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ВОЗМОЖНОСТИ ИСПОЛЬЗОВАНИЯ СИСТЕМЫ REDS В КЛИНИЧЕСКОЙ ПРАКТИКЕ

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The Possibilities of Using the Reds System in Clinical Practice

Резюме

Представлен обзор литературы, в которой описывается уникальная мобильная неинвазивная система для измерения совокупного объёма жидкости в лёгких — ReDS, исследование её эффективности на животных, добровольцах, а также опыт применения в клинической практике. Проведён анализ отечественных и зарубежных литературных источников порталов PubMed, Web of Science, Nature, опубликованных в период 2012–2024 годов. Ежегодно во всём мире наблюдается тенденция к увеличению числа больных с хронической сердечной недостаточностью. Ключевой проблемой диагностического поиска остаётся раннее выявление декомпенсации хронической сердечной недостаточности. Одним из надёжных и ранних маркеров надвигающейся острой декомпенсации хронической сердечной недостаточности служит мониторинг показателя объёма жидкости в лёгких. Определение показателя объёма жидкости может служить критерием проведения коррекции проводимой терапии, что, в свою очередь, должно повлиять на частоту повторных госпитализаций. Таким образом, жизненно необходимым для дальнейшего ведения пациентов с острой декомпенсацией хронической сердечной недостаточности является контроль волемии, а также выявление и количественное определение степени застоя. Оценка объёма жидкости является ключевым фактором при ведении пациентов с хронической сердечной недостаточностью в стационарных и амбулаторных условиях. Мониторинг ReDS значительно снижает вероятность повторной госпитализации с хронической сердечной недостаточностью в течение 3 месяцев после выписки, по сравнению с пациентами, у которых не проводилось исследование на системе ReDS.

Ключевые слова: *ReDS, отёк лёгких, сердечная недостаточность, диагностика отёка лёгких*

Конфликт интересов

Авторы заявляют, что данная работа, её тема, предмет и содержание не затрагивают конкурирующих интересов

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Abstract

A review of the literature is presented, which describes a unique mobile non-invasive system for measuring the total volume of fluid in the lungs ReDS, a study of its effectiveness on animals and volunteers, as well as experience of use in clinical practice. An analysis of domestic and foreign literary sources of the portals PubMed, Web of Science, Nature, published in the period from 2012–2024, was carried out. Every year around the world there is a tendency to increase the number of patients with chronic heart failure. The key problem of the diagnostic search remains the early detection of decompensation of chronic heart failure. One of the reliable and early markers of impending acute decompensation of chronic heart failure is monitoring of the fluid volume in the lungs. Determining the fluid volume indicator can serve as a criterion for adjusting the therapy, which, in turn, should affect the frequency of re-hospitalizations. Thus, vital for the further management of patients with acute decompensation of chronic heart failure is the control of volume, as well as the identification and quantification of the degree of congestion. Fluid volume assessment is a key factor in the management of patients with chronic heart failure in inpatient and outpatient settings. ReDS monitoring significantly reduces the likelihood of readmission to hospital with chronic heart failure within 3 months compared with patients not tested on the ReDS system.

Key words: *ReDS, pulmonary edema, heart failure, diagnosis of pulmonary edema*

Conflict of interests

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ACCHF — acute decompensation of chronic heart failure, CHF — chronic heart failure

Introduction

There is a global annual trend towards increased number of patients with chronic heart failure (CHF). According to statistical data, in 2022 the incidence of CHF in the Russian Federation was 7.2 % [1]. CHF decompensation was a cause of admission to cardiology and medical wards in 4.9 % of all cases. In 82 % of cases, readmitted patients with CHF had decompensated pulmonary oedema [2].

Early identification of CHF decompensation is still the key diagnostic challenge. One of the reliable and early markers of imminent acute decompensation of chronic heart failure (ACCHF) is monitoring of the amount of pulmonary fluid. Measurement of the amount of fluid can be a criterion to adjust the therapy, which, in turn, should affect the frequency of hospital admissions [3].

Therefore, for the management of patients with ACCHF, it is essential to monitor the amount of fluid, as well as to detect and quantify the degree of congestion. Measurement of the amount of fluid is the key factor in the management of patients with CHF both in inpatient and outpatient settings [4].

Biophysical basis of ReDS technology

Modern non-invasive methods to evaluate the amount of pulmonary fluid include physical examination, chest X-ray and measurement of brain natriuretic peptide, type B, as well as chest CT [5].

