Validation of Inter-Rater and Intra-Rater Reliability of Remote Dielectric Sensing Measurement

Masakazu Hori,1,* MD, Teruhiko Imamura,1,* MD, Atsuko Fukuo,1 MD, Takuya Fukui,1 MD, Takatoshi Koi,1 MD, Yohei Ueno,1 MD, Hiroshi Onoda,1 MD, Shuhei Tanaka,1 MD, Ryuichi Ushijima,1 MD, Mitsuou Sobajima,1 MD, Nobuyuki Fukuda,1 MD, Hiroshi Ueno,1 MD and Koichiro Kinugawa,1 MD

Summary
Remote dielectric sensing (ReDS) is a recently introduced non-invasive electromagnetic-based device used to quantify lung fluid levels. Nevertheless, its inter-rater and intra-rater reliability remain uncertain. In 10 healthy volunteers, ReDS values were measured three times successively by the officially trained expert examiner to validate intra-rater reliability. Similar measures were performed by a total of three examiners to validate inter-rater reliability. Intra-class correlation (ICC) was applied to validate each reliability. Ten healthy volunteers [median 34 (32, 40) years old, 10 men, body mass index 23.0 (21.2, 23.9)] were included. Median ReDS value was 28% (25%, 31%). For the intra-rater reliability, ICC (1, 1) and ICC (1, 3) were 0.966 and 0.988, respectively (P < 0.001). For the inter-rater reliability, ICC (2, 1) and ICC (2, 3) were 0.683 and 0.866, respectively (P < 0.001). Given almost perfect intra-rater reliability, an examiner does not need to repeat ReDS measurement. Given substantial inter-rater reliability, ReDS measurements had better be measured by multiple examiners if possible.

Key words: Congestion, Heart failure, Hemodynamics

Now is an era of heart failure pandemic. The number of heart failures is increasing and the severity of heart failure is progressing despite guideline-directed medication.1 Neurohormonal blockers including beta-blockers and renin-angiotensin-aldosterone system inhibitors are keys to improving mortality and morbidity for such a cohort. Additionally, management of systemic/pulmonary congestion using an adequate dose of diuretics is essential to ameliorate congestive symptoms and improve clinical outcomes.2 Nonetheless, one of the challenges is a lack of gold standard to accurately assess the degree of congestion.

Recently, remote dielectric sensing (ReDS™, Sensible Medical Innovations Ltd., Netanya, Israel) system, which is a non-invasive electromagnetic-based technology to quantify the lung fluid level, has been introduced and clinically available abroad.3 Several studies observed a strong correlation between ReDS value and lung fluid levels.4,5 Others demonstrated the clinical advantage of ReDS-guided heart failure management.6,7 However, given a few clinical pieces of evidence, the reliability of values measured using the ReDS system remains underdemonstrated. Our institute initiated to use the device before commercial marketing in Japan. In this study, we validated the inter-rater and intra-rater reliability of the ReDS system in healthy volunteers.

Methods

Participant selection: Healthy volunteers aged over 20 years old without any past medical histories, who agreed to the participation and signed informed consents, were prospectively included in this single-center study between September and October 2021. The institutional ethical review board approved the use of this device.

ReDS system: ReDS technology was detailed previously.8 Briefly, ReDS estimates the percentage of fluid level in the lung as a surrogate of pulmonary congestion. ReDS applies low-power electromagnetic signals emitted between two sensors (one each on the anterior and posterior body surfaces) embedded in a wearable device (Figure 1 A, B). The analyzed signal reflects the dielectric properties of the portion of the lung between the sensors. The dielectric coefficient of a material is represented by a frequency-dependent complex number describing its interaction with electromagnetic energy including the degrees of absorption, reflection, and transmission of the energy. Since water has a very high dielectric coefficient and air has a very low dielectric constant, the dielectric coefficient of tissue is determined predominantly by its fluid

From the 1Second Department of Medicine, University of Toyama, Toyama, Japan.
*These authors contributed equally to this work.
Address for correspondence: Teruhiko Imamura, MD, Second Department of Medicine, University of Toyama, 2630 Sugitani, Toyama, Toyama 930-0194, Japan. E-mail: teimamu@med.u-toyama.ac.jp
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Figure 1. ReDS system comprising a monitor and a sensor (A) and a representative of actual measurement (B).

