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Non-Contact Respiratory Rate Measurement Validation for Hospitalized Patients

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***Abstract*—This paper presents the first clinical results for validating the accuracy of respiratory rate obtained for hospitalized patients using a non-contact, low power 2.4 GHz Doppler radar system. Twenty-four patients were measured in this study. The respiratory rate accuracy was benchmarked against the respiratory rate obtained using Welch Allyn Propaq Encore model 242, the Embla Embletta system with Universal XactTrace respiratory effort sensor and Somnologica for Embletta software, and by counting chest excursions. The 95% limits of agreement between the Doppler radar and reference measurements fall within +/-5 breaths per minute.**

I. Introduction

Respiratory rate is considered the next critical vital sign and yet often goes under measured or ignored primarily due to shortcomings of the currently used measurement methods. Respiratory rate provides important information on a person's health condition and physiological stability, and an abnormal respiratory rate is a strong indicator that a health crisis is imminent [1]. In fact, a sudden change in respiratory rate is one of the strongest predictors of mortality [2]-[3]. Current methods to collect respiration data include use of respiration belts, impedance through EKG electrodes, spirometers, or clinical observation/counting. These techniques have drawbacks that limit the frequency and convenience of the respiratory monitoring. Recognizing that closer respiration monitoring can save lives and improve quality of life, reduce hospital stays, and lower medical costs [3], the heath care industry is seeking improved respiration monitoring products.

Physiological monitoring with Doppler radar systems has been known since 1970's [4]. Both contact [5] and non-contact [6] techniques were shown effective for detection of pressure pulse, and cardio-pulmonary activity [4]. While significant advanced were made in understanding of Doppler radar sensing of physiological signatures in the past few decades, its application in healthcare still remains largely under developed. Human studies on healthy volunteers have demonstrated good correlation between respiratory rates obtained using Doppler radar and respiratory effort belts [7]-[8]. In this study, we present the first reported clinical data validating the accuracy of Doppler radar respiratory rate on hospitalized patients.

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II. Human Testing Procedure

The human study was done at Queen's Medical Center under IRB number RA-2008-061 on clinically stable patients. The patients included in this study were not selected randomly; they were selected with intent to cover a broader range of respiratory rates and respiratory waveforms than a representative sample of hospital patients would cover. Patients receiving opioid pain medication, patients recovering from thoracic surgery, and patients with lung conditions such as COPD, pneumonia, obstructive sleep apnea, and pulmonary embolism were measured at a higher than representative frequency. Twenty-four patients were measured in this study. In pilot studies performed under the same IRB approval, the difference in respiratory rates between the Doppler radar respiratory rate and references had a standard deviation of approximately 1.3. To achieve a standard error of limits of agreement of approximately 0.5 breaths/minute, the desired sample size was determined to be between 20 and 25 patients:

$$n = 3\frac{(\text{expected standard deviation of difference})^2}{(\text{desired limits of agreement})^2} = 3\frac{1.3^2}{0.5^2} = 20.3$$

Twenty-four subjects were included in this study, including 15 males, and 9 females. Their age ranged from 43 to 91 years, with a mean age of 70 years. Body Mass Index ranged from severely underweight (BMI=14.0) to morbidly obese (BMI=48.1), with a mean BMI of 29.7. The demographic information is summarized in Table I. For one subject, clinical information beyond age and sex were not collected. Of the remaining 23 subjects, 5 had surgery during their current hospital admission, 3 of which were open heart surgeries. Six patients were receiving pain medications and 4 of those were receiving opioid

analgesics. Four patients were receiving supplemental oxygen during the measurements.

Patients were measured while their vital signs were being monitored by other equipment. Low power 2.4 GHz Doppler radar with proprietary hardware and software was used in the study, facing the device toward the patient's thorax at a distance of about 1 meter. The radio power emitted by this Doppler radar device is well below that of many consumer and hospital wireless electronic devices, so the radio power does not pose any significant safety risk. After measuring for the user-selected interval, the Doppler radar device processes the data to determine the quality of the signal, and if the signal is of adequate quality to provide an accurate rate, it displays the patient's respiratory rate on the screen. All patients had the reference measurements: the Welch Allyn Propaq provided respiratory rate via thoracic impedance measurement, and the Embla system provided respiratory rate through inductive plethysmographic measurement of respiratory effort. Several of the patients also had continuous pulse oximetry and ECG monitored by another device. A respiratory rate was also obtained by counting respiratory excursions for the same duration as the Doppler radar measurement interval, simultaneously with the Doppler radar measurement. The counting of chest excursions involved counting the number of peak inhalations in the specified time interval, as timed with a stopwatch, and multiplying by the appropriate number to calculate breaths/minute.

