Acoustic sensor versus electrocardiographically derived respiratory rate in unstable trauma patients

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ABSTRACT:

BACKGROUND: Respiratory rate (RR) is important in many patient care settings; however, direct observation of RR is cumbersome and often inaccurate, and electrocardiogram-derived RR (RR_{ECG}) is unreliable. We asked how data derived from the first 15 minutes of RR recording after trauma center admission using a novel acoustic sensor (RR_a) would compare to RR_{ECG} and to end-tidal carbon dioxide-based RR (RR_{CO2}) from intubated patients, the "gold standard" in predicting life-saving interventions in unstable trauma patients.

METHODS: In a convenience sample subset of trauma patients admitted to our Level 1 trauma center, enrolled in the ONPOINT study, and monitored with RR_{ECG}, some of whom also had RR_{CO2} data, we collected RRa using an adhesive sensor with an integrated acoustic transducer (Masimo RRa™). Using Bland-Altman analysis of area under the receiver operating characteristic (AUROC) curves, we compared the first 15 minutes of continuous RRa and RR_{ECG} to RR_{CO2} and assessed the performance of these three parameters compared to the Revised Trauma Score (RTS) in predicting blood transfusion 3, 6, and 12 hours after admission.

RESULTS: Of the 1200 patients enrolled in ONPOINT from December 2011 to May 2013, 1191 had RR_{ECG} data recorded in the first 15 minutes, 358 had acoustic monitoring, and 14 of the latter also had RR_{CO2}. The three groups did not differ demographically or in mechanism of injury. RR_a showed less bias (0.8 vs. 6.9) and better agreement than RR_{ECG} when compared to RR_{CO2}. At RR_{CO2} 10-29 breaths per minute, RR_a was more likely to be the same as RR_{CO2} and assign the same RTS. In predicting transfusion, features derived from RR_a and RR_{ECG} gave AUROCs 0.59-0.66 but with true positive rate 0.70-0.89.

CONCLUSION: RR_a monitoring is a non-invasive option to glean valid RR data to assist clinical decision making and could contribute to prediction models in non-intubated unstable trauma patients.

1. INTRODUCTION

Respiratory rate (RR) is one of the fundamental clinical vital signs. It is one of three key physiologic pre-hospital triage criteria in the Guidelines for Field Triage of Injured Patients,[1] one of the three components of the Revised Trauma Score (RTS),[2] and one of the minimum acceptable neurological observations required to be documented by the National Institute for Health Care Excellence head injured patients.[3] However, despite many studies demonstrating the utility of RR as a predictor of critical illness,[4–7] RR is the vital sign least often recorded and most often completely omitted from medical documentation.[8–11]

Direct observation of RR is cumbersome and conventional automated modalities are often inaccurate due to artifacts from coincident patient care activities. Continuous measurement of end-tidal carbon dioxide in intubated patients provides an accurate measurement of RR (RR_{CO2}). RR_{CO2} is also possible in non-intubated patients via nasal cannula or mask[12] but is often inaccurate, particularly in the non-sedated patient because of mouth breathing, mask displacement, and artifacts caused by activities like coughing, movement, and speaking. Continuous automated RR monitoring can be done with the electrocardiogram (ECG) impedance-derived method, but this is limited by interference from artifacts due to patient movement, poor ECG lead contact, or displacement. In the present study, we asked whether a novel non-invasive acoustic sensor applied directly to the neck of unstable trauma patients could provide accurate continuous RR monitoring data that performed as well as or better than RR_{ECG}-

derived data and on a par with RR_{CO2}-derived data in prediction models, including the RTS, for blood product transfusion during the first 12 hours of trauma resuscitation, the period of maximal risk for bleeding death.[13,14]