In 2015, a non-invasive technology for the measurement of the cumulative pulmonary fluid ReDS™ (abbreviation of «remote dielectric sensing», i.e., a portable system for non-invasive measurement of the cumulative amount of pulmonary fluid) was registered in the USA, which can be an alternative to the above methods and can be used in inpatient settings, outpatient clinics, and also at home [6].

ReDS (Sensible Medical Innovations Ltd, Netanya, Israel) measures dielectric properties of tissues. This technology was developed by Israeli R&D specialists using the military technology «See through wall», which allows sensing biological objects through walls. The technology was presented to the public at the largest international ground and airborne defence and security exhibition Eurosatory only in 2022, but the first article describing the «See through wall» principle was published in 2005 [7].

A ReDS device comprises two sensors fixed to a vest, which the patient puts on for a 90-second measurement. The sensors are located on the chest (in front) and on the right side of the patient's body (on the back). The vest is connected to a monitor console with a cable. Each sensor is a small, round device, which can transmit and intercept energy reflected by the lung tissue or transmitted through it.

Non-invasive measurement of the fluid volume using ReDS is performed as follows: a sensor sends low-power electromagnetic signals to the body, and intercepted signals represent dielectric properties of tissues, impacted mostly by the fluid accumulated in them [8]. The dielectric factor of a material is a frequency-dependent complex value, which describes its interaction with electromagnetic energy, including the degree of energy absorption, reflection and retention. Various tissues have varying dielectric factors. Since water has a very high dielectric factor (about 80), dielectric factors of tissues depend mostly on the amount of fluid in them. For instance, healthy fat tissue with a low amount of fluid has a relative low dielectric factor, whereas healthy muscular tissue, which is relatively rich in fluid, has a higher dielectric factor. The dielectric factor of the lung tissue is impacted by dielectric factors of each of its components and their concentrations (e.g., blood, lung parenchyma, air and their relative concentrations). Since air has the lowest dielectric factor, and dielectric factors of other blood components are approximately equal and significantly higher than that of air, one can assume that the lung tissue comprises two types of high-contrast components. Therefore, air makes the dielectric factor of the lung tissue a very sensitive and direct indicator of the volume ratio of fluid and air, i.e. an indicator of fluid volume. High sensitivity of this parameter to a high concentration of a fluid is a physiological basis for assumed high accuracy of the device in detection of pulmonary oedema and its progression over time [9].

Scope of ReDS application

The use of a ReDS system makes it possible to measure an absolute amount of a fluid in the lungs. High levels of a fluid in the lungs indicate decompensated CHF.

A key marker of heart failure development and diagnosis is urine output. ReDS system was tested in volunteers; the objective of the clinical trial was to evaluate the capability of ReDS system parameters to correlate both with the clinical course of ACCHF, manifesting as pulmonary congestion, and with changes in the fluid status. According to ReDS system, the levels of fluid in the lungs of patients with ACCHF strongly correlated with the urine output values. During hospitalisation, ReDS parameters demonstrated positive dynamics and corresponded to clinical improvements; when baseline ReDS values and discharge values were compared, significant improvements were noted [10].

Relative diagnostic value of ReDS system

The important task with the use of ReDS system is to compare its values with other methods measuring fluid levels in the lungs, as well as to correlate it with other methods of CHF diagnosis in general.

At the moment, the gold standard to measure fluid in the lungs is computer tomography. A study of the correlation between ReDS and CT values was conducted by a number of foreign and Russian scientists.

In 2013, a scientific article was published on an assessment of ReDS efficiency in animals and healthy volunteers. The study compared CT data with ReDS values. Results obtained with ReDS system demonstrated high sensitivity to changes in lung fluid content. A comparative analysis of ReDS values and CT data in the porcine heart failure model showed that ReDS technology is accurate in detecting changes in lung fluid concentrations, evidenced by high ICC values (intraclass correlation coefficient) and Pearson correlation of 0.95 [9].

In 2016, the International Journal of Cardiology published an article describing validation of ReDS technology for quantitative evaluation of pulmonary fluid, by comparing high-resolution chest CT scans of patients with and without acute heart failure. This study demonstrated that quantitative measurement of fluid using ReDS closely correlates with CT data in measurement of the amount of pulmonary fluid [11].

Another study comparing correlation between ReDS data and CT data demonstrated that ReDS accuracy is comparable to CT results; the level of correlation is 94 %. These data confirm potential replacement of CT with ReDS in the measurement of the absolute amount of pulmonary fluid [12].

As for other methods of CHF diagnosis, e.g., Swan-Ganz catheter, a study was published, the results of which allowed scientists to conclude that in some cases ReDS diagnostics can be used as a non-invasive alternative to Swan-Ganz catheter, since there is a correlation between ReDS values and pulmonary capillaries wedge pressure. Normal ReDS values have high prognostic value (95 %), demonstrating that the pulmonary capillaries wedge pressure is less than 18 mm Hg [13, 14].

