals. *P* values were considered significant when $p < 0.05$. All results are shown as n (%), Mean ± Standard deviation or Median (IQR) if not normally distributed.

Results

Participant demographics

The study population consisted of 180 participants (participants (60 ± 15 years old, 80 (44%) female). Participants were patients suspected for cardiovascular disease according to complaints, medical

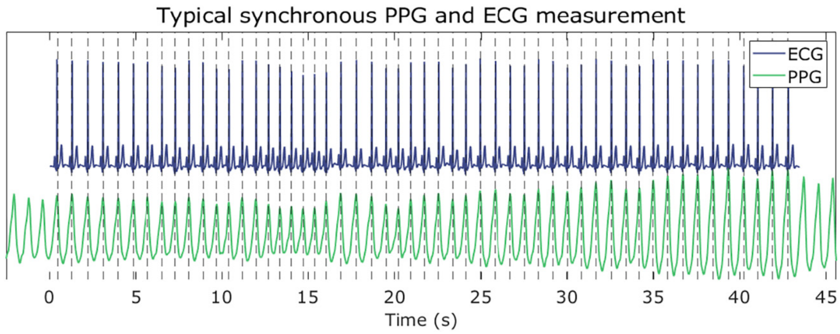


Fig. 1. Simultaneous recordings of PPG and ECG data. PPG measurement was started before and ended after the ECG registration. Non-matching PPG heartbeats were automatically matched to the closest P-top on the ECG-signal.

history and the presence of cardiovascular risk factors. The skin type heterogeneity was limited, as 74% of the participants were classified with a cream white skin (Fitzpatrick type III). The hair density (scored as nil, sparse, moderate) varied among the participants, with a slight predominance of sparse. Table 1 displays the baseline characteristics of the participants.

PPG accuracy

In 180 patients a total of 7914 ECG beats were recorded and 7880 (99%) were also recorded by PPG. Fig. 1 displays an example of a 45 s PPG and ECG measurement. The PPG-accuracy, defined as the proportion of PPG measurements within 100 ms of ECG measurements, was 94.6% (95%CI 94.1–95.1). The accuracy within 50 ms range was 89.2% (95%CI 88.5–89.9). Correlation was high for HR ($R = 0.991$ (95%CI 0.988–0.993), $n = 180$) (Fig. 2A). The 95% Limits of Agreement (LoA) were −3.89 to 3.77 (mean bias −0.06) beats per minute (Fig. 2B). For the RR-intervals, correlation was similarly high ($R = 0.891$ (95%CI 0.886–0.895), $n = 7880$) (Fig. 3A). The 95% LoA for RR-intervals were −173 to 171 (mean bias −1) ms (Fig. 3B).

Table 1
BMI - Body mass index. Cardiac history classified as Other: heart valve abnormalities, vascular disorders, structural abnormalities of the heart, pericarditis, aortic valve plastics and carotid stenosis Fitzpatrick scores - type I, pale white; type II, white; type III, cream white; type IV, moderate brown; type V, dark brown; and type VI, deeply pigmented dark brown. Hair density - nil, sparse, moderate and dense.

Participant characteristics	
n	180
Characteristics	Value
Female (%)	80 (44)
Age [years] (mean ± SD)	60 ± 15
BMI [kg/m2] (mean ± SD)	27.0 ± 5.0
General Cardiac history	n (%)
Ischemic heart disease	83 (46)
Heart failure	3 (2)
Other	54 (30)
None	17 (9)
History of Cardiac Arrhythmia	n (%)
Paroxysmal atrial fibrillation	31 (17)
Persistent atrial fibrillation	10 (6)
Atrial flutter	2 (1)
Other supraventricular arrhythmia	18 (10)
Ventricular arrhythmia	13 (7)
Conduction disorders	2 (1)
Risk factors	n (%)
Hypertension	60 (33)
Diabetes	13 (7)
Dyslipidemia	27 (15)
Fitzpatrick score	n (%)
Type I	2 (1)
Type II	20 (11)
Type III	133 (74)
Type IV	11 (6)
Type V	12 (7)
Type VI	2 (1)
Hair density	n (%)
Nil	50 (28)
Sparse	67 (37)
Moderate	42 (23)
Dense	21 (12)

Subgroup analysis

Subgroup analysis demonstrated statistically significant, yet low coefficients for gender, age and BMI and AF (Table 2). Female gender yields the most divergence between PPG and ECG measurements (7.45 ms, 95% CI 2.70 to 12.22), followed by age (5.91 ms per 10 years increment, 95% CI 4.67 to 7.16). Higher BMI results in less divergence between PPG and ECG (−7.34 ms, 95% CI −11.08 to −6.12). The magnitude of the divergence was small for all parameters.