2. METHODS

This study is a subgroup analysis of the Oximetry and Non-Invasive Predictors of Intervention Need after Trauma (ONPOINT) study. This 3-year project was designed to examine prediction models for life-saving interventions including blood product transfusion based on continuous automated physiologic data derived from novel non-invasive sensors.[15] After expedited approval and waiver of informed consent from the University of Maryland School of Medicine and United States Air Force Institutional Review Boards, adult patients (age ≥18 years) admitted directly from the scene of injury to the R Adams Cowley Shock Trauma Center, Baltimore, Maryland, with abnormal pre-hospital shock index (≥ 0.62),[15] were consecutively enrolled on arrival in the Trauma Resuscitation Unit (TRU) from December 2011 to May 2013. Enrollment occurred on all days and shifts when patients met eligibility criteria. For the purposes of the present study, we examined the first 15 minutes of continuous vital signs (VS) data, including VS waveforms, via BedMaster® software (Excel Medical Electronics, Jupiter, FL) from networked patient monitors (GE-Marquette-Solar-7000/8000, GE Healthcare, Little Chalfont, UK). Numeric monitored trend values of RR_{CO2} and GE Marquette ECG-derived RR (RR_{ECG}) were obtained every 5 seconds (0.2 Hz) via the Bedmaster VS server. In addition, if the patient's neck could be accessed, RR was also recorded by an acoustic transducer attached along the medial border of the sternocleidomastoid muscle with an adhesive pad (RRa™, Masimo Corporation, Irvine, CA). The accuracy of this device has been reported by the manufacturer, based on 26 healthy adults, as 0.18 (bias) ± 1.31 (standard deviation [SD]) bpm,[16] but use in instable trauma patients has not been previously reported. We focused on the first 15 minutes after admission because this time frame is of special interest in acute trauma involving massive hemorrhage. Clinicians must gather, interpret, and act on useful information very rapidly. Therefore, we choose the 15-minute time window to determine whether RR could serve as an important factor in supporting decisions, and if its accuracy would affect its usefulness.

Blood product use through the first 12 hours of resuscitation was documented from TRU and blood bank records and included units of uncrossmatched group O packed red blood cells (pRBC) kept in a TRU refrigerator and given in the first hour of resuscitation before crossmatched units are available from the blood bank. Patients were excluded if they had less than 5 minutes (33% of 15 minutes) of continuous VS data recorded during the first 15 minutes after hospital arrival. To avoid "prediction" of events that had already occurred, the outcome of blood product transfusion excluded transfusions given within the first 15 minutes.

3. STATISTICAL ANALYSIS

RR_a and RR_{ECG} were compared using three methods: 1) numerical difference between paired RR_a, RR_{ECG}, and RR_{CO2}, 2) clinical and triage difference based on RTS, and 3) transfusion prediction using the features derived from RRa versus RR_{ECG}. The bias (mean difference) and 95% limits of agreement were used to quantify the numerical difference between RR_a and RR_{ECG}. A Bland-Altman analysis adjusted for repeated measurement[17] was used to compare agreement for measurements of RR_a and RR_{ECG}. RR in breaths per minute (bpm) were divided into five categories, designated 0 to 4: 0) RR=0, 1) RR=1-5, 2) RR=6-9, 3) RR=10-29, and 4)

RR ≥30.[1] Since none of the patients had RR of 0 bpm, comparison was performed for categories 1 to 4.

As RTS is a well-known trauma triage score that uses RR and has been used to predict the need for transfusion,[13] we compared the RTS values obtained using each of the three RR measurements. We also tested the predictive power of additional RR features including time series of RR_a and RR_{ECG} and their mean; 1^{st}, 2^{nd}, and 3^{rd} quartiles; and the cumulative amplitude and duration of RR below (<10 bpm) and above (>29 bpm) thresholds. The percentage of time, mean, and SD in the low and high RR ranges was also calculated. Patient age and sex adjustments were included in every model.

Prediction models used a generalized linear model with a “boosting” algorithm family for comparison and validation. The reason for selecting this “boosting” algorithm was to create a “strong” model from an ensemble of “weak” models[18] to allow comparison of the best performance of different RR features. To avoid over-fitting, the “weak” models were regularized by the elastic net method, a weighted combination of least absolute shrinkage and selection operator (LASSO) and ridge regression. To examine the generalization capability of the models, we used 4-fold cross-validation repeated 25 times, with stratified sampling to test prediction performance. Area under the receiver operating characteristic (ROC) curve was used to compare the transfusion prediction performance of the RR_a and RR_{ECG} features with the RTS. The RTS was calculated based on the models for the first 15 minutes average RR_a or RR_{ECG},[19] and Delong’s method was used to compare ROCs.[20] True positive rate (TPR or “sensitivity”), true negative rate (TNR or “specificity”), and positive predictive value (PPV or “precision”) were reported. All statistical analyses, predictive model building, and evaluations were implemented with R software version 3.1.1 (R Development Core Team, Vienna, Austria). $p<0.05$ was considered statistically significant.

