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A noncontact RF-based respiratory sensor: results of a clinical trial

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ABSTRACT

Background: Respiratory rate (RR) is a critical vital signs monitored in health care setting. Current monitors suffer from sensor-contact failure, inaccurate data, and limited patient mobility. There is a critical need for an accurate and reliable and noncontact system to monitor RR. We developed a contact-free radio frequency (RF)–based system that measures movement using WiFi signal diffraction, which is converted into interpretable data using a Fourier transform. Here, we investigate the system's ability to measure fine movements associated with human respiration.

Materials and methods: Testing was conducted on subjects using visual cue, fixed-tempo instruction to breath at standard RRs. Blinded instruction-based RRs were compared to RF-acquired data to determine measurement accuracy. The RF-based technology was studied on postoperative ventilator-dependent patients. Blinded ventilator capnographic RR data were collected for each patient and compared to RF-acquired data to determine measurement accuracy.

Results: Respiratory rate data collected from 10 subjects breathing at a fixed RR (14, 16, 18, or 20) demonstrated 95.5% measurement accuracy between the patient's actual rate and that measured by our RF technology. Ten patients were enrolled into the clinical trial. Blinded ventilator capnographic RR data were compared to RF-based acquired data. The RF-based data showed 88.8% measurement accuracy with ventilator capnography.

Conclusions: Initial clinical pilot trials with our contact-free RF-based monitoring system demonstrate a high degree of RR measurement accuracy when compared to capnographic data. Based on these results, we believe RF-based systems present a promising noninvasive, inexpensive, and accurate tool for continuous RR monitoring.

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Introduction

Respiratory insufficiency is a leading cause of cardiopulmonary arrest in the acute care hospital setting. An American Heart Association sponsored study of 14,720 inpatient adult cardiac arrest events found that respiratory insufficiency was the proximate cause of 37% of all cases of inpatient cardiac arrest.[1] Furthermore, the 2009 HealthGrades Patient Safety in American Hospitals Study, based on Medicare data, showed that postoperative respiratory failure was the third leading cause of medical errors in U.S. hospitals; occurring in 17 of every 1000 patients and responsible for >5000 deaths annually, at a cost of >$1.8 billion each year.[2]

Respiratory rate monitoring of at-risk patients with or without concurrent continuous pulse oximetry is used in the inpatient setting in an effort to identify early stage respiratory insufficiency and prevent cardiorespiratory arrest. Respiratory rate is one of the most critical vital signs monitored in the health care setting, and yet, it is one of the least reliable metrics available to clinicians.[3] The standard manual method of counting a patient's respiratory rate by trained clinical staff has been shown to be inaccurate and frequently goes unmeasured. A study of patients requiring a medical emergency team intervention in the acute care hospital setting found that 77% of patients suffering an adverse event had a vital sign missing from the chart just before the event and the most frequently missing measurement was respiratory rate (RR).[4,5] Several technologies have been developed in an effort to automate RR measurements and improve the accuracy of the data. A disadvantage of all of the solutions currently available for use in the clinical setting designed for continuous RR monitoring require some level of patient-sensor contact leading to tethering of the patient to the device. Additionally, current technologies suffer from data loss due to inadequate device-patient contact. The most frequently used methodologies for measuring RR in nonintubated patients include intermittent manual counting, thoracic impedance pneumography using ECG leads, and continuous nasopharyngeal tube capnography.[6] The most accurate method is invasive monitoring through ventilator-acquired capnography in intubated patients. Even the most accurate of these invasive and semi-invasive systems suffer from data unreliability due to movement artifact, sensor-contact failure, inaccurate data acquisition, and limited patient mobility.[7] Given the importance of RR in identifying patients at risk of impending respiratory distress, there is a critical need for an accurate, reliable, and costeffective, noncontact system that will allow monitoring in the clinical setting.

In an attempt to address this issue, a contact-free radio frequency (RF)−based respiratory sensor was developed in our laboratory. It uses standard off-the-shelf wireless devices to measure changes in the radio channel caused by inhalation and exhalation of the patient. These measurement changes are used and to estimate the breathing rate of a stationary person. The system has been used to estimate breathing rate and location in a home.[8-10] Existing studies used only one participant in an idealized setting who was told to breathe at a constant rate. No study has confirmed the performance of the system across a variety of people or those in a postoperative care setting. In this clinical pilot study, we sought to investigate the ability of the RF-based respiratory sensor to accurately measure a subject's RR in a healthy control population and in mechanically ventilated patients in the immediate postoperative period after undergoing a midline sternotomy and open-heart surgical procedure.

Materials and methods

Contact-free RF-based respiratory sensor development

The transmitter and receiver system previously described in[10] was further developed to use standard WiFi (IEEE 802.11n) transceivers to make measurements of received signal strength (RSS). The key benefit of 802.11n is its use of multiple input multiple output, which in our case allows us to measure the nine pairwise channels between the three antennas (standard monopoles) on each transceiver, providing us with nine times as many RSS measurements compared to the single antenna system previously described.[11] For this prototype, we use a Lenovo laptop with a Intel WiFi 5300 card, collecting measurements with CSITool[11] and Ubuntu Linux 10.04. One computer runs a script that transmits in the 5.8-GHz band, via injection mode, data packets more than 10 times per second. The other laptop records the RSS on the nine channels (between three transmit antennas and three receive antennas) for each packet received.

