**Study protocol**

***Evaluation of the Welch Allyn® Connex® Spot Monitor in measuring respiratory rate in the emergency department: an observational study protocol***

**Location of the study**

Department of Emergency Medicine, Semmelweis University, 1082 Budapest, Üllői út 78/A.

**Objective of the study**

The study aims to evaluate the level of agreement between respiratory rate (RR) measurements obtained using an automated RR monitor and those obtained through manual counting. Moreover, the study aims to determine whether the evaluated automated RR monitor can be reliably used as an alternative to manual counting.

**Background**

RR monitoring is essential as it is often the first vital sign to change when a patient deteriorates.1 RR has been shown to be a predictor of adverse events, including intensive care unit admission, cardiopulmonary arrest, and in-hospital mortality.2-4 Therefore, it is often a component of risk prediction scores.5,6 Despite its clinical relevance, it is often neglected or measured inaccurately, leading to misclassification of disease severity.7,8

In the emergency department (ED), patient care pathways and workflow are primarily driven by triage. Triage involves assessing various factors to prioritize patients, including vital signs (e.g. RR).9

While most vital signs are measured objectively using automated technology (e.g. pulse rate, blood pressure, body temperature), RR is usually obtained by manual spot measurements: breaths are visually counted (usually by the nursing staff) for 1 minute or shorter. Sometimes by spot estimates only. These measurement methods are easily prone to errors and depend highly on the observer.10,11 In a study, trained observers recorded significantly different RR values than nurses in routine observation, highlighting that RR assessment is often inaccurate in clinical practice.12

To overcome the limitations of manual counting in clinical practice, wearable devices have been developed and are commercially available.13 One of the wearable sensors, the Welch Allyn® Connex® Spot Monitor equipped with a Masimo SpO2 finger sensor, has not yet been tested in the clinical environment for accurate measurement of RR.

**Aims**

The primary aims are to

* assess the accuracy of the Welch Allyn® Connex® Spot Monitor in RR measurement in comparison with manual spot measurement performed by the nursing staff;
* assess the accuracy of the Welch Allyn® Connex® Spot Monitor in RR measurement in comparison with manual spot measurement performed by trained observers.

The primary objective is to assess the agreement of the Welch Allyn® Connex® Spot Monitor with manual counting methods performed by different observers. A secondary objective is to investigate whether the presence of cardiac arrhythmias affects the accuracy of respiratory rate measurement.

**Patient selection**

**Recruitment**

Patients admitted to the Department of Emergency Medicine, Semmelweis University, will be consecutively recruited to the study.

**Inclusion criteria**

* male or female patients aged ≥18 years.

**Exclusion criteria**

* mechanically intubated patients;
* patients receiving non-invasive respiratory support;
* patients with disorders causing involuntary movements;
* skin or digit abnormalities preventing proper application of the pulse oximeter;
* clinically unstable patients on arrival (requiring immediate transfer to the resuscitation area);
* intravascular dyes (e.g. indocyanine green or methylene blue).

**Suspension of patient participation in the study**

The investigator determines that continued participation would, for any reason, be disadvantageous to the patient.

**Study Design**

A single-center, prospective, observational study will be conducted. During triage, RR will be measured by the nursing staff and documented in the patient’s medical record. Patients not requiring immediate transfer to the resuscitation area are transported to the waiting room or an examination room, where study measurements will be performed. If there are no exclusion criteria, two observers will perform the measurements. The Welch Allyn® Connex® Spot Monitor, equipped with a Masimo SpO₂ finger sensor, will be placed on the opposite hand from the blood pressure cuff. Observer A will manually count each complete breath cycle (from the start of inspiration to the end of expiration) over a 60-second period, using a hand placed on the patient’s torso. At the same time, Observer B will record the monitor’s RR values every 15 seconds during the same 60-second interval. The 60-second interval will begin after the monitor displays the first RR value. Observer B will start a stopwatch and signal Observer A to begin manual counting. At the end of the 60 seconds, Observer B will instruct Observer A to stop counting. Observer A will be blinded to the RR values displayed on the monitor. All RR measurements from the three methods will be recorded for later analysis. The RR of all patients included in the study will be measured once.

The measurements and data recording happen at the site of the study. The following data will be collected:

* demographics (age, sex);
* patient identification number (case number);
* vital signs assessed by the triage nurse (RR, blood pressure, oxygen saturation, heart rate);
* RR measured by manual counting;
* RR measured by the Welch Allyn® Connex® Spot Monitor, equipped with a Masimo SpO₂ finger sensor;
* presence of cardiac arrhythmia (type of arrhythmia);
* presence of venous congestion;
* presence of externally applied coloring (e.g. nail polish, acrylic nails, glitter).

**Phases of the study**

1. Planning phase January 10, 2025 – April 30, 2025
2. Data collection/Study phase May 15, 2025 – June 01, 2025
3. Data analysis May 15, 2025 – August 31, 2025

**Study interval**

Measurements and data collection are planned to take place between May 15, 2025, and June 01, 2025. Data analysis and processing will be carried out in parallel with data collection from May 15, 2025, to August 31, 2025. The finalization of data gathering and the preparation of the publication are expected to be completed by October 31, 2025.

**Data collection and statistical analysis**

All study data will be collected and managed using the REDCap electronic data capture tool hosted at Semmelweis University. A total of 400 patients will be recruited into the study.

The study’s primary endpoint is the RR, assessed by multiple measurement methods. The primary objective is to evaluate the agreement between the automated respiratory rate monitoring device and other RR measurement methods. Agreement between each pair of measurement methods will be assessed by calculating the mean difference along with 95% confidence intervals. The distribution of differences between methods will be visually examined using Bland-Altman plots.

A pre-specified subgroup analysis will be conducted in patients presenting with cardiac arrhythmia to assess the impact of arrhythmic conditions on the agreement between measurement methods.

**Device used in this study**

Welch Allyn® Connex® Spot Monitor equipped with a Masimo SpO2 finger sensor

**Ethical Considerations**

This study will not be initiated before the protocol has received approval from the Semmelweis University Regional and Institutional Committee of Science and Research Ethics​.

**Funding of the study**

This research will be conducted without any financial support.

**References**

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