4. RESULTS

Of the 1200 patients enrolled in ONPOINT over the 18-month study period, 1191 had RR_{ECG} data recorded in the first 15 minutes after admission and 358 had acoustic monitoring, 14 of whom were also monitored via RR_{CO2} and so were able to provide simultaneously recorded data from all three RR monitoring and data recording modes for the purposes of this study. Table 1 summarizes the demographics and mechanism of injury of all enrolled patients. The two groups that are the focus of this study, RR_a/RR_{ECG} (n = 358) and $RR_a/RR_{ECG}/RR_{CO2}$ (n=[358 – 344]=14), did not differ demographically or in mechanism of injury from the wider ONPOINT study group monitored by RR_{ECG} alone.

4.1. Numerical Comparison

Among the 14 $RR_a/RR_{ECG}/RR_{CO2}$ patients, Bland-Altman analysis adjusted for repeated measurement showed a bias of 0.8 bpm for RR_a and RR_{CO2} and 6.9 bpm for RR_{ECG} and RR_{CO2}, and the respective 95% limits of agreement were -9.2 to 10.8 and -13.1 to 26.8 (Figures 1-3). RR_{ECG} tended to overestimate RR_{CO2} or RR_a, while RR_a and RR_{CO2} were systematically similar. As shown in Table S1 (Supplemental Digital Content), measures of volatility showed a smaller mean square of RR_a and RR_{CO2} between and within groups than RR_{ECG} and RR_{CO2}. Table S2 (Supplemental Digital Content) shows mean, SD, and median of the first 15 minutes after admission for the 14 $RR_a/RR_{ECG}/RR_{CO2}$. There was no difference between the first 15 minutes mean RR_a and RR_{CO2} (p=0.42); however, the difference of 7.9 mean bpm ± 4 SD between RR_{ECG}

and RR_{CO2} was significant (p=0.0002). Among the 358 RR_a/RR_{ECG} patients, the difference of 8.6 mean bpm ± 5 SD was also significant (p<0.0001).

To overcome the Bland-Altman plot's limitation as an overall evaluation that does not reflect measurements in different categories with different clinical meaning, we used the confusion tables to count the number of points that each pair of sensors had measurements in the same or different categories. When two sensors have RR measurement in the category, the clinicians may make decisions similarly based on either sensor's reading. Tables S3a-S3c show that RRa and RR_{CO2} had more agreed measurements in the same clinical categories. RR_{ECG} had more data points off the main diagonal cells, compared with RRa and RR_{CO2}.

4.2 Transfusion Prediction

Predictions of blood product use in the first 3, 6, and 12 hours after admission for the 358 RR_a/RR_{ECG} patients are shown in Table 2. RR-based transfusion prediction performance on testing dataset resulted in ROCs of 0.59 to 0.66 but a true positive prediction rate of 0.70 to 0.89. The ROC 95% confidence intervals derived from models using RTS calculated from RR_a or RR_{ECG} were not statistically different. Transfusion prediction models using RTS as a predictor had a significantly higher ROC than RR_a or RR_{ECG} alone (Table 2).

5. DISCUSSION

RR and respiratory patterns are linked with other physiological changes. Because of its importance, RR is included in mortality prediction scoring systems such as RTS and the Trauma Injury Severity Score. However, because of the difficulty of accurate measurement, RR is often ignored in trauma patient management. In this exploratory study of a novel proprietary acoustic

RR monitoring device deployed in the TRU of a busy Level 1 trauma center, we found that the RR_a device produced continuous RR monitoring data that performed equivalently to that derived from end-tidal carbon dioxide monitoring on intubated patients.

