2019 ACMT Annual Scientific Meeting
MedTox Shark Tank Research Forum

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Title: Contactless respiratory rate monitoring

Significance and Innovation

Respiratory rate abnormalities are among the first indicators of severe pathology in medication overdoses such as from opioids and salicylates. Despite this critical importance, respiratory rate is inconsistently documented in hospitalized patients, earning recognition as the neglected vital sign. The most common techniques for respiratory rate measurement include manual respiratory rate counting and transthoracic impedance plethysmography (which measures chest wall movement through cardiac telemetry electrodes); both techniques are suboptimal. Manual counting is time consuming and not continuous, making detection of subtle changes difficult. Transthoracic impedance plethysmography is susceptible to erroneous measurements, as patient movements can lead to significant interference. Improving accuracy of respiratory monitoring will increase early detection of significant changes in clinical status, such as bradypnea in opioid overdose, and prevent adverse outcomes.

To enable a more simplified and accurate method of respiratory rate monitoring, researchers at UMass Amherst have developed the P440 Radar Module, an Ultra-Wideband (UWB) radio transceiver capable of detecting subtle movements in subjects such as chest wall rise. An electromagnetic wave is sent with a transmitter antenna, and the reflections are caught by the receiver antenna. The device uses two-way time of flight ranging to measure the distance between the radar and a target. In addition, this radar is a coherent radio transceiver which allows the energy in each transmitted pulse to be summed, improving the signal to noise ratio (SNR) of received transmissions. This module has demonstrated high accuracy in laboratory testing, is less than 2 cm in size, and can perform scanning at rates up to 125 Hz and at distances up to 30 meters. This module operates at approximately 50 mW; this is considered a very low power transmission. For comparison, a standard incandescent lightbulb operates at 60W. Because of its extreme accuracy in detecting small movements, this radar module can be used in various domains including measuring the respiratory rate of patients and differentiating between individuals. Researchers have successfully used the P440 Module to accurately measure respiratory rates in laboratory test scenarios, but have yet to study the device in clinical settings.

Aims:

The overarching goal of this study is to prevent morbidity and mortality associated with medication overdose by early detection of changes in respiratory rate, specifically periods of bradypnea. In order to accomplish our goals, we will:

1. Validate the device by comparing the P440 Radar Module against telemetry respiratory rate monitoring and standard manual respiratory rate counting. We hypothesize that the contactless device will accurately detect respiratory rate.
2. Compare metrics among subgroups based on age, gender and comorbidities to assess the device's performance in various clinical scenarios. We hypothesize the P440 Radar Module will be able to provide real-time continuous respiratory rate monitoring capable of detecting a difference as small as 2 breaths/minute.
3. Explore various machine learning techniques to predict error rates in various subgroups.

Research Approach (Methods) and Timeline

The University of Massachusetts Memorial Medical Center (UMMMC) is a tertiary care medical center and level 1 trauma center. The emergency department (ED) is spread across two campuses and treats approximately 135,000 patients per year. With the significant volume of high-acuity patients, there are a large number of patients in the ED that are being monitored at any given time. We will initially be recruiting 52 participants. Our sample size is calculated to detect a mean difference of 2 breaths per minute with a maximum allowable difference of 5 breaths per minute on a Bland Altman plot at an alpha level of 0.05 and 80% power. We will include patients in the UMMMC University or Memorial campus ED who are greater than or equal to 18 years old, are being monitored by cardiac telemetry for respiratory rate, and are able to provide informed consent. Patients will be excluded from participation if they are pregnant women or prisoners.

The first aim of the study will be to validate the P440 Radar Module. Once the participant has provided consent, basic demographic information (including age, gender, past medical history, presenting complaint, admitting diagnosis) will be recorded. Two radar modules will be placed in the room with the participant for two hours, during which time respiratory rates will also be collected from cardiac monitors and by manual counting by two study staff at 15-minute intervals. Since movement of the participant is known to interfere with accurate respiratory monitoring, the study will also monitor and quantify participant movement through a commercially available, noninvasive biosensor with accelerometer (E4, Empatica, Milan, Italy), which will also be placed on the participant's nondominant wrist at the beginning of the 2-hour time frame.

For the analysis, we will first compare respiratory rate measured by the P440 with the respiratory rate from standard cardiac telemetry monitoring using the Bland-Altman plot method. This approach uses the means and differences between the pairs of readings to

calculate the upper and lower limits of agreement. We will subsequently calculate correlation coefficients for two methods of measurement. We will then repeat this procedure for P440 respiratory rate vs respiratory rate measures obtained by manual counting. As an exploratory aim, we will also compare metrics among subgroups based on age, gender and comorbidities to assess device performance in various clinical scenarios. Finally, we will explore supervised and unsupervised machine learning techniques in addition to methods such as attention and encoder-decoder models to predict error rates in different subgroups. We anticipate that data collection will take 12 months and primary data analysis will be complete by December 2020.

The P440 Respiratory Module could facilitate detection of subtle changes in clinical status. Future studies will be aimed at detecting changes in respiratory rates associated with therapeutic and adverse medication events. These studies will focus on patients at-risk for medication overdose, such as those with opioid use who are being monitored following an overdose or patients who are prescribed high-dose opioids for pain control. The ultimate goal is to deploy the machine both inside and outside of hospital settings to help signal clinically concerning respiratory rate changes, such as bradypnea and periodic apnea, during opioid use.

Major Limitations/Questions

The first stage of the study is to acquire pilot data to validate the device for detection of respiratory rate. Once validated, future studies will focus on specific interventions and uses such as improving detection of apnea associated with opioids. As this is a directly observational study, there is no ability to blind the study staff from the telemetry monitor which may contribute to bias for manual respiratory counting. However, study staff will not have access to the device data during the time of collection of manual counting and telemetry monitor recording.