DOI: https://doi.org/10.17816/DD633033

Remote monitoring of patients with chronic heart failure: a non-invasive approach

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ABSTRACT

Remote monitoring of patients, including those with chronic heart failure, has been actively used in recent years. Unlike invasive methods, non-invasive methods are not associated with surgical risks and offer a wide range of patient management options such as telemonitoring, virtual visits, emergency department pre-triage, in-hospital telemedicine, telemedicine rehabilitation, psychological support, etc. Previously, remote monitoring required a multidisciplinary medical team to ensure high efficiency, and attempts to use advanced technology to reduce human involvement were often unsuccessful. However, all electronic and telemedicine technologies in healthcare have been dramatically transformed by the COVID-19 pandemic. There is currently a wide variety of remote monitoring methods and technologies. But it is still impossible to clearly assess their effectiveness due to a lack of common standards, inadequate legislation, and regional, social, and economic differences in the availability of these technologies. However, in 2021, remote monitoring was included in the European Society of Cardiology clinical guidelines for the diagnosis and management of acute and chronic heart failure (IIb). This review describes the history of modern remote monitoring methods and the problems they are designed to solve in order to improve outpatient health monitoring for patients with chronic heart failure.

Keywords: chronic heart failure; remote monitoring; telemedicine; e-health.

To cite this article:
Emelianov AV, Kozhevnikova MV, Zheleznykh EA, Panova AL, Privalova EV, Belenkov YN. Remote monitoring of patients with chronic heart failure: a non-invasive approach. *Digital Diagnostics.* 2024;5(4):794–807. DOI: https://doi.org/10.17816/DD633033

Received: 30.05.2024 **Accepted:** 11.07.2024 **Published online:** 05.11.2024

DOI: https://doi.org/10.17816/DD633033

Дистанционное наблюдение за состоянием пациентов с хронической сердечной недостаточностью: неинвазивный подход

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АННОТАЦИЯ

Дистанционное наблюдение за состоянием здоровья пациентов активно используют в последние годы, в том числе у пациентов с хронической сердечной недостаточностью. В отличие от инвазивных методов, неинвазивные не сопряжены с операционными рисками и предоставляют широкие возможности для ведения пациентов: телемониторинг, виртуальные визиты, предварительная сортировка на пути в приёмное отделение, внутригоспитальная телемедицина, телемедицинская реабилитация, психологическая поддержка и многое другое. Ранее дистанционое наблюдение осуществляли с привлечением мультидисциплинарной команды из медработников разных специальностей, что обеспечивало высокую эффективность, а попытки внедрения современных технологий для снижения участия людей часто оказывались безуспешными. Однако пандемия COVID-19 подтолкнула к радикальному изменению всех электронных и телемедицинских технологий в здравоохранении. На сегодняшний день существует огромное разнообразие методов и технологий дистанционного наблюдения, но из-за отсутствия единых стандартов, несовершенства законодательства, региональных, социальных и экономических различий в доступности этих технологий всё ещё нельзя однозначно судить об их эффективности. Тем не менее в 2021 году дистанционное наблюдение включили в клинические рекомендации Европейского общества кардиологов по диагностике и лечению острой и хронической сердечной недостаточности (IIb). Данный обзор посвящён истории развития современных методов дистанционного наблюдения, а также проблемам, которые они призваны решить с целью повышения эффективности амбулаторного наблюдения за состоянием здоровья пациентов с хронической сердечной недостаточностью.

Ключевые слова: хроническая сердечная недостаточность; дистанционное наблюдение; телемедицина; электронное здравоохранение.