After analysing the results and conclusions in scientific publications on this topic, we can conclude that ReDS data are accurate if compared to chest CT, which is confirmed with high coefficients of concordance.

ReDS as an indicator of ACCHF risk

ACCHF in patients with a history of CFH imminently leads to repeated hospitalisations, a high risk of complications and negatively impacts the clinical course of CHF. There is a study to evaluate the use of ReDS values as criteria of eligibility for discharge, judging by the total amount of fluid in the lungs of patients, who are clinically ready for discharge.

The ReDS study results showed premature discharge in 32 % of cases, because these patients still had higher than normal amount of fluid in their lungs. The use of ReDS as a criterion of an optimal therapy result allows preventing discharge of patients with higher than normal amount of fluid in their lungs, thus reducing the re-admission rates [4, 15, 16].

In 2012, Dan Rappaport published the first clinical study of ReDS system in healthy volunteers. ReDS values were evaluated in inpatient settings, as well as in outpatient clinics after discharge from the hospital for three months. According to ReDS, during hospitalisation, patients had lower concentrations of fluid in their lungs (by 18 ± 8 %), indicating lungs "drying". Lower ReDS values correlated with clinical manifestations (Pearson correlation = 0.85). In outpatient settings, the study of ReDS values showed clinical stability in 67 % of cases with CHF therapy. These patients had minimal changes in the values of fluid concentrations in the lungs (ReDS (2.5 ± 4)), evidenced by no need in re-admissions. In 33 % of cases, patients were re-hospitalised with pulmonary oedema 28 ± 12 days later. Changes in ReDS values demonstrated an increase in the total amount of fluid in the lungs (17 ± 7) vs. values upon discharge. Worse results in patients demonstrated by ReDS preceded re-admission 22 ± 5 days later. Based on the study results, the authors concluded that quantitative evaluation of the amount of pulmonary fluid using ReDS can be useful in the monitoring of pulmonary congestions both in inpatient settings and outpatient clinics. This fact makes it possible to use ReDS data for identifying the changes in CHF and possible development ACCHF [17].

A metaanalysis of the data of 985 patients from seven studies showed a low risk of re-admissions in patients with heart failure, who were monitored for ReDS values, as compared to patients who did not have their ReDS values evaluated [18-20].

High sensitivity of ReDS system ensures identification of pulmonary congestions prior to significant clinical (symptomatic) aggravation of CHF, thus making it possible to use ReDS as a risk indicator of ACCHF.

ReDS in the management of patients with CHF

Taking into account high correlation between ReDS values and CT findings, as well as urine output and brain natriuretic peptide values, the authors of several studies suggest that ReDS values could help in defining the management strategy in hospital settings. Changes in ReDS values correspond to the clinical course, improvement of the patient condition during hospitalisation, because pre-discharge values improve significantly vs. ReDS values upon admission, it being also confirmed with changes in brain natriuretic peptide levels. The use of ReDS allows evaluating data within a broad range of fluid levels, including the applicable clinical range [11, 21].

Also, researches insist on continued outpatient monitoring of ReDS values in patients after discharge for timely therapy adjustments [9].

In 2017, the International Journal of Cardiology published an article titled "Evaluation of remote dielectric sensing (ReDS) technology-guided therapy for decreasing heart failure re-hospitalizations". The article described a study to decrease the number of re-hospitalisations in patients with CHF and development of ACCHF, using ReDS monitoring at home [22, 23].

In 2012–2015, a study was conducted, which allowed concluding that the non-invasive ReDS technology makes it possible to alert on early detection of decompensated CHF with a relative low burden for patients. Maintaining healthy levels of pulmonary fluid after therapy adjustments using ReDS values results in decreased brain natriuretic peptide levels and lower rates of hospitalisations [24].

It has been noted that ReDS-guided therapy of CHF during the 30-day follow-up period of patients after hospitalisation for ACCHF can result in a lower (by 54 %) risk of re-hospitalisations, including cardiac causes — by 78 % [25].

A retrospective analysis of 112 medical records of patients with ACCHF demonstrated that ReDS value monitoring and therapy adjustments reduced hospitalisation duration in patients admitted with CHF and extended doctor's possibilities to adjust the therapy [26].

ReDS system was used in 2020, during the COVID-19 pandemic, in the pulmonology ward in Ospedali Riuniti Hospital in Ancona, Italy. ReDS measurements were performed at bedside. Evaluation of changes in ReDS values allowed assessing the therapy efficacy [27].