We isolated RR as a single data source for transfusion prediction for the purpose of comparing the usefulness of different RR measurements. The results show that using RR_a or RR_{ECG} features does not predict the first 12 hours transfusion as well as using RTS calculated either from RR_a or RR_{ECG} (Table 2). Challenging the utility of RR at all in trauma triage, a recent 22-center French study enrolled 937 trauma patients with single-value manual recording of RR, RR categories of RTS, and dichotomous values (abnormal or normal) and found that RR did not add value in predicting mortality or prognosis.[21] However, RR-based features had non-trivial TPR, 0.84-0.89, in predicting transfusion within the first 6 hours. This suggests that RR-based features, if accurately measured, could be used as a component in prediction models with other predictive features.

This study population is the largest to date in which RR_a has been measured and is the only study in which RR data were collected during active resuscitation of unstable trauma patients. Our study compared RR measured from three different sensors, including simultaneously in 14 of 358 patients admitted to a busy TRU and showed that RR_a was significantly less volatile than RR_{ECG} and agreed better with RR_{CO2} in intubated patients, the latter often considered the "gold standard" measurement for RR. We believe that this work suggests that for the larger group of non-intubated patients, in whom end-tidal carbon dioxide is not an accurate option, some form of robust, accurate, and non-invasive acoustic RR monitoring device could be a useful alternative for RR measurement and can support more accurate RTS calculation than RR_{ECG} or direct-observation methods, particularly in the critical first hours of trauma resuscitation. In our study, RRa also discriminated among patients who were more or less likely to receive blood products in the first 12 hours of care.

Various prior studies have examined the accuracy of RR_a by comparing RR_a to RR_{CO2} in spontaneously breathing post-operative patients[22,23] and have shown good agreement between RR_a and RR_{CO2} with 0 bias and -1.4 to 1.4 bpm 95% limit of agreement.[22] A study of 53 anesthetized patients ventilated with laryngeal masks reported a small bias with 95% limit of agreement of -2.1 to 2.2 bpm between RRa and RR_{CO2}.[24]

Different approaches for RR monitoring have also been examined. A recent study compared a piezoelectric sensor RR monitor, ECG-based monitor, and nurse measurement in 48 post-anesthesia care unit patients.[25] Piezoelectric-derived RR had a mean difference of -0.41 bpm (SD=1.79) compared to ECG-derived RR and a mean difference of -0.58 bpm (SD=2.50) compared to nurse evaluation. However this piezoelectric sensor's accuracy in an unstable environment has not yet been examined. A non-contact Doppler radar-based RR sensor was compared with inductance plethysmographic belts around the rib cage for 24 patients who had surgery or received analgesics, with 95% limit of agreement of ± 5 bpm.[26] However, the accuracy of this method may be limited by motion artifact.[27] Another study of 139 healthy volunteers showed that RR derived from the pulse oximeter signal had good agreement with RR_{CO2}, with -0.23 bpm ± 1.14 SD.[28] If this accuracy could be extended to other clinical environments, a single sensor could give both RR and blood oxygen saturation, which is promising for use in transfusion prediction models.

The potential utility of RR_a extends further than RR data collection. It has been reported to be useful in detecting changes in depth of breathing and warning of impending respiratory failure after resuscitation[29] and thus to have potential value for airway and ventilation monitoring. An accurate RR measurement would also be valuable if integrated into decision support software that detects clinically significant conditions such as over-sedation, hemorrhagic shock, or neurologic deterioration. Future studies of RR should focus not only on designing more accurate instrumentation but also on extracting additional features from RR measurement associated with specific clinical conditions. In addition, specific factors that interfere with accurate RR sensing (coughing, speaking, snoring, etc.) and are associated with other forms of data loss or failures of documentation need to be investigated. Mimoz et al. have reported that speaking, moving, and coughing affected RR_{CO2} more frequently than RR_a.[22] Although the number of events was small, they found that repeated swallowing was the only event found to affect RR_a more than RR_{CO2}. Our study did not examine the effect of ambient noise on RR_a accuracy; however, our study was performed in a noisy TRU setting. Prior studies[22,23,30] were conducted in intensive care units and patient recovery areas likely to have less ambient noise.