Subgroup analysis for the categorical variables (gender, BMI, skin type and hair density) showed comparable accuracy among all subgroups (see appendix A-D).

Signal quality indicator

The median signal quality indicator of the recordings was 94% (IQR 85–100). From the total set of recordings ($n = 180$), 37 (20%) were classified with an SQI < 80% and excluded for this analysis, leading to a new subgroup of 144 high-quality measurements. In this group, a total of 6165 ECG beats were recorded and 6139 (99%) were also recorded by PPG. The accuracy of the PPG-signal in a 100 ms range from the ECG measurement was superior and showed to be 98.2% (95%CI 97.9–98.5). The RR-intervals on the PPG were highly correlated with those on the ECG ($R = 0.966$ (95%CI 0.964–0.968), $n = 6139$) (Fig. 4A), with a narrow 95% LoA of −85 to 85 (mean bias −1) ms (Fig. 4B).

Discussion

We analysed the accuracy of the Corsano 287 bracelet and watch using PPG-technology for detecting heart beats and measuring HR and RR-intervals in comparison with ECG as a golden standard. We observed an accurate heartbeat detection and determined a high correlation between PPG signals and ECG recordings when measuring HR and RR-intervals in an at-risk study population. This indicates that the current device could benefit our cardiovascular patient population. Divergence between PPG and ECG differed slightly among predefined subgroups; however, discrepancies were small and unlikely to be clinically relevant. Applying a signal qualifier led to an increase in accuracy of the PPG-signal, paving the way for potential future use in daily clinical practice for detection of AF. Early detection of AF is essential, as preventive

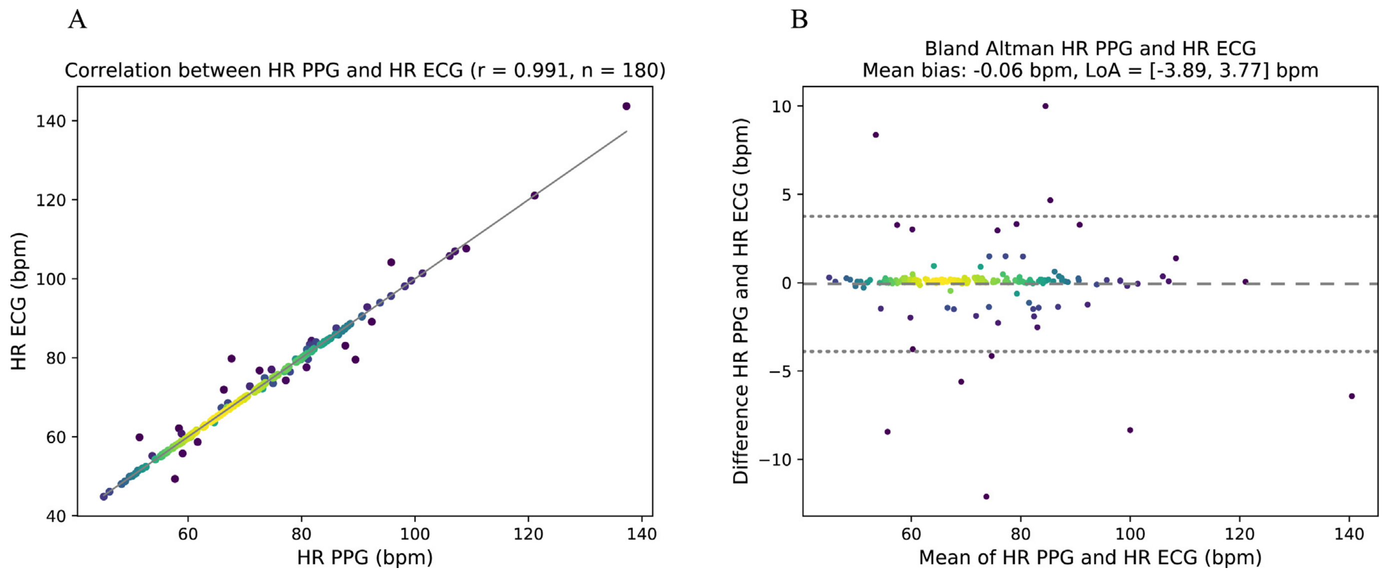


Fig. 2. A. Correlation of HR-determination (beats per minute) between PPG and ECG. B. Limits of Agreement (LoA) of HR-determination between PPG and ECG, the 95% LoA are marked by the dotted lines.