Как цитировать:
Емельянов А.В., Кожевникова М.В., Железных Е.А., Панова А.Л., Привалова Е.В., Беленков Ю.Н. Дистанционное наблюдение за состоянием пациентов с хронической сердечной недостаточностью: неинвазивный подход // Digital Diagnostics. 2024. Т. 5. № 4. С. 794–807. DOI: https://doi.org/10.17816/DD633033

Рукопись получена: 30.05.2024 **Рукопись одобрена:** 11.07.2024 **Опубликована online:** 05.11.2024

DOI: https://doi.org/10.17816/DD633033

远距离观测慢性心力衰竭患者：一种无创方法

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摘要

近年来，对患者健康状况的远距离观测得到了积极应用，包括慢性心力衰竭患者。与侵入性方法不同，非侵入性方法不存在操作风险，并为患者就医提供可能：远程监护、虚拟就诊、前往急诊室途中的预分诊、院内远程医疗、远程医疗康复、心理支持等等。此前，远距离观测是由来自不同专业的医护人员组成的多学科团队进行的，这确保了高效率，但试图引入现代技术以减少人工参与的努力往往并不成功。然而，COVID-19大流行推动了医疗保健领域所有电子和远程医疗技术的彻底变革。目前远距离观测的方法和技术种类繁多，但由于缺乏统一标准、立法不完善，以及这些技术的可用性存在地区、社会和经济差异，仍然无法明确判断其有效性。然而，2021年远距离观测被纳入欧洲心脏病学会诊断和治疗急慢性心力衰竭（IIb）的临床指南。本综述介绍了现代远距离观测方法的发展历史，以及它们旨在解决的问题，以提高慢性心力衰竭患者健康状况的门诊监测效率。

关键词：慢性心力衰竭；远距离观测；远程医疗；电子健康。

引用本文：

Emelianov AV, Kozhevnikova MV, Zheleznykh EA, Panova AL, Privalova EV, Belenkov YN. 远距离观测慢性心力衰竭患者：一种无创方法. *Digital Diagnostics.* 2024;5(4):794–807. DOI: https://doi.org/10.17816/DD633033

收到： 30.05.2024 **接受：** 11.07.2024 **发布日期：** 05.11.2024

INTRODUCTION

Globally, chronic heart failure (CHF) affects approximately 60 million individuals and continues to be a major healthcare concern [1]. In Russia, the overall prevalence of CHF is 8.2%. The most frequent causes of CHF include hypertension, coronary artery disease, or their combination, which occurs in half of the patients [2]. Research indicates that the 5-year survival rate in CHF is 50%; however, it declines further in decompensated heart failure patients. The outpatient or inpatient treatment is associated with a significant economic burden [1].

Only sodium-glucose cotransporter-2 (SGLT2) inhibitors have been demonstrated to be effective in heart failure with preserved or moderately reduced ejection fraction (EF). Quadruple therapy, including angiotensin-converting enzyme inhibitors, β-blockers, mineralocorticoid receptor antagonists, and SGLT-2 inhibitors, is indicated in heart failure patients with reduced EF. This therapy lowers the readmission rate for decompensated CHF and the cardiovascular (CV) mortality rate by 72% [3].

Given the challenges of ongoing monitoring and the concern about adverse effects, including hypotension and hyperkalemia, only 16.2% of patients in Russia receive optimal drug therapy [4]. However, the revised dose titration guidelines may result in a decrease in the incidence of these adverse effects [1, 5].

Another crucial element is compliance, which depends on individual patient characteristics and comorbidities. Poor compliance is typically linked to an unfavorable prognosis and decreased physical activity and quality of life [6, 7]. Studies show that the compliance rates vary from 10% to 98%, depending on the assessment technique. Negative factors impacting compliance include inadequate medical assistance, lack of funding, asymptomatic disease, cognitive impairment, adverse reactions, depression, low awareness, polypharmacy, and inconveniences associated with diuretic therapy [8].

Other crucial elements of effective treatment include the doctor–patient relationship, training, rehabilitation, and outpatient follow-up. These issues require complex, modern strategies that consider the current challenges and trends. One of these approaches is remote monitoring.

POTENTIAL SOLUTION

Technological advancements have enabled patients to transmit data regarding their condition that was collected using invasive or noninvasive devices and receive specialist consultations at any time and from any location.