This is an exploratory study. It is limited by being a single-center study and one based on secondary sub-analysis of data gleaned from another study of the instrumentation being tested, and the primary study was closely related to but not specifically designed for the purposes of this study. Moreover, the lack of comparison of RR measurement in the field, e.g. during helicopter transportation or on the battlefield, leaves more work to be done to evaluate the accuracy of acoustic-sensor-derived RR and its usefulness in support of clinical decision-making in austere and unstable settings.

6. CONCLUSION

Our study of RR data collected during the critical initiation of trauma patient assessment and resuscitation shows that RR_a has less volatility and correlates better with RR_{CO2} than RR_{ECG}

and can provide RR data that are potentially clinically useful in decision support models such as those for blood product use. RR_a may be useful as an alternative to RR_{ECG} for ongoing assessment of non-intubated patients and may improve the accuracy of triage scoring systems.

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TABLE 1. Demographic, Mechanism of Injury, and Outcome Characteristics of Patients

Characteristic	**n=1191***	**n=358****	**n=14†**	**$p^{1 \text{ vs. } 2}$**	**$p^{1 \text{ vs. } 3}$**	**$p^{2 \text{ vs. } 3}$**
Mean age, yr (SD)	40.4(17.7)	39.1(17.4)	41.3(10.6)	0.20	0.47	0.28
Admission GCS (1st,2nd,3rd quartiles)	14,15,15	15,15,15	12,14,15	-	-	-
Sex, n (%)						
Male	823 (69.1)	252 (70.4)	12 (85.7)	0.69	0.29	0.35
Female	368 (30.9)	106 (29.6)	2 (14.3)	-	-	-
Injury type, n (%)						
Blunt	955 (80.2)	298 (83.2)	12 (85.7)	0.23	0.86	0.90
Penetrating	176 (14.8)	53 (14.8)	2 (14.3)	0.94	0.74	0.74
Other	60 (5.0)	7 (2.0)	0 (0.0)	0.02‡	0.81	0.64
Mechanism of injury, n (%)						
Motor vehicle associated	557 (46.8)	174 (48.6)	7 (50.0)	0.58	0.98	0.87
Falls	253 (21.2)	83 (23.2)	2 (14.3)	0.48	0.76	0.65
Interpersonal violence	230 (19.3)	72 (20.1)	2 (14.3)	0.80	0.89	0.85
Other	151 (12.7)	29 (8.1)	3 (21.4)	0.02‡	0.57	0.21
Outcome, n (%)						
pRBC 15 min-3 h	80 (6.7)	10 (2.8)	4 (28.6)	0.008‡	0.008‡	<0.001‡
pRBC 15 min-6 h	106 (8.9)	12 (3.4)	4 (28.6)	<0.001‡	0.04‡	<0.001‡
pRBC 15 min-12 h	121 (10.2)	18 (5.0)	5 (35.7)	0.004‡	0.008‡	<0.001‡

*n=1191 patients from the ONPOINT study.

**n=358 patients with both acoustic and ECG-based respiratory rate monitoring recorded.

†n=14 intubated patients with acoustic, ECG-based, and RR_{CO2} monitoring.

‡Statistically significant difference at the significance level 0.05.

Mann-Whitney U test was used to test mean age difference among groups. Chi-square test was used to compare two proportions.

GCS, Glasgow Coma Scale.

TABLE 2. Performance Evaluations for Models Predicting Packed Red Blood Cell Transfusion (n=358)

Model	**TPR**	**TNR**	**PPV**	**ROC**	**ROC 95% CI**
Within 15 Minutes – 3 Hours after Admission					
RRa	0.86	0.59	0.14	0.59	0.56 – 0.62
RR_{ECG}	0.84	0.64	0.10	0.61	0.57 – 0.64
RTSa*	0.89	0.75	0.14	0.73	0.69 – 0.76
RTS_{ECG}**	0.93	0.71	0.20	0.74	0.71 – 0.78
Within 15 Minutes – 6 Hours after Admission					
RRa	0.88	0.65	0.10	0.66	0.64 – 0.69
RR_{ECG}	0.89	0.63	0.12	0.64	0.61 – 0.67
RTSa	0.90	0.71	0.14	0.71	0.67 – 0.74
RTS_{ECG}	0.87	0.75	0.19	0.70	0.66 – 0.74
Within 15 Minutes – 12 Hours after Admission					
RRa	0.86	0.53	0.09	0.61	0.60 – 0.63
RR_{ECG}	0.70	0.67	0.16	0.61	0.58 – 0.63
RTSa	0.79	0.75	0.20	0.73	0.70 – 0.75
RTS_{ECG}	0.77	0.77	0.20	0.72	0.70 – 0.74

*RTSa: Revised Trauma Score calculated using RRa as the RR component.
**RTS_{ECG}: Revised Trauma Score calculated using RR_{ECG} as the RR component.
CI, confidence interval.