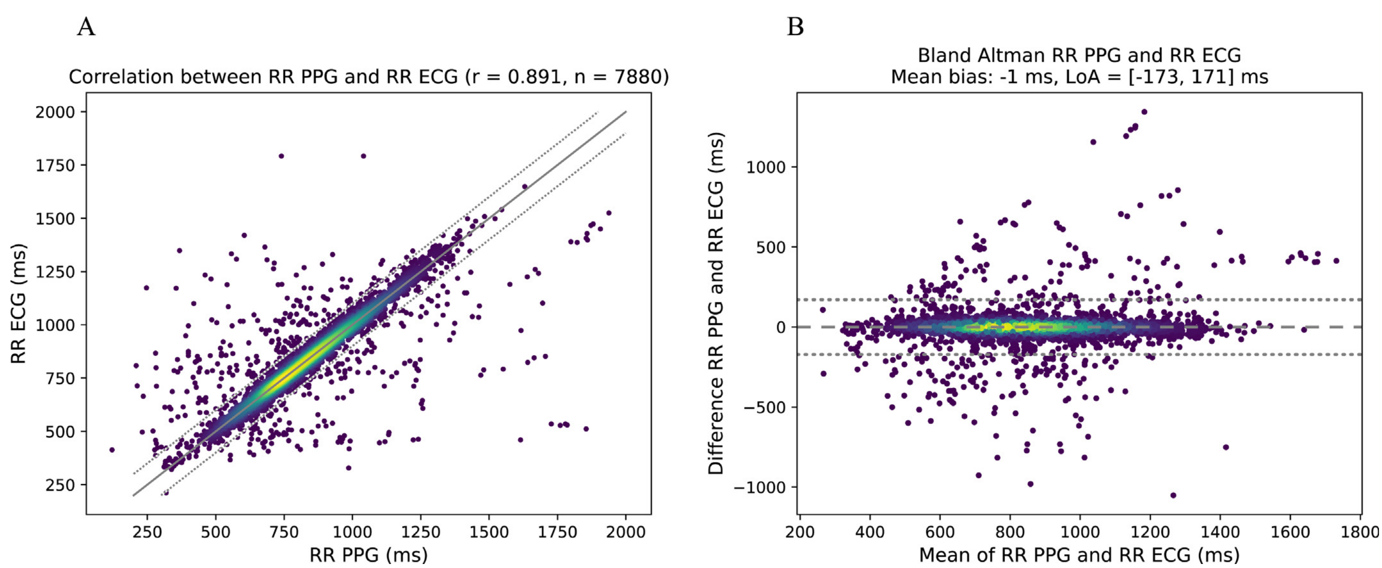


Fig. 3. A. Correlation of determined RR-intervals between PPG and ECG; the +/− 100 ms range is marked by the dotted lines. B. Limits of Agreement (LoA) of determination of RR-intervals between PPG and ECG; the 95% LoA are marked by the dotted lines.

anticoagulation therapy significantly reduces risk of complications such as stroke and death [18]. In addition to diagnostic purposes, wearable devices with PPG-technology are specifically suited for long term remote monitoring of patients already diagnosed with arrhythmias. Current remote monitoring programs are mainly symptom-driven, continuous monitoring with PPG-technology would add possibilities for asymptomatic patients [19].

Table 2
BMI: Body Mass Index. (*) denotes statistical significance. Linear regression for absolute ECG-PPG difference.

Parameter	Coefficient (ms) [95% CI]	*P*-value
Model intercept	−0.93 [−0.96–7.79]	0.834
Female gender	7.45 [2.70–12.22]	0.002*
Age (10-year increments)	5.91 [4.67–7.16]	<0.001*
High BMI	−7.34 [−11.08 – −6.12]	<0.001*
Dark skin type	−2.33 [−7.69–3.02]	0.393
Dense hair type	−0.23 [−5.26–4.80]	0.929

PPG devices using incorporated software algorithms have been studied in comparison to traditional 12-lead ECG devices, showing that data from 12-lead ECG recordings and the pulse rate variability based on photoplethysmographic correlate between 0.94 and 0.99 for HR estimates [3,6,10]. The large majority of these data were established in a consumer (i.e. non-clinical) setting, but it was anticipated that the diagnostic benefit of these devices is high, especially in patients with cardiovascular diseases. Accuracy of PPG devices in comparison to ECG recordings is generally defined as the proportion of PPG measurements within 100 ms of ECG measurements [3,14]. In addition to this usual definition, we show that a stricter range of 50 ms leads to a slight decrease of accuracy, as more PPG-detected heartbeats are defined as inaccurate for being outside of this range. For future research with improving PPG-technology, high accuracy within a narrow range of 50 ms should be pursued.