Invasive approaches assess various parameters with remarkable accuracy and respond even to any minor alterations in patients with CHF . There are devices that evaluate pulmonary artery pressure (CardioMEMS), right ventricular pressure (Chronicle IHM), left atrial pressure (The HeartPOD), cardiac rhythm and conduction, lung tissue bioimpedance, and other deterioration markers [9, 10]. However, the study findings and meta-analysis data demonstrate that these devices are ineffective in patients with CHF. This is due to a lack of standard remote monitoring protocols and the inconsistency of the assessment techniques and parameters. The benefits of devices that measure hemodynamic parameters—particularly pulmonary artery pressure, a well-established marker of clinical deterioration are evident [11]. Invasive techniques demonstrate drawbacks, including the need for surgical intervention, risk of infections, having a limited power supply, and being expensive. These devices are primarily employed in high-risk patients requiring close monitoring and are not suitable for routine practice [12].

Conversely, there are diverse noninvasive devices and techniques for patient monitoring and management. The simplest solutions include devices that evaluate multiple parameters (scales, tonometers, pulse oximeters, smart watches, fitness trackers, etc.). More complicated monitoring techniques include phone interviews and various software. These strategies enable one to collect and process subjective and objective patient data, exchange information with other devices, maintain feedback, provide training and rehabilitation, and facilitate lifestyle adjustments. The spectrum of alternative monitoring methods is expanding, increasing availability and lowering costs, and the cumulative experience demonstrates the efficacy of this approach [12].

DEVELOPMENT OF NON-INVASIVE REMOTE MONITORING

Rich et al. [13] discovered that multidisciplinary management (MDM) of patients aged ⩾70 years was effective. MDM includes training, consultations with social services and geriatric cardiologists, additional interactions, and phone interviews. This strategy lowers the overall readmission rate, including for decompensated CHF patients, enhances the quality of life, and saves $460 per patient.

Fonarow et al. [14] validated the advantages of MDM in a study involving transplant-eligible patients with the New York Heart Association (NYHA) Class III–IV CHF. Training patients and family members as well as conducting additional visits and phone interviews improved functional status, lowered readmission rates, and saved $9,800 per patient. Cline et al. [15] demonstrated that while there were no differences in survival rates, training and remote nurse monitoring lengthened the time to readmission.

In 1999, patients with EF < 45% participated in the Pharmacist in Heart Failure Assessment Recommendation and Monitoring Study, the first study to be conducted without face-to-face visits. The treatment group was followed up by a clinical pharmacologist via telephone interviews. The study included status assessment, information, training, discussions with an attending physician, and therapy modifications. The treatment group had considerably lower all-cause

mortality and CHF-associated events, and the patients were more likely to attain the target dose with the same prescription rate [16].

Over time, the inclusion requirements expanded, and the number of publications increased. In 2004, McAlister et al. [17] published a large systematic review of 29 studies in 5,039 patients. The review revealed that MDM was the only approach that lowered the overall readmission rates (including for decompensated CHF patients) and mortality rates. Self-care improvement programs had no impact on mortality. Phone interviews and recommendations to contact a physician in the event of worsening condition improved the readmission rate for decompensated CHF, but all-cause hospitalization and mortality rates were unaffected. The Trans-European Network–Home-Care Management System (TENS-HMS), a landmark randomized clinical study conducted in 2005, demonstrated the potential of telemonitoring (TM). Diuretic-treated patients with an EF < 40% following a decompensation episode were divided into three groups based on the monitoring technique. In Group 1, TM was performed employing specialized devices that collected data on patient status, including body weight, blood pressure (BP) parameters, heart rate (HR), and cardiac rhythm, and transmitted them to a server. In Group 2, patients were followed up by trained nurses via phone interviews. In Group 3, conventional monitoring was conducted. Although the study demonstrated no differences in mortality rates or intensive care admission rates, the one-year mortality in patients belonging to Groups 1 and 2 was lower than in those from Group 3 [18]. The outcomes of the CHANCE study, the first Russian multicenter study to assess training with subsequent follow-up (scheduled phone interviews and three face-to-face visits) for 12 months, were published in 2007. The study revealed reduced all-cause mortality and readmission rates for patients with decompensated CHF, increased six-minute walk distance (6MWD), lowered use of diuretics, and enhanced quality of life. Application of this approach mitigated the relative risk of death by 37% [19].