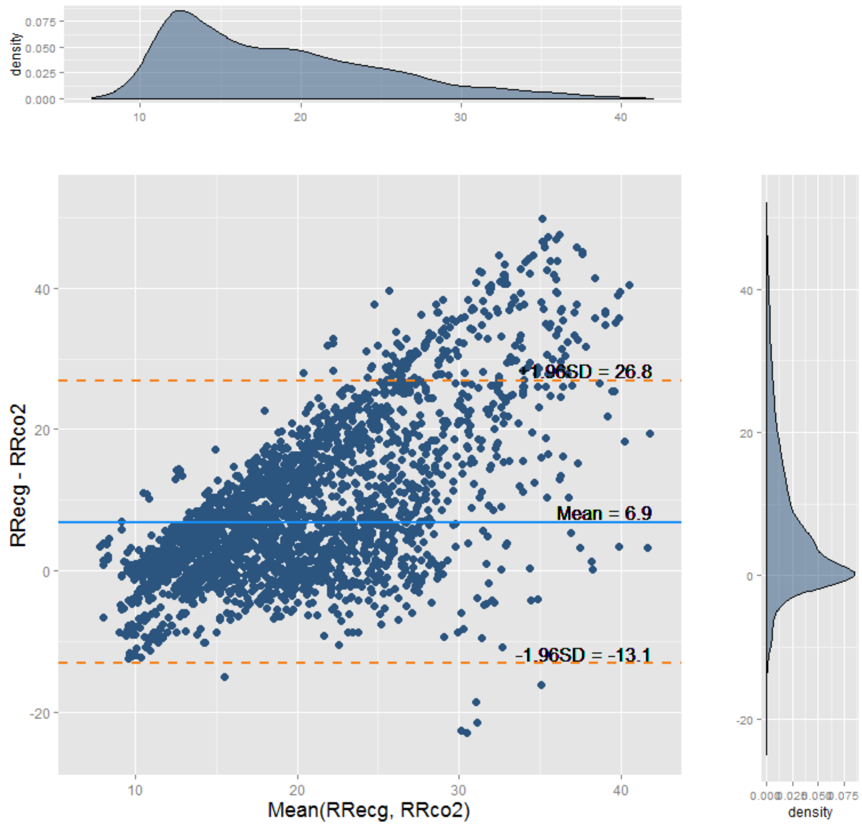

Figure 1. The Bland-Altman plot adjusted for repeated measurement for the agreement of RR_{ECG} and RR_{CO2} (n=14). Bias=6.9 and 95% limit of agreement is -13.1 to 26.8. Right and top subplots show the density of x and y directions in the Bland-Altman plot. This plot illustrates that RR_{ECG} tends to overestimate RR_{CO2}, as the average gets higher.

