Screening of Patients With Suspected Heart Rhythm Disorder on Primary Health Care Level With the Use of Personal Digital ECG Sensor

DEVELOPMENT OF A PROTOCOL FOR THE USE OF ECG SENSOR IN THE CARE OF PATIENTS AT THE PRIMARY HEALTH CARE LEVEL

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1. PURPOSE, GOALS AND HYPOTHESES

1.1. Purpose

The purpose of the study is to develop and validate a protocol for the use of the ECG sensor device to detect arrhythmias in the care of patients at the primary level and to show that the use of the device is safe and contributes to better and more economical treatment of the patient.

1.2. Goals

1. Develop and validate a protocol for the use of an ECG sensor device to detect arrhythmias in patients in a family medicine practice.
2. Analyze the most common arrhythmias in patients with undiagnosed arrhythmias.
3. Assess the quality and safe use of the ECG sensor device in the treatment of patients at the primary level with the help of qualitative indicators.
4. Assess the economic efficiency of the new tool in treating patients at the primary level.

4.3. Hypothesis

1. It is possible to develop a validated protocol for the use of an ECG sensor device to detect arrhythmias in patients in a family medicine clinic.
2. The most common arrhythmias in patients with undiagnosed arrhythmias are benign and do not require additional cardiac treatment.
3. Patients and doctors are satisfied with the use of the ECG sensor device in the treatment of patients at the primary level, its use is safe.
4. The use of an ECG sensor device reduces referrals to specialist cardiologists and additional diagnostics, thus reducing the cost of medical care.

2. JUSTIFICATION

2.1. Introdution

Cardiovascular diseases are a great problem. In Europe, 50% of all deaths occur due to these diseases. (1)

In 2016, cardiovascular diseases were a cause of 40% of all deaths in Slovenia. This makes up 47% of women's deaths and 32% of those of men. From 2009 until present, cardiovascular

diseases are the second most common cause of death, right after neoplasms. When talking about cardiac diseases, the three main causes of death are acute myocardial infarction, arrhythmia and heart failure. The age-standardized mortality rate in Slovenia had surpassed European average in the eighties and nineties of the previous century. However, this difference is decreasing since 2000 and is getting closer and closer to the European average. (2)

Considering the causes of primary care visits, cardiac diseases represent 5.60% of the total number of visits, i.e. 283,143 medical check-ups. Cardiac diseases are the seventh most common cause for primary care visits. (3)

This data shows us that the medical service expenses, especially those that concern cardiovascular diseases, are high. Arrhythmia affects millions of people each year. Some types of arrhythmia are hard to diagnose as they occur sporadically, whereas others do not present any danger for health (e.g. supraventricular extrasystole (SVES) or paroxysmal supraventricular tachycardia (PSVT). Nevertheless, there are still some dangerous arrhythmia, such as ventricular tachycardia (VT), that can affect human health. (4, 5)

Despite the progress in medicine, doctors are still using the common methods, such as referring patients to a cardiologist and/or recording an ECG, when treating their patients. The rest of the methods, e.g. an ultrasound, an MRI/CT scan or a scintigraphy require specialists' time, are very expensive and the waiting time is long. Considering the dimension and the gravity of the problem, the need for cheaper, yet reliable continuous monitoring of cardiovascular system has occurred.

The use of the so-called eHealth (telehealth), supported by micro- or nanoelectromechanical systems, is increasing in the last years. Here we are talking about for example low-cost sensors that trace various physiological parameters that are connected to human health, such as body temperature, heartbeat and blood pressure. (6)

Digital technology is becoming a more and more important tool for a family doctor, especially in communication with patients and colleagues or specialists, with the presumption that connections in telecommunications network are secure enough for the exchange of delicate data. (7)

Telemedicine is a concept that describes telecommunication and information technology with the purpose of providing medical help from a distance. It enables medical service with the help of information and communications technology when the healthcare workforce and patients are not in the same place geographically. It helps to reduce the distance and improves access to medical service that is not available in distant rural areas. The early form of telemedicine

included the telephone and the radio, while in modern times video calls, progressive diagnostic methods available in various mobile apps and telemedical devices became more and more popular. (8)

Secure data and text, sound, image or other information transmission has to be assured for the performance. With the help of these data, a physician can perform or control the course of treatment, prevent deterioration and make diagnoses. (9)

Telecardiology is a specialized version of telemedicine, where the ECG records are being forwarded via telephone or wireless connection. (10) With its use, the quality, quickness and cost-effectiveness of treating heart patients on primary level can be improved.

The purpose of this article is, with the help of already published literature, to evaluate the state of the activity in telemedicine on primary level in Slovenia as well as in the world.

2.2. Study design

In collaboration with medical experts, the Jožef Stefan Institute of Slovenia developed a personal portable ECG sensor that works in conjunction with a smartphone. The Personal Digital Mobile Body Sensor is listed in the medical device category, has the status of a medical device with all necessary certifications, and is owned by Savvy (Figure 1). It includes a personal sensor, ECG electrode kit, MobECG mobile application (Figure 2), and computer program called VisECG (Figure 3), which is currently available for Android only. The ECG sensor consists of two electrodes, which are placed 8.5 cm apart, and measures the potential between these two closely placed body-surface electrodes. The gadget weighs 21 g and has several possible positions of placement. The measurement is transmitted via Bluetooth connection to a smartphone, where the device is paired and managed via the MobECG mobile application.