Available data indicates that MDM is the primary contributor to the enhanced efficacy of remote monitoring in patients with CHF. However, this strategy requires skilled professionals and is linked to an increased workload as well as significant training and labor expenditures. Physicians invest a significant amount of their professional and leisure time in data analysis, and the scarcity of healthcare workers is a global issue [20]. Working after hours has been shown to significantly raise the risk of professional burnout [21]. Patient monitoring in remote areas and low-income countries is another issue [22]. Given the increased workload, novel approaches aimed at identifying effective patient management strategies that reduce the personal engagement of healthcare professionals and financial expenses are garnering substantial attention.

However, studies frequently yield inconsistent results. A meta-analysis of 20 randomized clinical trials (6,258 patients) and 12 cohort studies (2,354 patients) conducted between 2000 and 2008 verified that remote monitoring is effective in lowering mortality and readmission rates [23]. However, it also included studies that used MDM [17]. The subsequent research findings were not promising. For example, Chaudhry et al. [24] assessed the efficacy of remote monitoring using phone interviews to gather data on complaints and body weight, as well as for follow-up physician consultations. This approach had no influence on readmission rates, including for patients with decompensated CHF, duration of hospitalization, and all-cause mortality. The Telemedical Interventional Monitoring in Heart Failure (TIM-HF) study used devices for at home ECG, BP, and body weight monitoring. The devices were connected via Bluetooth to a digital assistant, which provided data to the telemedicine centers. All-cause mortality, cardiovascular mortality, and hospitalization rates for decompensated CHF patients were unaffected by this strategy [25]. Lyngå et al. [26] assessed the efficacy of TM based on body weight changes in two groups of patients. In Group 1, electronic scales were used to transmit data to a clinic; in Group 2, patients kept track of their own body weight. The mortality and readmission rates did not differ between the groups, according to the study. The multicenter, randomized, controlled study Telemonitoring in Heart Failure used a device with a display and four buttons. Data on BP and HR were collected, and interviews with preset questions were conducted. The buttons were used to submit responses, which were subsequently transmitted to a server, and displayed on the nurse's desktop. If any anomalies were found, a consultation was offered. There were no differences in hospitalization and mortality rates, which is due to the small sample size and carefully selected groups. However, there was a reduction in the number of events requiring interaction with a nurse [27].

Additionally, some encouraging outcomes were observed. The Telemonitoring in the Management of Heart Failure (TEMA-HF) study assessed the effectiveness of BP, HR, and body weight monitoring using electronic devices that were connected via Bluetooth to a telephone for data transfer. If there were any abnormalities, a physician was notified to determine the further treatment strategy. For decompensated CHF, the readmission rate, days lost from hospitalization, dialysis, or death, and all-cause mortality all decreased ($p = 0.06$) [28]. In 2015, Inglis et al. [29] published a systematic review of 41 studies, comprising structured phone interviews ($n = 25$) and non-invasive TM ($n = 18$). The review found that remote monitoring can lower all-cause mortality and readmission rates for decompensated CHF, as well as enhance the quality of life, self-care, and awareness of the disease. Most patients, including older adults, mastered the technologies easily and expressed high satisfaction levels. The review revealed the absence of a uniform structure, heterogeneity of studies, and impact on all-cause mortality and readmission rates for patients with decompensated CHF. The European Society of Cardiology's position was reflected in a document published

in 2016 as remote monitoring gained popularity, more research was conducted, and its efficacy was established [30]. This seminal document underscored the significance and efficacy of remote monitoring, considered current issues and potential solutions, and outlined the future development strategy. The issues included a lack of awareness and trust in eHealth solutions, insufficient evidence of cost-effectiveness, absence of clear legal regulations for healthcare mobile applications and transparency regarding data use, including those stored abroad, as well as regional, social, and economic disparities in technology availability [30]. However, the results of the Better Effectiveness After Transition–Heart Failure (BEAT-HF) study were unsatisfactory. Post-training phone interviews and TM were utilized for monitoring. TM employed equipment that tracked BP, HR, symptoms, and body weight, and trained nurses performed monitoring and phone interviews and recorded the actions. There were no intergroup differences in the readmission and all-cause mortality rates; however, there were differences in the quality of life [31].