Our results are in keeping with previous research that showed considerable accuracy of the PPG signal for pulse detection, specifically when recorded at rest [6,10,20]. Our study adds to this knowledge by

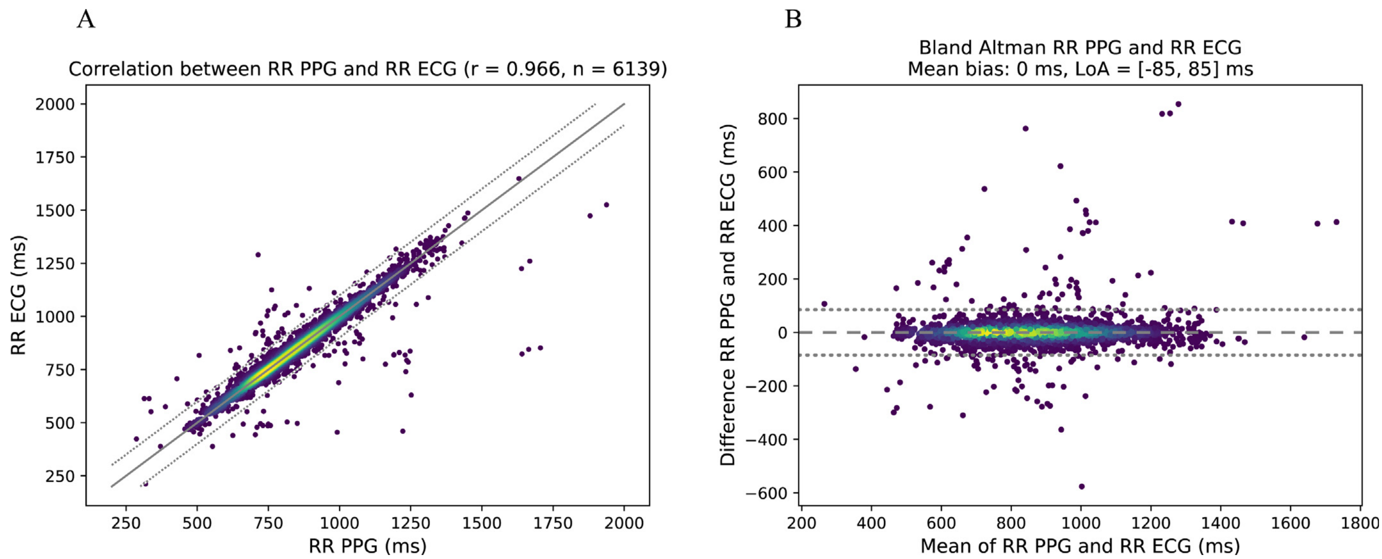


Fig. 4. A. Correlation of determined RR-intervals between PPG and ECG, after excluding low quality data; the +/− 100 ms range is marked by the dotted lines. B. Limits of Agreement (LoA) of determination of RR-intervals between PPG and ECG, the 95% LoA are marked by the dotted lines.

establishing a high accuracy in a relatively large and heterogenous cohort of cardiovascular patients in a real-life outpatient cardiology clinic. Since these patients may ultimately benefit from continuous heart rhythm monitoring, establishing its accuracy in this specific setting is paramount.

We determined overall 95% LoA for HR to be −3.89 to 3.77 (mean bias 0.06) beats per minute (bpm). This is well within the maximal allowable error ± 5 bpm for heart rate meters as described by the Association for the Advancement of Medical Instrumentation [21]. The agreement was high for all subgroups, although we found slight yet significant differences among them. The highest magnitude of the divergence between PPG and ECG was 7.45 ms for female gender, (95% CI 2.70 to 12.22) which is likely not to be of clinical significance, as was the magnitude for age. We found that in our study, higher BMI is correlated with a slightly higher accuracy, while the opposite was expected. This higher accuracy may be caused by a tighter fit of the bracelet on the wrist, preventing ambient light introducing noise on the sensor.

We additionally demonstrate the added value of the application of a signal qualifier to increase reliability of the RR-interval measurements. A range of external variables, such as interference from electrical devices or movement of the subject, can influence the quality of the PPG-signal [15]. For PPG-technology to eventually base clinical decision-making on, excluding low-quality episodes is crucial for achieving medical precision. By applying a previously described signal qualifier, accuracy within 100 ms range increased from 94.6% (95%CI 94.1–95.1) to 98.2% (95%CI 97.9–98.5).

