THE AMULET PROJECT – A NEW MODEL OF AMBULATORY TELECARE OF PATIENTS WITH HEART FAILURE

AMULET – nowy model teleopieki ambulatoryjnej nad chorymi z niewydolnością serca

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Streszczenie: Konsorcjum naukowe, którego liderem był Wojskowy Instytut Medyczny, zakończyło realizację projektu AMULET, którego celem było wypracowanie sposobu postępowania w poszpitalnej opiece ambulatoryjnej. Wyniki badań klinicznych modelu AMULET wykazały, że zwiększa on szanse pacjentów na regularną opiekę specjalistyczną i umożliwia wczesne wykrywanie objawów zaostrzenia choroby. Teleopieka realizowana w punktach opieki pielęgniarskiej, z wykorzystaniem szczegółowej oceny hemodynamicznej i wsparcia zdalnego kardiologów, wiązała się z 38-proc. zmniejszeniem liczby hospitalizacji z powodu zaostrzenia niewydolności serca w obserwacji rocznej. Również telemonitoring domowy z wykorzystaniem mobilnego rejestratora kardioimpedancyjnego okazał się dobrze akceptowany przez pacjentów i przydatny klinicznie. Kompleksowy model teleopieki stworzony w projekcie AMULET może być jednym ze sposób zwiększenia dostępu pacjentów z niewydolnością serca do wysokiej jakości opieki medycznej.

Abstract: The scientific consortium, led by the Military Institute of Medicine, completed the AMULET project, with the goal of determining the procedures for post hospital outpatient care. The findings from the clinical studies on the AMULET model demonstrated that it increases patients' chances of receiving specialist care and makes possible detection of early symptoms of disease exacerbation. Telecare provided in nursing care offices, including detailed haemodynamic assessment and remote support from cardiologists, was associated with a reduction of 38% in hospitalisations due to exacerbation of heart failure in one year of observation. Home telemonitoring with the use of a portable impedance cardiograph was also well accepted by patients, and demonstrated clinical usefulness. The comprehensive model of telecare developed in the AMULET project offers a method of increasing the access of patients with heart failure to high-quality medical care.

Słowa kluczowe: niewydolność serca, e-zdrowie, telemedycyna, badanie kliniczne, kardiografia impedancyjna.

Key words: heart failure, e-health, telemedicine, clinical trial, impedance cardiography.

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Interview with Col. Paweł Krzesiński MD, PhD, Professor of the Military Institute of Medicine, Head of the Department of Cardiology and Internal Medicine of the Central Clinical Hospital of the Ministry of Internal Affairs, Military Institute of Medicine, Poland, Head of the AMULET Project.

What problems in the care of patients with heart failure can the AMULET model that you developed help to solve?

The idea of AMULET project was created as an answer to the shortcomings of healthcare systems: shortage of medical staff and

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low availability of effective tools for non-invasive haemodynamic monitoring of cardiac patients. Current guidelines for heart failure management indicate the importance of frequent and meticulous patient monitoring in ambulatory care. Meanwhile, a growing number of patients with heart failure in Europe, there are already about 1.4 million of them in Poland alone, requires increasing involvement of health care system resources. As a result, there is an increasing shortage of physicians, which significantly limits the possibility of conducting face-to-face visits with cardiologists with the intensity and quality that patients with heart failure require. These problems are known around the world and effective solutions have been sought for years. The AMULET model combines a number of proven components: involvement of nursing staff, advanced methods for assessing cardiovascular function, and telemedicine solutions that bridge the gap of space and time.

What does the AMULET model of care for patients with heart failure consist of?

In our model, after an episode of exacerbation of heart failure symptoms, the patient visits an outpatient clinic run by nursing staff according to a defined schedule. The visit schedule can, of course, change if, for example, due to their condition, a patient needs more frequent monitoring. A cardiologist is directly involved in the first visits, but later on the cardiologist holds remote consultations and performs a face-to-face examination only if absolutely necessary. This decision depends greatly on key indicators of patient assessment classified according to defined alerts generated by a decision support module. It should be emphasised that nursing assessment is complemented by a detailed assessment of the patient's haemodynamic conditions: their heart rate, blood pressure and hydration status with the use of bioimpedance methods (impedance cardiography and body composition assessment). It is on the basis of these parameters that patients at risk of deterioration are identified. Therefore, it is not an "ordinary" visit, but a thorough assessment of key vital parameters of heart failure. This is a significant innovation and added value to the diagnostic tools previously used in ambulatory care.

What did the results of the randomised, prospective, controlled clinical trial AMULET[1], which were published in the European Journal of Heart Failure, show?

First and foremost, AMULET had a positive primary outcome: in this model telecare reduced the risk of cardiovascular death or urgent hospitalisation due to heart failure symptom exacerbation by 31 percent. Analysis of secondary outcomes showed that this effect resulted from a significant reduction in hospitalisations, both first-time hospitalisations, by 38 percent, and overall hospitalisations, by 36 percent. The results of the study confirmed our assumption that the combination of good nursing care, modern methods of cardiovascular function assessment and remote cardiology consultations with the use of a telemedicine platform created according to clinicians' requirements is a better solution than the current management standard. I would like to emphasise the important role of the decision support module in formulating the medical recommendations – the recorded percentage of compliance in this regard was nearly 90%!

How significant are the results of this study for everyday clinical practice in the diagnosis, therapy, and care of patients with heart failure?