In 2017, Grebennikova et al. [32] assessed the potential of enhancing self-care via mobile application-based remote monitoring. The study showed a significant improvement in self-care, as evidenced by a decrease in the mean score on the Russian version of the European Heart Failure Self-care Behavior Scale.

The Telemedical Interventional Management in Heart Failure II (TIM-HF2) study evaluated remote monitoring in patients with NYHA Class II–III CHF and EF ⩽ 45% (or >45% in combination with oral diuretic therapy) who were hospitalized for decompensated CHF in the previous 12 months. While there were no intergroup differences in CV death rates, remote monitoring lowered the number of days lost due to hospitalization for decompensated CHF and all-cause mortality [33]. Mareev et al. [34] reviewed clinical studies on telemetry in CHF. The outcomes were inconsistent due to inadequate compliance without direct interactions with healthcare professionals, parameters with insufficient sensitivity, and participants with a stable disease that did not require TM in multiple studies.

Zhu et al. [35] performed a meta-analysis of controlled studies in 10,981 patients conducted between 1999 and 2018. The analysis revealed that remote monitoring mitigated all-cause readmission rates, including for decompensated CHF, all-cause and CV mortality, and length of hospitalization; however, it had no effect on CHF-related mortality. The meta-analysis revealed the heterogeneity of the included studies. The publications that examined the need for MDM corroborated its effectiveness; however, the meta-analysis did not include the TIM-HF2 study results. More comprehensive information is presented in Appendix 1.

The model remains mostly unchanged, despite numerous studies. It includes phone interviews, video calls, and/or home-use devices that automatically transmit data on the patient's condition. The COVID-19 pandemic, during which remote monitoring technology evolved rapidly, had a significant impact. It was found that many tasks and areas can be effectively and safely supplemented, as well as partially or totally replaced. Along with TM advancements, strategies such as virtual visits, preliminary triage on the way to the emergency room, inpatient telemedicine, telerehabilitation, and psychological support have been implemented [36]. Nasonova et al. [37] performed a systematic review of invasive and noninvasive TM for 2010–2020. The review revealed that the heterogeneity of the studies made it impossible to make direct comparisons of remote monitoring systems and to determine an unambiguous efficacy assessment, highlighting the need for standardization. However, noninvasive TM was included in the guidelines of the European Society of Cardiology in 2021 (recommendation class IIb, evidence level B) [1]. Furthermore, novel examination techniques and results continue to be published.

A MODERN NON-INVASIVE TELEMONITORING MODEL

Contemporary non-invasive TM comprises data collection and feedback, server-side data storage and processing, and a healthcare professional interface for data analysis to evaluate the patient's status (Fig. 1) [10].

Interactions with patients are also important, as evidenced by the last mile problem. This problem is common in various sectors and describes how the success of the whole system depends on this particular stage, which includes interactions, data collection method, data type, and user convenience for patients. If the service is costly, the solution is complicated, and the use is challenging and too intrusive, patients will be reluctant to use the system regardless of its worth and complexity. Thus, the quest for an effective, convenient, secure, and inexpensive solution remains relevant.

One option is an application that enables a wide range of possibilities, restricted only by the intended use and the creators' imagination. Web applications and mobile applications serving as digital assistants are already available to patients for teleconsultation, feedback, and data collection via surveys and devices at home, including Russian software[1], training, rehabilitation, and other services. Available publications exhibit strong compliance and high satisfaction levels, improved self-care, and decreased readmission rates for decompensated CHF and all-cause mortality [38–40].