Figure 2. Shema of ReDS measurements in this study. ReDS values were measured three times successively in a volunteer (A) by an examiner (a). Examiner (b) and examiner (c) also measured ReDS values in the same manner. A volunteer (A) eventually received a total of nine-time ReDS measurements. Similar measurements were performed for the other nine volunteers.

The measurement takes 45 seconds. The overall procedure to complete the ReDS measurement takes up to five minutes. We can obtain ReDS value just by imputing patient information and pushing the start button. The manufacture-proposed normal range for the ReDS value is between 20% and 35%.

Study protocol: All ReDS measurements were performed by the formally trained expert examiners in a single center using a single ReDS device. This is the only one device that can be used clinically in Japan. In the early morning, volunteers were made to sit for 5 minutes at rest and ReDS values were measured as detailed above. A total of three examiners and 10 volunteers participated.

A volunteer [volunteer (A)] received ReDS measurements three times successively by the same examiner [examiner (a)] for the test of intra-rater reliability (Figure 2). In the same manner, other examiners [examiner (b) and examiner (c)] also measured ReDS in a volunteer A for the test of inter-rater reliability. Similar measurements were performed for other volunteers [volunteer (B), volunteer (C)—volunteer (J)].

Statistical methods: Statistics were performed using SPSS Statistics 23.0 software (IBM Corp, Armonk, NY, USA) and two-sided P values < 0.05 were considered significant. Continuous variables were presented as median (25% interquartile, 75% interquartile). Categorical variables were presented as numbers (%). ReDS value comparison among three groups (i.e., three successive measurements and three examiners) were performed using the Friedman test. Intra-rater and inter-rater reliability were analyzed by intra-class correlation (ICC). ICC 0.41-0.60
RELIABILITY OF ReDS MEASUREMENT

Results

Baseline characteristics: Ten healthy volunteers participated in this study and received ReDS measurements from three examiners. Each examiner performed ReDS measurements three times successively. Consequently, each healthy volunteer received an ReDS measurement a total of nine times.

As median, age was 34 (32, 40) years, body mass index was 23.0 (21.2, 23.9), and all were men (Table). Median ReDS value was 28% (25%, 31%).

Intra-rater reliability: According to the protocol, all volunteers received successive three ReDS measurements without any complications. Median ReDS values at first, second, and third measurements were displayed in Figure 3 [28% (25%, 31%), 28 (25%, 31%), and 27% (25%, 31%), \( P = 0.19 \)]. ICC (1, 1), which indicated a reliability of one-time measurement, was 0.966 (95% confidence interval 0.952-0.976) (> 0.80: almost perfect, \( P < 0.001 \)). ICC (1, 3), which indicated a reliability of three-time measurement, was 0.988 (95% confidence interval 0.978-0.994) (> 0.80: almost perfect, \( P < 0.001 \)).

Inter-rater reliability: Also according to the protocol, all volunteers received ReDS measurements by three examiners. Median ReDS values measured by three examiners are displayed in Figure 4. ReDS values were 26% (25%, 30%), 29% (26%, 30%), and 24% (28%, 32%), respectively. ICC (2, 1), which indicated a reliability of measurement by one examiner, was 0.683 (95% confidence interval 0.664-0.697) (> 0.60: substantial, \( P < 0.0001 \)). ICC (2, 3), which indicated a reliability of measurements by three examiners, was 0.866 (95% confidence interval 0.851-0.877) (> 0.80: almost perfect, \( P < 0.001 \)). A minimally required examiners’ number to achieve almost perfect reliability (> 0.80) was calculated as 1.857 (i.e., two times is sufficient).