Respiratory rate calculations

At each time, the most recent 30 seconds of RSS values recorded is converted into a breathing rate estimate. First, for each channel's RSS data, the average (DC) value is removed. Second, the power spectral density (PSD) function is computed for each channel for a range of frequencies that are considered to be possible breathing rates, for which we use 6.0 to 40.0 breaths per min (BPM). Next, the average of all nine PSD functions is computed. Finally, we take the frequency at the maximum of the average PSD to be the breathing rate estimate.

Although not implemented for this test, the sensor could also include an automatic motion detector and a "no breathing" detector. If the subject is moving, the RSS variance is very high, and the motion of their chest cannot be distinguished from their larger motions; however, algorithms can classify the RSS data as due to either breathing or larger motions.[9] Furthermore, if the PSD within the possible breathing rate range is too low, the algorithm could decide that breathing is not present and raise an alarm.[8]

Respiratory rate measurements in rate-controlled healthy subjects

Initial feasibility studies were conducted using our RF-based respiratory sensor on healthy volunteers in a nonclinical setting. Subjects were instructed to breathe at a prescribed fixed respiratory rate of 14, 16, 18, or 20 BPM. An application in LabVIEW provides visual cues to a subject to inhale and exhale

at a specified rate, for a minimum of 2 min, whereas data were collected using our RF-based respiratory sensor. The experimentally estimated breathing rate was compared to the rate at which the subject was prescribed to breathe to determine measurement accuracy of the experimental data.

Clinical pilot study

A pilot clinical trial was conducted under institutional review board approval to study the RF-based respiratory sensor on ventilator-dependent intensive care unit (ICU) patients in the immediate postoperative period after open heart surgery. Informed consent to participate in the trial was obtained from each participant before surgery. Initial enrollment of ten subjects was chosen and approved by our institutional review board for this pilot trial to allow for feasibility testing. All subjects underwent a previously planned open heart surgical procedure with full-length median sternotomy on the day of the study. All patients received standard preoperative and postoperative care unaltered by our study, including the use of a full-body thermal air warmer and cotton blankets on arrival to the ICU. Patients entered the ICU directly from the operating room in the full supine position under the care of the cardiac anesthesia team. All participates were sedated, intubated, and mechanically ventilated on arrival to the ICU. Before patient entry into the ICU, the two-laptop RF-based respiratory sensor was placed in the patient's room with laptops placed on opposite sides of the bed approximately 10 feet apart. One transceiver was placed in a cabinet located in the patient's bedside table (6 inches above ground level), and the other was placed on top of the wardrobe located on the opposite side of the bed (at a height of approximately 6 feet from ground level and 6 feet from the bed). These locations were chosen for convenience to keep the devices out of the way and minimally visible to the patient and medical staff. In general, as long as we place the devices on opposite sides of the bed (patient), the relative height of the sensors has minimal effect.[8,9] Continuous ventilator capnographic RR data and RF-system RR data were acquired simultaneously in a blinded fashion and averaged over 10 min. In postprocessing, the experimenter identifies periods of time during which no other person was present in the room with the patient. For these periods, the experimental BPM estimate was compared to the control data (the ventilator capnograph value) to determine measurement accuracy of the experimental data. Manual RR counting was not conducted to avoid multiperson movement artifact during this initial study.

Results

Respiratory rate measurements in rate-controlled healthy subjects

Initial feasibility studies were conducted on ten healthy volunteers. Subjects were instructed to use the LabVIEW application for a minimum of two full minutes without interruption. The application display provided graphical instruction for initiation and dwell time for inspiration and expiration allowing for a fixed RR. Control application data

from ten subjects breathing at a fixed RR (i.e., two subjects at 14 BPM, two subjects at 16 BPM, three subjects at 18 BPM, and three subjects at 20 BPM). Data from this trial demonstrated an average 95.5% overall measurement accuracy between the patient's actual rate and that measured with the RF technology. The RF-technology measurements also demonstrated a high precision when compared to LabVIEW-based controls with 100% of measurements noted to be within a 2 BPM variance (Table 1).

Clinical trial

We enrolled a total of 10 patients, six men and four women, in the study, each of whom were previously scheduled for elective open-heart surgery. On entry into the ICU in the immediate postoperative period, ventilator capnographic respiratory rates were collected and averaged for at least 10 minutes by the clinical intensive care team and blinded from the RF research team until data analysis. Experimental RF data were collected simultaneous to the ventilator data. A complete data set was collected on all patients entered into the study. Data from this trial demonstrated an average 88.9% overall measurement accuracy between patients' ventilator capnography rates and that measured by the RF-based respiratory sensor. The measurements showed reasonably high precision in the clinical setting when compared to controls with 90% of measurements noted to be within a ±2.5 BPM compared with the control rate (Table 2).