To further develop the PPG-technology and make it suitable for usage in clinical practice, future research should focus on the impact of movement and activity on the accuracy of the PPG-signal, and on the application of algorithms to analyse heart rate variability and detect arrhythmias such as AF.

Strengths and limitations

In this study we analysed a large and heterogenous patient population, taking additional confounders such as risk factors, BMI, skin type and hair density into account, increasing the external validity of our study. From these confounders, skin type was unevenly distributed, as 74% of the participants was classified as type 3. This overrepresentation may limit generalizability of our results for other skin types.

All recordings in the trial were performed on patients at rest. It is therefore unknown whether the wearable and algorithm will produce similar results in an unsupervised ambulant setting. Other studies have shown that movement and physical exercise influence the quality of PPG recordings in a similar way as ECG [6,20]. Hence, future studies should evaluate the current device under dynamic circumstances.

Additionally, recordings were relatively short, about 45 s. As the PPG-signal requires a “start-up phase” in which the signal is seeking to detect pulse, this short recording period may have led to a relatively lower accuracy. It can be anticipated that in patients who are monitored for a longer time at rest, the accuracy of the PPG recording will be higher. The short recording time also forced us to discard complete recordings with a low signal quality score for the signal quality subgroup analysis, instead of removing low quality parts within single recordings, as it would not leave sufficient RR-intervals for analysis. In longer recordings, the signal quality indicator can typically be used to remove low quality segments within one patient's measurement to increase the overall quality and accuracy of PPG derived parameters such as RR-intervals, rather than deleting a complete record.

Conclusion

This validation study showed that the Corsano 287 CardioWatch/Bracelet with PPG-technology can determine HR and RR-intervals with high accuracy in a cardiovascular patient population, with high quality output in different subgroups, especially when combined with a signal quality indicator. Due to their non-intrusive and convenient nature, wearable devices like these have great potential for high volume accessible long-term monitoring at-risk cardiac patients.

Funding

We received an unrestricted educational grant from Corsano for the execution of this research.