[1] Zingerman B.V., Demkina A.E., Fistul I.A., Borodin R.A. [software No. 2021613872] Medsenger. Cardio: A Customizable Script-Based Remote Monitoring System for Patients with Cardiovascular Diseases, 2021

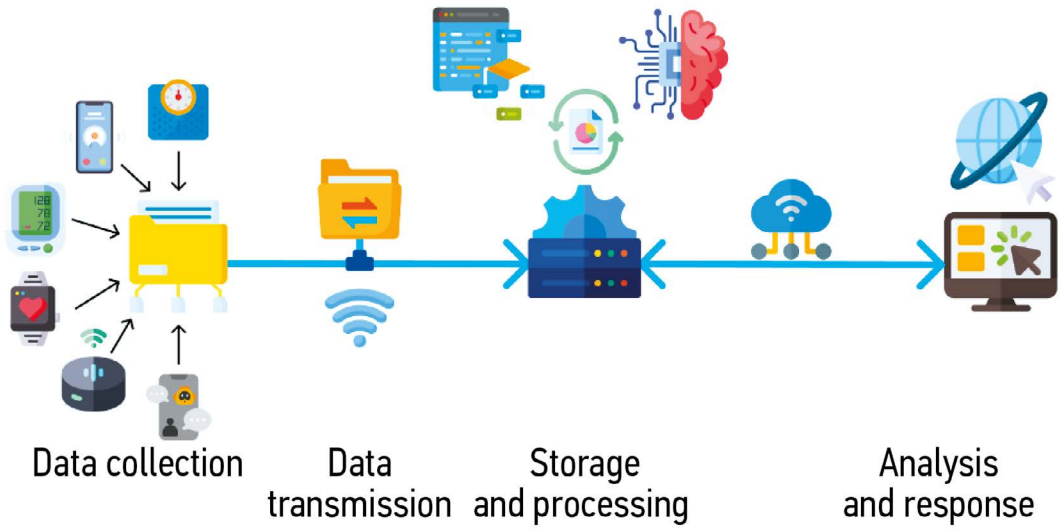

Fig. 1. A modern noninvasive telemonitoring model.

Game models require particular consideration. They are being actively tested as a tool for patient training, behavior modification, and enhanced quality of life, motivation, and self-care. Individual preferences, availability concerns, and computer proficiency are among the limitations. The model must represent real-world challenges that patients encounter during self-care. Moreover, reward-based strategies must be carefully planned to avoid unforeseen consequences [41, 42].

Questionnaires and noninvasive devices linked to an application or telemedicine hub are still convenient. The Heart failure Events reduction with Remote Monitoring and eHealth Support study, one of the landmark studies, demonstrated that an application with video feedback, BP and body weight monitoring, and questionnaire functions mitigates CV mortality rates and the incidence of decompensated CHF by 50% and 64%, respectively. Moreover, it lowers all-cause readmission rates, healthcare resource consumption, all-cause mortality, and CHF mortality. This is especially relevant for patients hospitalized for decompensated CHF during the "vulnerable phase," which lasts for six months following discharge [43].

Voice assistants are also gaining popularity. Moreover, research is exploring alternatives to applications that can be problematic for older patients, as well as the use of questionnaires to gather subjective and objective information. High satisfaction levels have been demonstrated; however, significant variability of responses and the lack of correlation between the severity of symptoms and the risk of readmission necessitate a patient-specific approach to ensure the reliability of acquired data and fully unlock the potential of this technique [44].

Chatbots, which are messenger-based applications controlled by question/answer text commands that are suitable for surveys, are another popular option. These approaches have been shown to boost the quality of life and lower healthcare resource utilization. The disadvantages include the high heterogeneity of the questionnaires, small sample sizes, and brief follow-up periods [45].

Due to the substantial economic and social disparities, tried-and-true, low-cost methods are still applicable. For example, SMS reminders, both monthly and unscheduled, have been proven to augment quality of life, self-care questionnaire scores, and compliance [46]. The Kansas City Cardiomyopathy Questionnaire, completed online or sent by e-mail, assisted researchers in identifying CHF symptoms following myocardial infarction and determining high-risk groups. The most crucial factors included impaired gait, pedal edema, and the progression of symptoms [47].