Discussion and conclusions

Respiratory insufficiency is a leading cause of inpatient morbidity and mortality in U.S. acute care hospitals. Respiratory rate monitoring of at-risk patients is used in this setting as a mean to detect patients with early signs of impending respiratory compromise, typically manifest by bradypnea or tachypnea. Current methodologies used to measure RR in the acute care setting include intermittent manual measurements, thoracic impedance pneumography using ECG leads,

Table 1 — RF-acquired data from fixed respiratory rate control trial.

Patient	GUI rate (BPM)	RF system rate (BPM)	Percent accuracy (%)
1	14	13.7	97.8
2	14	13.5	96.4
3	16	15.6	97.5
4	16	15.2	95.0
5	18	17.2	95.5
6	18	16.4	91.1
7	18	17.4	96.6
8	20	19.1	95.5
9	20	18.6	93.0
10	20	19.3	96.5
		Avg. accuracy	95.5

Table 2 – RF-acquired data from clinical ICU trial.			
Patient	Hospital rate (BPM)	RF system rate (BPM)	Percent accuracy (%)
1	28.0	25.6	91.4
2	15.6	15.4	98.7
3	18.8	17.0	90.4
4	18.0	13.3	73.8
5	14.8	13.0	87.8
6	13.9	13.1	94.2
7	21.6	20.1	93.1
8	12.0	14.1	85.1
9	22.0	18.4	83.6
10	19.0	17.2	90.5
		Avg. accuracy	88.9

and continuous nasopharyngeal tube capnography. Each of these methods suffers from biased data acquisition. Intermittent manual measurements are labor intensive, do not capture concerning RR deviations between scheduled measurements, suffer from poor accuracy, and are often not recorded or conducted. Technology-based solutions have been created as a means to reduce manual measurement inefficiencies and allow for continuous monitoring. However, these technologies require continuous patient-device contact, are poorly tolerated by patients, limit patient mobility, and demonstrate substantial movement-based data artifacts.

The results of this pilot study demonstrated the promising potential of the contact-free RF-based respiratory sensor developed in our laboratory. The outstanding results of our system on healthy subjects demonstrated over 95% accuracy of the system when compared to our LabVIEW-instructed control rates. We recognize that the LabVIEW-instructed rates were conducted in an idealized setting and thus had the potential to induce exaggerated chest wall movement during each phase of respiration to both observer effect and LabVIEW-instructed phase dwell. However, the accuracy of the technology in this setting exceeded our initial expectation and directed our decision to conduct a pilot clinical trial. Additional studies will need to be conducted to determine the measurement accuracy of the device at higher respiratory rates and small tidal volumes accompanied by reduced chest wall excursion. We plan to address this concern in a future study on intubated infants in our neonatal intensive care unit.

We chose to study the accuracy of the RF-based technology in a clinical setting where the gold standard ventilator capnography respiratory rate data could be continuously collected over a minimum 10-min interval. We chose to conduct the trial on patients in the immediate postoperative period after undergoing a median sternotomy. This population was chosen because they routinely arrive to our cardiothoracic ICU sedated and mechanically intubated. Patients typically remain intubated for at least 1 h after arrival, allowing us the necessary time to conduct simultaneous measurements. The data from our trial demonstrated

reasonably high accuracy of the contact-free RF-based system to continuous patient respiratory rates with an overall accuracy of 89% when compared to ventilator-acquired capnography data. Although the averaged RF-acquired data from one patient showed a 5-BPM variance from the ventilator data, the RF-acquired data from the remaining 90% of subjects studied correlated with ventilator-acquired measurements within a variance of 2.5 BPM. Unlike RF-acquired RR data from the LabVIEW-instructed healthy volunteers, these patients' chest wall respiratory movements were captured in the supine position while obscured by a median sternotomy surgical dressing, chest tubes, layers of cotton blankets and an inflated full-body thermal air blanket. In this experiment, we saw the signal being affected (and thus breathing rate could not be measured) when other people were in the room. However, we used omnidirectional antennas in this experiment. Other tests show that directional antennas could be used provide robustness to the motion of nearby people.[9]

Once the technology has been optimized to meet clinical performance requirements, we believe we can improve the technology's accuracy in the clinical setting. Furthermore, we believe RF-based measuring systems will provide a significant improvement in data availability and reliability, as measurements are not dependent on physical contact with the patient. Additionally, we believe RF-based measuring systems will be better tolerated by patients, as it is noninvasive and will not limit patient movement and mobility.

We note there are radar-based respiration sensors proposed for breathing rate measurement.[12] In comparison, our WiFi-based sensors will be lower in cost because of the quantities in which WiFi devices are produced. Furthermore, WiFi has the advantage of many years of evidence of its compatibility for use alongside medical equipment.[13]

In conclusion, our initial clinical pilot trial with a contact-free RF-based respiratory sensor developed in our laboratory has demonstrated a high degree of respiratory rate measurement accuracy when compared to capnographic data. Based on these data, we believe that RF-based systems present a promising noninvasive, contact-free, inexpensive, and accurate tool for continuous respiratory rate monitoring.

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Disclosure

The authors reported no conflicts of interest.

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