Discussion

We validated intra-rater and inter-rater reliability of ReDS measurement in a healthy cohort. Three examiners and 10 volunteers participated. Intra-rater reliability was almost perfect. Inter-rater reliability was substantial.

ReDS system: ReDS is a recently introduced system that quantifies lung fluid volume non-invasively and easily.3) In patients with and without heart failure, ReDS was demonstrated to be non-inferior to the computed tomography-incorporated lung fluid volume estimation.4) ReDS value had also a moderate correlation with pulmonary capillary wedge pressure.5) ReDS-guided management, during which medications including diuretics were intensified when ReDS value was high, improved clinical outcomes in patients with congestive heart failure.6,7) However, intra-rater and inter-rater reliability of this system remain undemonstrated thus far.

Reliability of ReDS measurements: We investigated for the first time the reliability of ReDS measurements. Given the almost perfect reliability of a single measurement, which was comparable to the three-time measurement (0.966 versus 0.988), we may not necessarily have to repeat measurements. In other words, a single measurement

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Table. Baseline Characteristics

| n = 10                                      |
|--------------------------------------------|
| Age, years 34 (32, 40)                     |
| Men 10 (100%)                              |
| Body height, cm 175 (172, 180)             |
| Body weight, kg 69 (68, 75)                |
| Body mass index 23.0 (21.2, 23.9)          |
| ReDS value, % 28 (25, 31)                  |

ReDS indicates remote dielectric sensing.

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was assumed to be moderate, 0.61-0.80 to be substantial, and 0.81-1.00 to be almost perfect. For the calculation of appropriate examiners’ numbers to achieve almost perfect reliability, the following Spearman-Brown’s formula was used: \( \kappa = 0.8 \times [1 - \text{ICC}(2, 1)] / [\text{ICC}(2, 1) \times (1 - 0.8)], \) in which \( \kappa \) meant minimally required examiners’ number.
would be sufficient for the reliable ReDS measurement. By contrast, a reliability of a single examiner was substantial. Theoretically, two examiners are required to achieve almost perfect reliability. Given that median ReDS values were 29% in an examiner (b) and 24% in an examiner (c), approximately 5% of the ReDS value might fluctuate in each examiner. However, the clinical implication of such a fluctuation remains uncertain.

As with other tests and examinations, the same examiner had better follow the ReDS value in a person. If several examiners engage in the measurements, ReDS values had better be measured by at least two examiners concomitantly and averaged to maintain the reliability. It is uncertain why the inter-rater reliability was not perfect. There are several tips to appropriately measure ReDS value. For example, the device censors should be correctly fixed during the measurement. Further studies are warranted to establish an appropriate educational strategy to spread correct measurement.

**Study limitations:** This is a proof-of-concept preliminary study, and we should state several limitations, which should be approached in the next studies. Given the lack of a gold standard to quantify lung fluid levels, only a few studies validated the accuracy of ReDS measurement. As shown, the body size included in this study was relatively homogeneous. There were no participants who were obese/skinny and had comorbidities and medications. All participants were men aged between 20 and 50 years. All ReDS values were within the normal range between 20% and 35%. The applicability of our findings to those with other unique categories requires further investigations. As a next step, we will conduct another study that validates our findings among those with comorbidities such as heart failure and renal impairment.

All examiners were formally trained by the manufacturer’s educational team. Given our findings, ReDS values measured by the untrained examiners might not be reliable. In this study, we used only one device. Inter-device reliability remains uninvestigated.

**Conclusion**

Given almost perfect intra-rater reliability, an examiner does not need to repeat ReDS measurement. Given substantial inter-rater reliability, ReDS measurements should better be measured by multiple examiners.

**Disclosure**

**Conflicts of interest:** TI receives grant support from JSPS KAKENHI: JP20K17143. Other authors have no conflicts of interest.

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