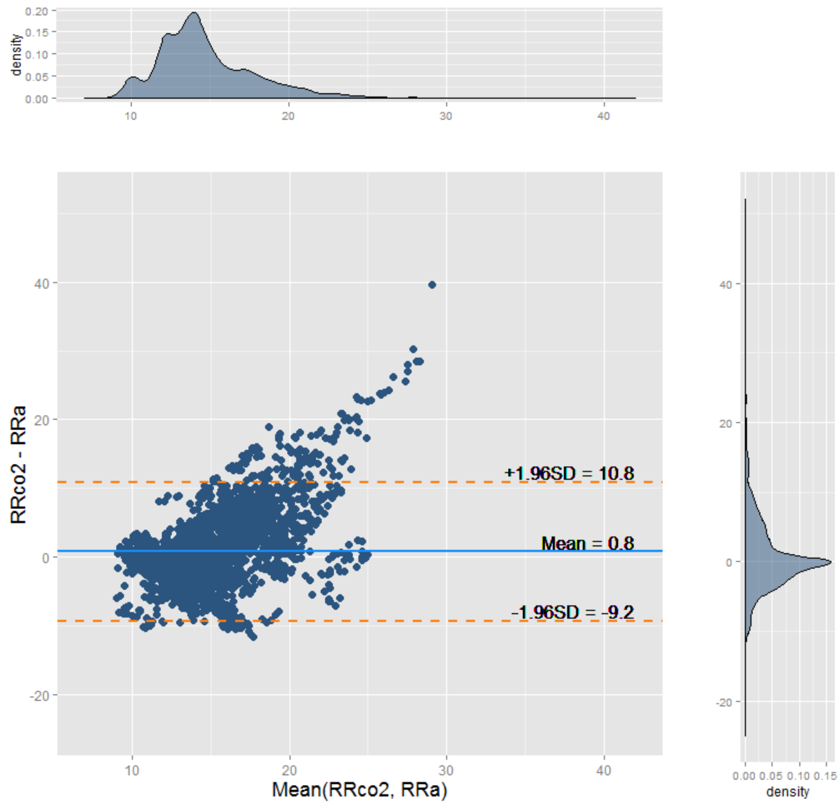

Figure 2. The Bland-Altman plot adjusted for repeated measurement for the agreement of RRa and RR_{CO2} (n=14). Bias=0.8 and 95% limit of agreement is -9.2 to 10.8. Right and top subplots show the density of x and y directions in the Bland-Altman plot. This plot illustrates that RRa and RR_{CO2} have small bias and narrow limits of agreement.

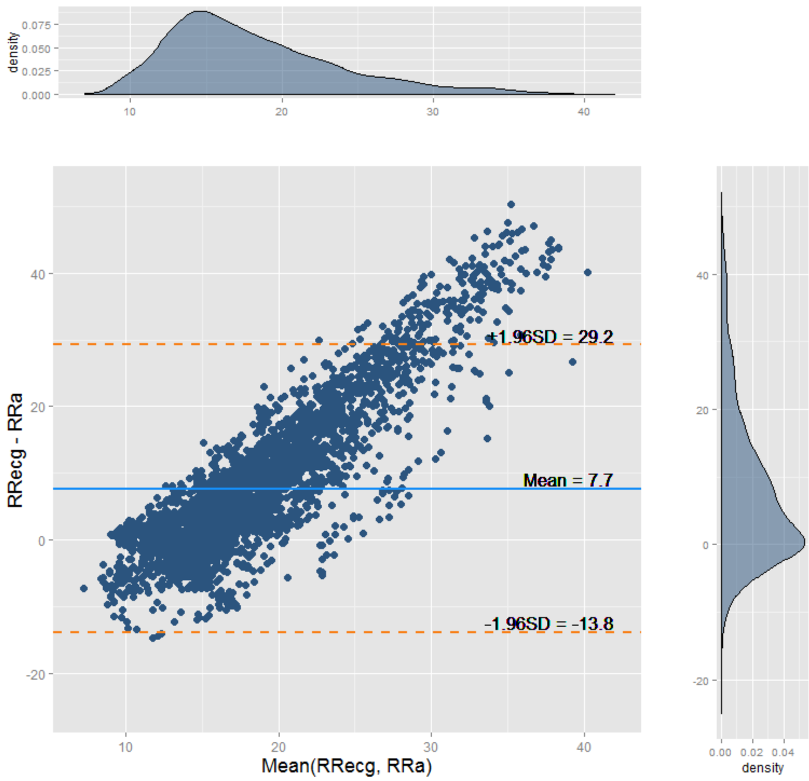

Figure 3. The Bland-Altman plot adjusted for repeated measurement for the agreement of RR_{ECG} and RRa (n=14). Bias=7.7 and 95% limit of agreement is -13.8 to 29.2. Right and top subplots show the density of x and y directions in the Bland-Altman plot. This plot illustrated that there is a trend between RR_{ECG} and RRa, as the difference grows larger when the average increases.