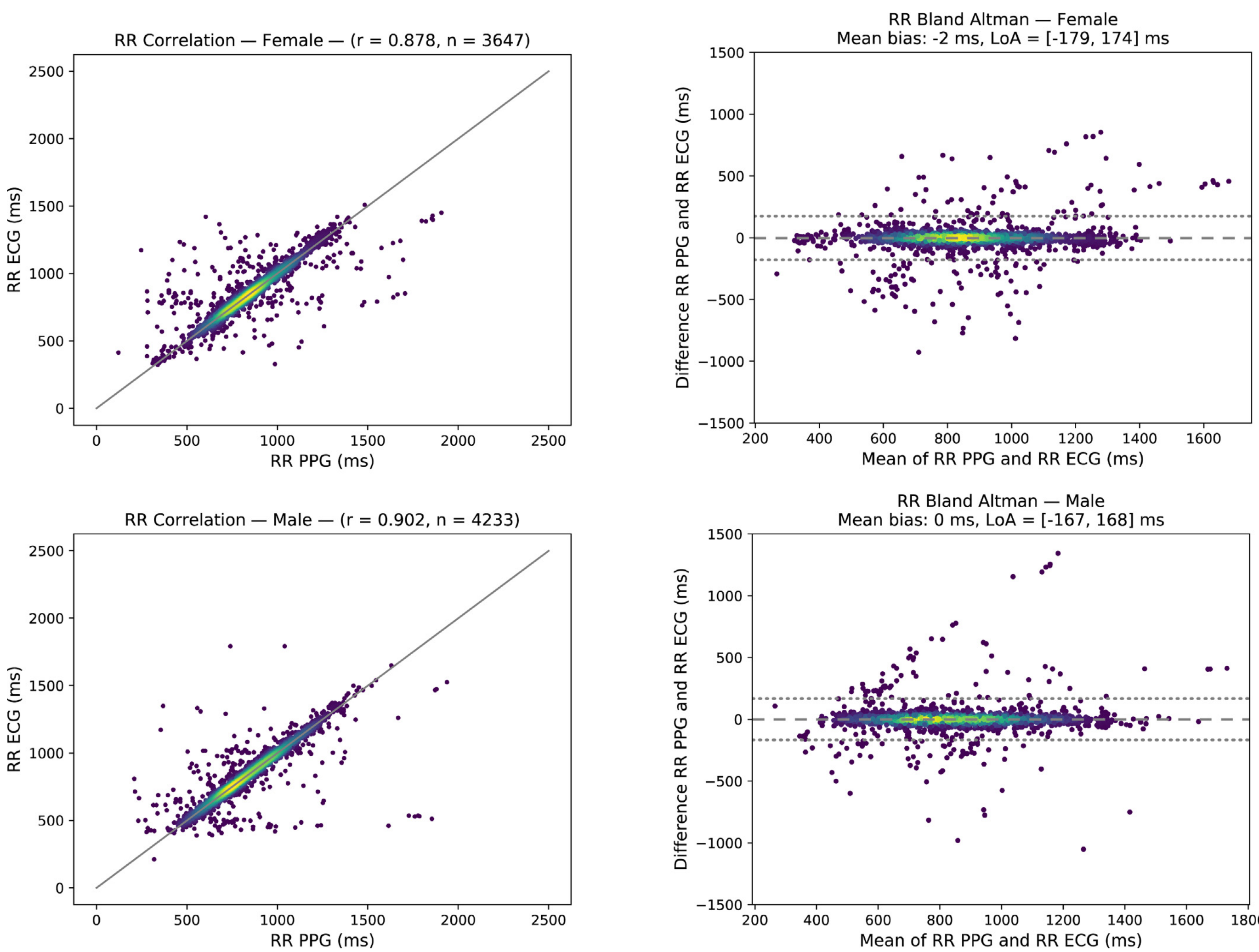
Authors contribution

SB, GAS and MMW contributed to the conception and design of the study. SB and MMP contributed to the acquisition, analysis and interpretation of the data and drafted the article. GAS, MMW and IIT critically revised the article for important intellectual content. All authors discussed the results and combined this to the final article and gave final approval of the version to be submitted.