TABLE I.
PATIENT DEMOGRAPHIC INFORMATION

	Age (n=24)	**Sex (n=24)**	**BMI (n=23)**	**Resp Rate (n=24)**
Mean	69	15 males 9 females	29.7	18
Standard Deviation	15		8.3	4
Max	91		48.1	26
Min	43		14.0	11

Once powered and connected to the patient, the Welch Allyn Propaq Encore model 242 continuously updates and displays a respiratory rate if the RESP function is enabled. The Welch Allyn Propaq requires affixing electrodes on the patient's skin, attaching lead wires to the electrodes, and plugging the ECG leads into the Propaq 200-series unit. It measures respiratory effort by running a small AC current between the electrodes and monitoring the change in impedance as the patient breathes. Cardiogenic artifact is removed from the impedance waveform, and it is analyzed to determine a respiratory rate. This rate is displayed on the local screen. For this study, the rate displayed at the end of the Doppler radar measurement was recorded for comparison.

The Embla Embletta GOLD system with XactTrace belts and Somnologica software is a body-worn system which continuously records respiratory signals. Once an XactTrace abdomen belt and an XactTrace thorax belt are connected to the patient, the recording is initiated by pressing the "start" button. In this configuration, the Embletta system records the respiratory effort waveforms in the Embletta unit. After the measurement is complete and the belts are detached from the Embletta unit, the data is transferred to a PC running the Somnologica software. The Somnologica software analyzes the signal, and provides a respiratory rate. The XactTrace belts, when used with the Embletta system, use inductance pneumography to obtain a respiratory effort. These chest belts include an embedded wire coil; the respiratory effort signal is obtained by sending an AC signal through the wire in the chest belts, and measuring the change in the chest belts' inductance as the shape of the patient's chest changes with breathing. This system cannot be configured to provide a respiratory rate in real time. For the measurements in this study, the time stamp button on the Embletta unit was pressed at the beginning and end of each spot check respiratory measurement. The rate used for this analysis was the rate presented by the system at the time stamp at the end of the measurement interval.

III. EFFICACY RESULTS

For a respiratory rate spot check, literature on the repeatability and interobserver variability in visual assessment provides indication of the clinically relevant range for agreement. Lim et al [9] found a repeatability coefficient of 4.1 breaths/minute for respiratory rate measurements made sequentially by the same observer, and a repeatability coefficient of 5.7 breaths/minute for sequential respiratory measurements made by different observers, and a repeatability coefficient of 4.3 breaths/minute for simultaneous measurements made by different observers, with all the measurements performed on adults. Based on this data, the 95% limits of agreement for a respiratory rate spot check should be less than ±4 to ±6 breaths/minute.

The primary data analysis method used was Bland-Altman analysis: identification of the 95% limits of agreements. It is expected that 95% of differences in measurements made simultaneously with the two analyzed methods would lie within these limits. The 95% limits of agreement are calculated as the bias (the mean difference between each method) +/- 2 standard deviations of the difference between the measurements from each method. The data and the 95% limits are plotted in the Bland Altman plots for each method comparison, and the bias, standard deviation, and 95% limits are shown in the table for each method comparison. The difference between the methods is

also shown as the root mean square of the difference between measurements with each method. Finally, a linear regression is performed, and the equation of the regression line and the correlation coefficient are plotted. The agreement between Doppler radar and the three references is summarized in Table II. As shown in Table II, the 95% limits of agreement between the Kai RSpot and all three reference measurements fall within +/-5 breaths per minute. Correlation coefficient between the Doppler radar respiratory rate and that obtained by all three references is at least 0.89. Standard deviation of difference between measurements and the root mean square of the difference are both below 2 breaths per minute.

TABLE II.