In addition, numerous gadgets are being actively researched and extensively used. For example, an ECG sensor with accelerometry, impedancemetry, and skin thermometry capabilities allowed for the prompt detection of deteriorating conditions, as well as their prediction with a high sensitivity (comparable to that of implantable devices) [48]. Remote monitoring of CHF patients in rural areas using a tonometer and the Russian ECG recorder CaRe 1.0 decreased the rate of emergency room visits and readmissions [49]. The INME-01 tonometer lowered the hospital admission and CV mortality rates [50]. Lung water measurement is considered a promising method. Impedance and dielectric meters have demonstrated high efficacy, comparable or superior to that of other indicators such as N-terminal prohormone of brain natriuretic peptide (NT-proBNP), body weight, X-ray findings, NYHA class, auscultation findings, edema, and jugular venous pressure. There was a documented decrease in the duration of hospitalization, readmission rate, all-cause mortality, and decompensated CHF mortality [51–53]. Although these devices are still undergoing testing, their relative ease of use and safety are considered additional benefits, and they will eventually be made available to patients.

Decompensated CHF can also be predicted based on fluid accumulation in the lungs, larynx, and vocal cords, as well as voice and breathing changes. A pilot study revealed that

euvolemia is marked by a clearer voice, better articulation, and more fluent speech with longer sentences compared with decompensated CHF. The rate of silent pauses was 14.9% higher in patients with acute heart failure, regardless of sex, age, and EF. This phenomenon persisted in patients with mild edema and dyspnea, which can be interpreted as a marker of deteriorating condition, especially in the absence of typical clinical signs. Moreover, a direct correlation with NT-proBNP levels has also been demonstrated [54, 55].

Applications of telemedicine for rehabilitation are emerging rapidly. Their functionality includes multimedia content, TM activity, patient status assessment with home-use devices and smart watches, motivational messages, and progress reports. These methods are highly valued by patients for their ease, acceptance, and enjoyment, all of which boost physical activity. One disadvantage is the lack of a patient-specific approach that considers individual goals, physical activity, and environmental factors. Patients with lower functional capacity and less experience at baseline were more likely to think favorably of the intervention [56, 57]. However, the Telerehabilitation in Heart Failure Patients (TELEREH-HF) study revealed no differences in mortality and readmission rates when employing invasive TM [58]. Efficacy studies of remote monitoring using various techniques are ongoing [59].

Inpatient TM is a recent area of research. Currently available data indicates that it has no effect on treatment quality. Only one in nine patients receives optimal drug therapy recommendations at discharge. This necessitates further improvements in notifications and physician incentives [60]. Appendix 2 contains more detailed information.

Although there are diverse TM techniques, only 20% of them comply with regulatory requirements and are tested in clinical studies [61]. However, active development in this area is beyond doubt; it is becoming a vital component of patient management, as evidenced by the current guidelines.

CONCLUSION

Non-invasive remote monitoring is a rapidly emerging, promising field that stems from MDM and seeks to minimize the involvement of healthcare professionals. Automated data collection and software-based interactions were initially ineffective due to the existing limitations. However, a unified model is progressively being developed, and efforts to find practical, secure, and efficient methods are still ongoing. Standard remote monitoring protocols for CHF patients and patient-specific approaches, which consider all available options based on patient characteristics and preferences, would substantially boost efficacy.

ADDITIONAL INFORMATION

Appendix 1. The most valuable studies in non-invasive remote monitoring in patient with heart failure. doi: 10.17816/DD633033-4221677

Appendix 2. The modern directions of non-invasive remote monitoring in patient with heart failure. doi: 10.17816/DD633033-4221678

Funding source. This research was funded by Sechenov University Innovative Scientific School.

Competing interests. The authors declare that they have no competing interests.

Authors' contribution. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work. A.V. Emelianov — literature review, collection and analysis of literary sources, writing the text and editing the article, organization of the figures; M.V. Kozhevnikova — conceptualization, methodology, guidance, writing the text and editing the article, funding acquisition; E.A. Zheleznykh — guidance, writing the text and editing the article; A.L. Panova — literature review, collection of literary sources, preparation and writing of the text of the article; E.V. Privalova — literature review, writing the text and editing the article; Y.N. Belenkov — conceptualization, methodology, funding acquisition.

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