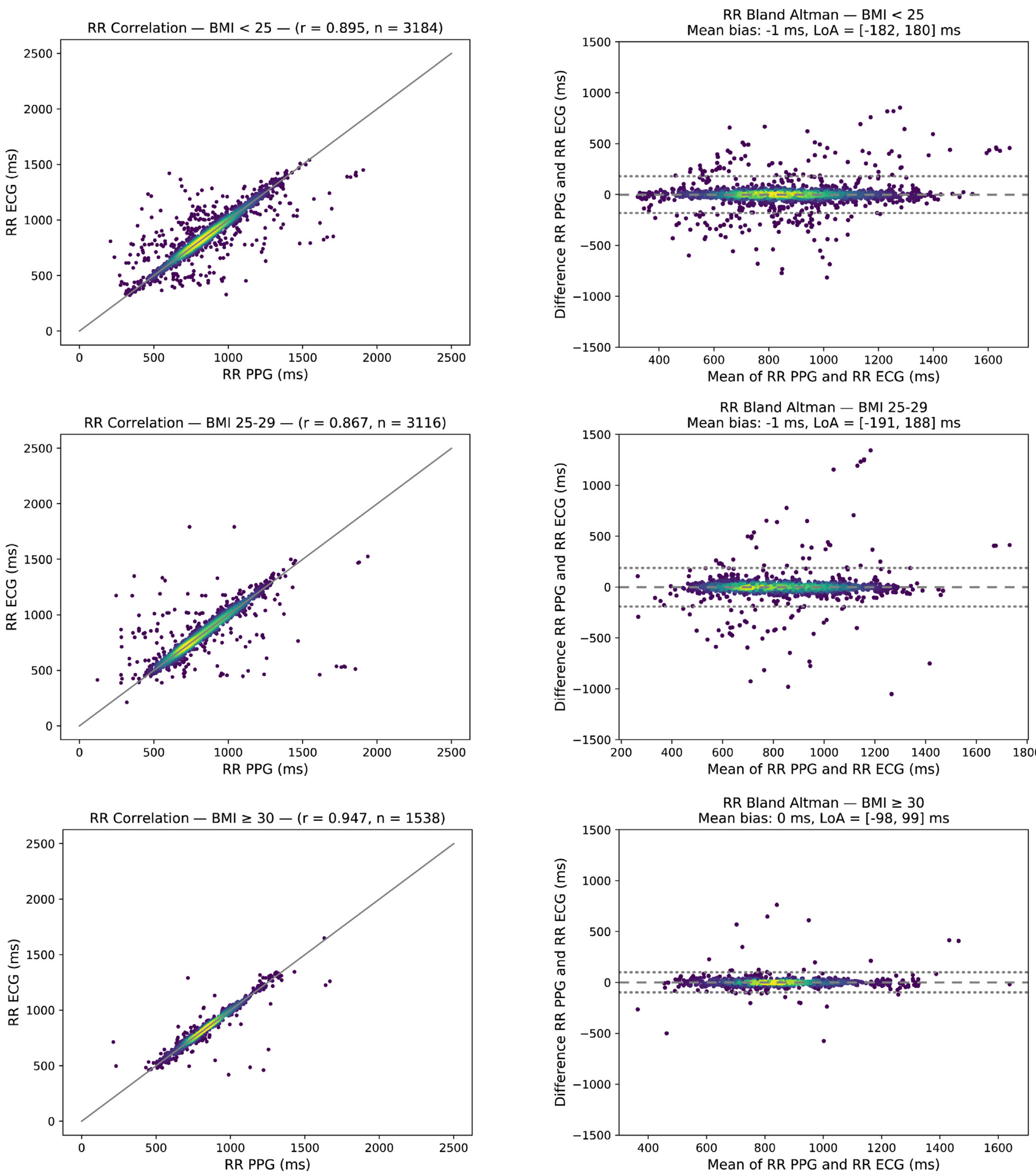
Declaration of Competing Interest

None.