Publication of the AMULET trial results in such a renowned journal as the European Journal of Heart Failure is the proof of recognition of the advantages of this telecare model by the scientific community. One of the main goals of heart failure patient's care is to significantly reduce hospitalisations, and our solution has shown great potential in this regard. The ability to provide the patient with the most modern treatment methods, taking into account their individual needs, represents "tailor-made" care and use of the full potential of 21st century cardiology. I think that the reviewers also appreciated the pragmatic approach to creating such a solution. From the beginning, we were aware that our model cannot be too complicated and full of expensive technologies. The AMULET solution is relatively simple to implement. The clinical trial itself was a "mini implementation", because it was carried out in nine Polish centres. It involved telecare of nearly 300 patients, who attended over 1,500 visits. Undoubtedly, both the technological solutions and the trained nursing and medical teams passed the test. Patient satisfaction, and frequently their positive emotional attachment to this form of care, is another argument for widespread implementation of this model.

How significant is the potential for implementation of the AMULET model in Polish clinical practice?

The number of potential beneficiaries of the AMULET model in Poland is hundreds of thousands of Poles with heart

[1] Effects of an outpatient intervention comprising nurse-led non-invasive assessments, telemedicine support and remote cardiologists' decisions in patients with heart failure (AMULET study): a randomised controlled trial (wiley.com) DOI: https://doi.org/10.1002/ejhf.2358

failure, because, unfortunately, so many citizens of our country are hospitalised at least once a year due to exacerbation of heart failure symptoms. There is a profound need to prevent unplanned hospitalisations in this group of patients because of their negative clinical, social and economic consequences. In fact, it is a priority in outpatient care for patients with heart failure. The proposed solution is universal and can be implemented, for example, in primary care and other medical specialties. We have encouraging cost-effectiveness data. Of course, widespread application requires including this procedure in the range of public benefits or offering it as a medical service by private facilities. This is worth being done, because the results clearly show that implementation of the AMULET model reduces the workload of the cardiology specialist, who is involved only in the necessary activities related to remote issuance of medical recommendations, while maintaining the safety and accurate assessment of the patient. Moreover, the competence of nursing staff, whose central role in telecare is one of the trends of modern medicine, increases. The image value cannot be overlooked either. Implementation of the AMULET model can be a showcase of Polish development in the field of cardiology and e-health.

You have said a lot about telecare in nursing practice. But this is not the only aspect of the AMULET project. What are the results of work and research on the mobile device and the whole system of home telemonitoring?

The second main path of research was to produce and test the home monitoring system in a clinical setting. It should be emphasised that within the AMULET project, we did not create only a miniaturised version imitating stationary devices. We built a complex home telemonitoring system consisting of the following components: a recorder for non-invasive recording of bioimpedance signals compatible with Bluetooth-enabled devices (e.g., smartphone, tablet), a mobile application used to transmit the recorded signal between the measuring device and the electronic platform and to report symptoms, and finally a telemedicine platform where the data are integrated, analysed, and presented to the supervisory staff.

What are the implications of these results for the overall model and for patients?

The results are very promising. Analyses of the user surveys of the system showed a high level of acceptance from patients undergoing monitoring. Patients used the system efficiently and the percentage of examinations sent according to the schedule was very high. In general, no significant problems with the operation of the equipment were reported. In analyses of the results obtained, we found satisfactory consistency between the parameters measured with our device and the reference measurements. The possibility of home monitoring, especially of the chest fluid content, may guarantee even more effective identification of patients at risk of overhydration. With this solution, we bridge the "gap" between ambulatory visits. This is particularly useful in patients prone to rapid deterioration of their health and at particularly sensitive periods of the disease, such as just after an episode of hospitalisation due to symptom exacerbation.

The results of the AMULET project are the effect of several years of work of an interdisciplinary team of physicians, nurses, engineers, computer scientists, promotion and commercialisation specialists. The consortium consisted of units with complementary potential: Military Institute of Medicine, Military Clinical Hospital with the Polyclinic in Wroclaw, Medical University in Wrocław, Medical University of Gdańsk, Military University of Technology, Łukasiewicz Research Network – Institute of Medical Technology and Equipment and Infoscan SA and casusBTL Group businessmen. Within four years, we developed an advanced telemedicine platform, conducted a series of clinical trials and created prototypes of new types of devices.

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Where people and institutions interested in the AMULET model can find more information about it?

First of all, the results of the AMULET project are included in the monograph "Ambulatory Telecare in Heart Failure", which is available for free download in electronic form at https://amulet.wim.mil.pl/pl/monografia. It summarises the state of knowledge about the current possibilities and future prospects for the use of telemedicine in the care of patients with heart failure. It presents the problems and needs of patients with heart failure and describes in detail the solutions developed in the AMULET project and the principles of interpretation of measurement results, including the use of the decision support module. It also presents the concept of future use of the AMULET solutions in a broader perspective of IT solutions in health care, taking into account already existing systems. A rich source of knowledge about the project can also be found on the website https://amulet.wim.mil.pl/, where we present a lot of substantive content and audiovisual materials.

Secondly, we want the knowledge about the project to reach a wide audience: medics, patients, business representatives and policymakers. Therefore, in September 2021, we organised an international scientific conference "Innovation in heart failure in telecare and therapy". It was actively participated by the project executors and other prominent Polish experts, including: prof. Przemysław Mitkowski, President of the Polish Cardiac Society, prof. Ryszard Piotrowicz, chairperson of the Informatics and Telemedicine Committee, executive board of the Polish Cardiac Society, and foreign guests: prof. Friedrich Koehler and Mario Klessascheck. We invited a wide range of stakeholders to the conference; 311 participants were registered. Videos were recorded and can be viewed on the conference website: https://amulet.care/.