SUMMARY OF AGREEMENT OF DOPPLER RADAR WITH REFERENCE MEASUREMENTS

	Doppler Radar & Welch Allyn Propaq Encore	Doppler Radar & Embla Embletta System	Doppler Radar & Visual Assessment
Bias (mean of difference between measurements)	-0.5	-1.31	-0.81
Standard Deviation of Difference Between Measurements	1.8	1.6	1.1
95% confidence limit: high	3.0	1.8	1.4
95% confidence limit: low	-4.0	-4.5	-3.1
RMS difference	1.8	2.0	1.4
Linear regression equation	y=0.81x +2.65	y=0.92x +0.14	y=0.97-0.29
Correlation coefficient	$R^2 = 0.89$	$R^2 = 0.89$	$R^2 = 0.94$

Figure 1 shows the linear regression of the respiratory rate provided by the Doppler radar system and that provided by the Embla system, showing strong correlation between the two measurements. Figure 2 shows the Blant-Altman plot of the difference versus the mean of measurement of respiratory rates provided by the Doppler Radar and by the Embla system. As indicated in Table II, the 95% confidence intervals fall in between +1.8 and -4.5 breaths per minute.

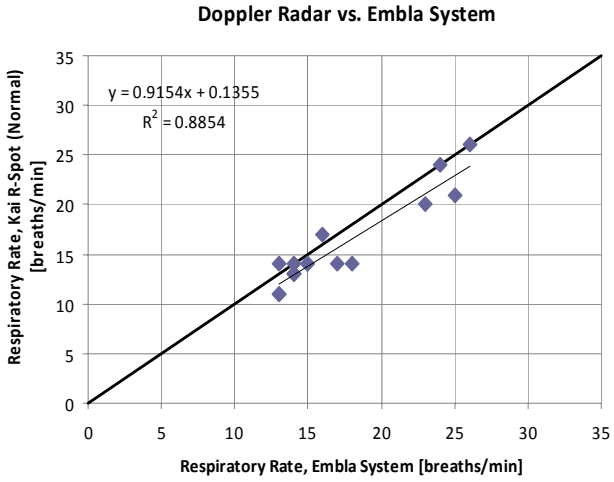

Fig. 1. The linear regression of the respiratory rate provided by the Doppler radar system and that provided by the Embla system.

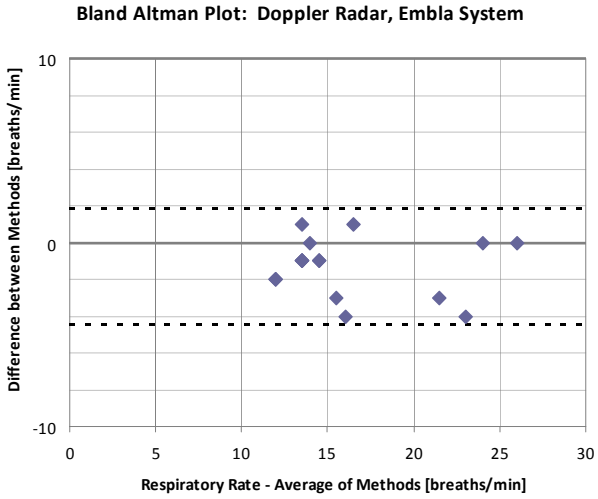

Fig. 2 Bland Altman Plot: the difference versus the mean of measurement of respiratory rates provided by the Doppler radar and by the Embla system.

IV. CONCLUSIONS

The difference between simultaneous respiratory rate measurements made with the Doppler radar and with the reference methods were assessed on hospitalized patients. The 95% limits of agreement between the Kai RSpot and reference measurements fall within +/-5 breaths per minute. This level of agreement has been shown to be within the repeatability for the reference methods in this study and within the inter-observer and intra-observer variability of visual assessment of respiratory rate, which is commonly used to obtain the respiratory rate in vital signs assessments. Therefore the Doppler radar respiratory rate agrees sufficiently well with the respiratory rates provided by the

Welch Allyn Propaq Encore model 242 and the Embla Embletta system with Universal XactTrace respiratory effort sensor and Somnologica for Embletta software that it can be used interchangeably for hospitalized patients.

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