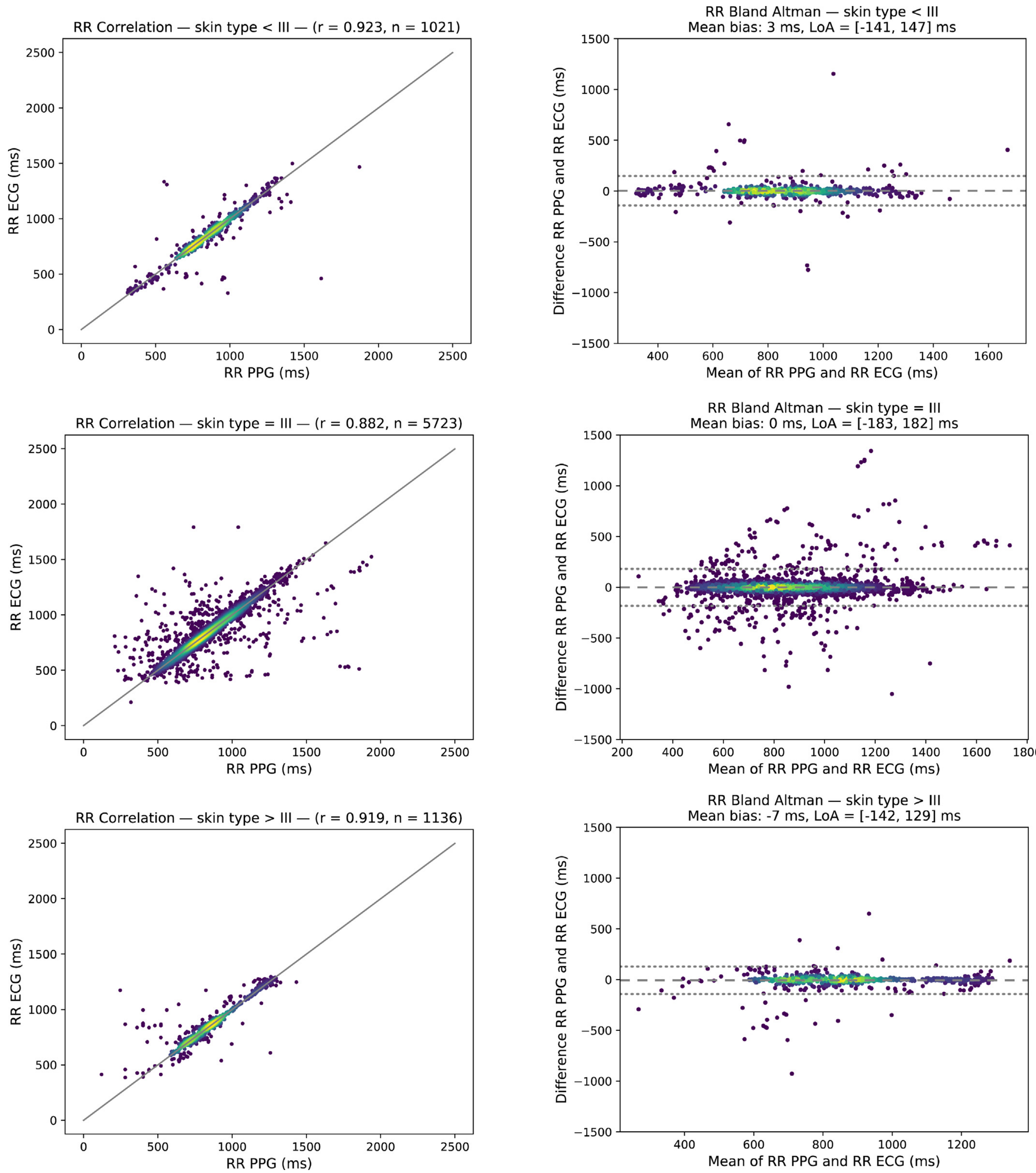
Appendix A. Sub analysis gender



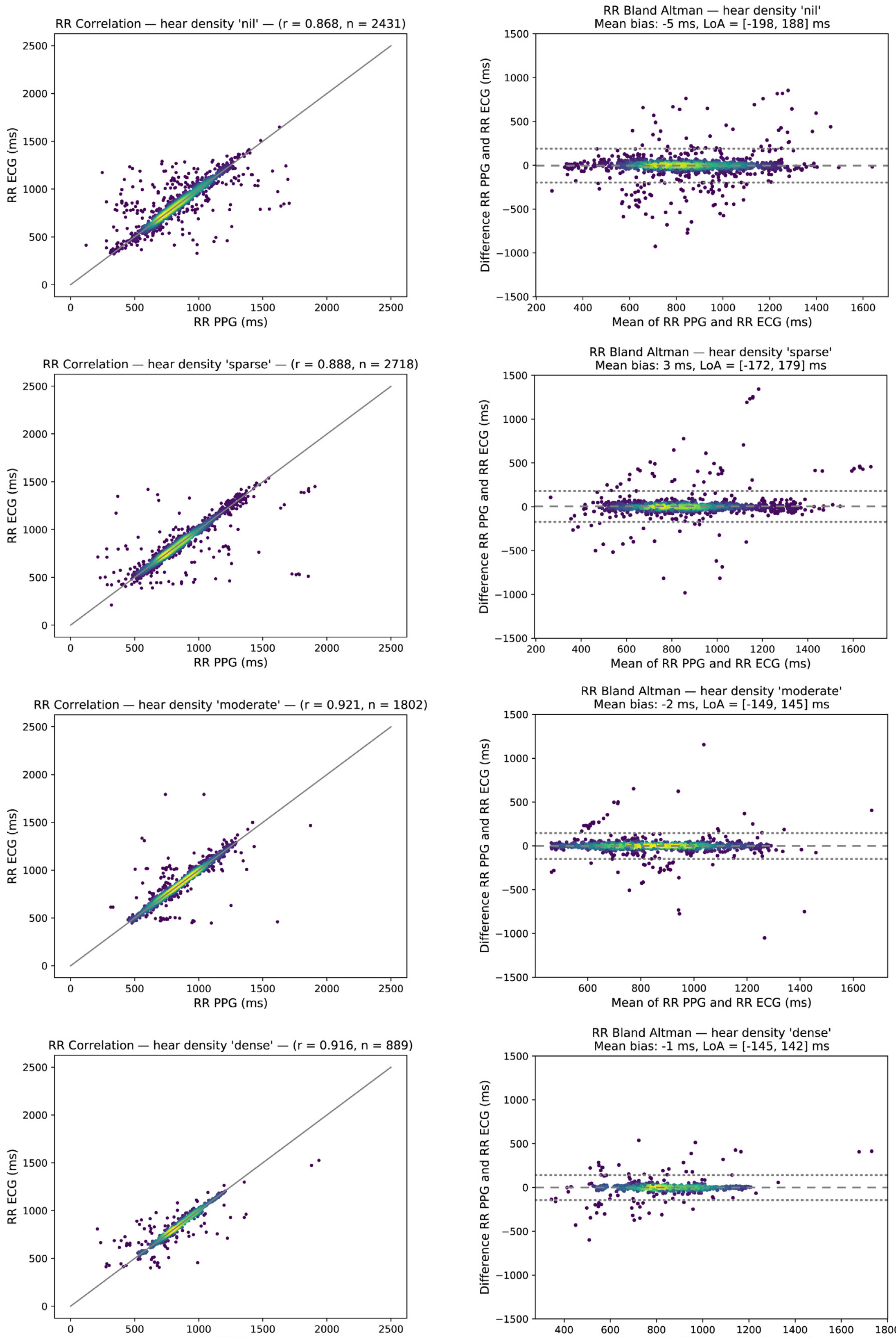
Appendix B. Sub analysis BMI



Appendix C. Sub analysis skin type



Appendix D. Sub analysis hair density



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