The study results confirm the potential clinical usefulness of ReDS monitoring of patients with CHF. Monitoring ReDS values and maintaining the normal total amount of pulmonary fluid result in decrease in brain natriuretic peptide levels and reduced number of re-hospitalisations. Thus, the ReDS technology is a useful tool for remote outpatient management of patients at risk of re-hospitalisation for CHF.

Advantages and drawbacks of ReDS

The distinctive features of the ReDS system are high sensitivity and rapid measurement of parameters within seconds after a minor change in pulmonary congestion, resulting from manipulations in studies simulating ACCHF [9].

Besides, the ReDS system is superior to computer tomography: rapid monitoring of changes, compact design of the device, rapid measurements, possibility of frequent measurements and diagnostics of even tiny changes in pulmonary congestion, and absence of radiation exposure. All these factors make it possible to replace CT with ReDS examinations in order to measure the absolute amount of pulmonary fluid. Since the device is portable, it can be used at home to monitor condition and possible therapy adjustments.

Also, the device is useful as ReDS can be used as an alternative to Swan-Ganz catheter, i.e., it is a potential non-invasive tool to evaluate the right and left cardiac ventricle function, monitor efficacy of the therapy of myocardial infarction, cardiogenic shock, pulmonary oedema, volume depletion and hypertension monitoring, various cardiac arrhythmias. The ReDS technology is highly sensitive and specific for the identification of abnormally high pulmonary capillaries wedge pressure and ensures timely adjustment of drug therapies [14].

The simplicity of the method, time for examination, comparable result reliability, and safety for patients and staff (the measurement uses low-power electromagnetic waves, less than 1/1,000 of the cell phone radiation) indicate an apparent advantage of the ReDS technology for early diagnosis of decompensated CHF.

However, spatial resolution prevents from telling where in the lungs fluid accumulates: intravascular, interstitial or alveolar sections [9].

The drawbacks also include high costs of the ReDS system and just a few publications in Russian journals describing the use of the technology and its advantages.

Use of ReDS in Russia and its cost-effectiveness

Russian scientists also conduct studies demonstrating the efficacy of the ReDS system in outpatient settings. For instance, ReDS values were monitored in rural areas. A dynamic study of ReDS values in outpatient settings made it possible to timely adjust the therapy, diagnose the onset of decompensated CHF and reduce the rate of re-hospitalisations. The authors of the study note that measurements with the ReDS system can be performed in a remote clinic, and a cardiologist can remotely evaluate the values and correct therapy. This medical care model improves healthcare for patients with CHF and reduces the mortality and re-hospitalisation rates [28].

In summary, drug therapy of patients with CHF can be adjusted using ReDS value monitoring.

Introduction of the ReDS technology in the federal healthcare in Russia and its use in outpatient and inpatient settings are a promising area. Clinical efficacy and cost-effectiveness are justified, since it will reduce the number of hospitalisation and save money in the healthcare starting from the third year of use. The evaluation demonstrated that in order to enrol 95 % of the population, 1,129 to 1,234 ReDS devices will be needed [6].

Conclusion

Therapy adjustment using the ReDS system can help in identifying the urine output and rate, prescription of other medicinal products, e.g., vasodilators, and in preventing early discharge of patients.

The advantages of the ReDS method in the measurement of the amount of pulmonary fluid are a non-invasive procedure, short duration of the procedure, no need in consumables and preparation of rooms. The device is portable and can be transported from one room to another (from a ward to a ward), while a CT device cannot. The device can perform measurements over clothes, at home. Also, an important factor is patient and staff safety and the possibility to perform multiple measurements during one 24-hour period.

ReDS value monitoring significantly decreases the probability of re-hospitalisation of patients with chronic heart failure within three months, as compared to patients who did not undergo ReDS measurements. The method is clinically justified and allows performing adjustment of heart failure therapy after ReDS measurements. At the same time, it is worth noting that the use of the ReDS system in comorbid patients has been understudied. The developer has provided a diagram of ReDS measurements, but it is up to the medical organisation to set the frequency of examinations. The studies do not provide any clarity as to the frequency of examinations. The use of the ReDS system in patients with CHF is clinically justified, and results are comparable to CT results; however, it is essential to develop algorithms of ReDS measurements depending on CHF severity and comorbidities.

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Елфимов Д.А.: создание идеи и концепции рукописи, утверждение окончательного варианта

Елфимова И.В.: создание дизайна рукописи, критический обзор материала, окончательное редактирование рукописи

Харченко Д.Д.: написание обзорной части и заключения рукописи

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Elfimov D.A.: creation of the idea, conceptualisation, approval of the final version

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