3. **Figure 1. Personal Digital Mobile Body Sensor by Savvy**

Initially, personal and other necessary information are entered into the smartphone application; then, the user can forget that he or she is wearing the device. The application works reliably in the background, even when using the phone for calls or other applications. If desired, the user can monitor the heart rate on the meter display with a curve and calculate it on an ongoing basis.

Finally, the measurements are collected on the phone and can be transmitted to the physician in two ways: (1) pressing the button, the user can prepare a PDF report and send it to the physician's e-mail address or (2) transfer the data via USB cable to the physician's computer, where he or she can closely monitor the entire recording using VisECG. The first method is useful in the case of a severe disorder in which it is necessary to inform the physician. However, it is still related to the availability and responsiveness of the physician.

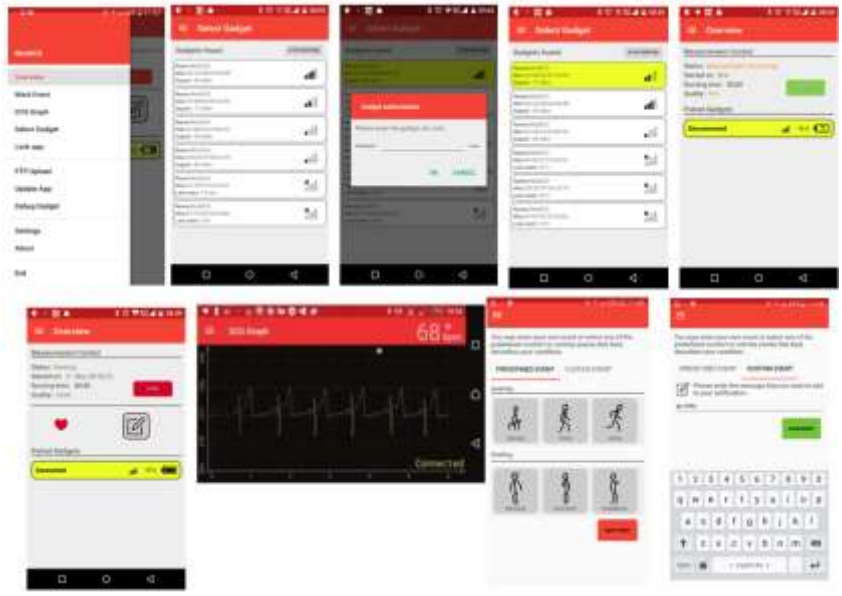

Figure 2. Application MobECG on a smartphone

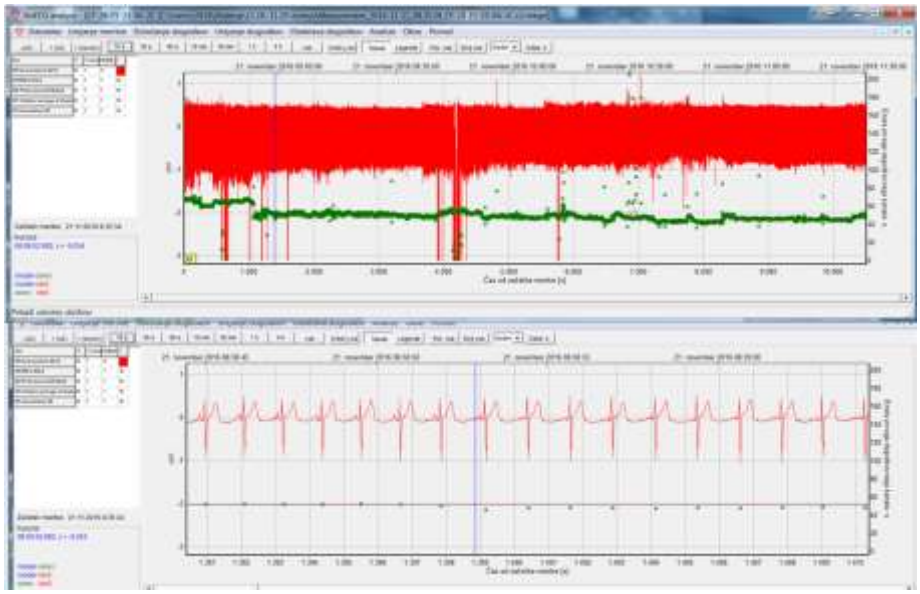

Figure 3. Application VisECG on a computer

When reading the recording, one should remember that it is not any standard lead typically used in a Holter monitor and that it is a single-channel measurement that is performed live on a patient moving and performing daily activities. The recordings can show different disorders but

need to be evaluated so that artefacts can be distinguished from the actual disturbance of the rhythm. VisECG enables us to review and accurately analyze the recording and produce a report that can be submitted to physicians of other specialities for consultation or delivered to the patient and his or her physician as a measurement result. Given that the measurement is only a single channel, we can estimate the frequency and possible disturbances of rhythm but not ischemia.

2.1. Cost-effectiveness assessment

The assessment of economic efficiency is divided into two groups, regardless of the area under consideration. We first encounter input and output, which can be described as costs and consequences. Second, the assessment of economy is a consequence of choice. Our resources are not unlimited and in order to achieve the best possible output, it is necessary to make a choice.

Over the past 20 years, 2 factors have significantly influenced the assessment of cost-effectiveness in medicine; first, increased pressure on the health system to be effective both clinically and in cost control; therefore, decision-making processes have been developed that result in better cost-effectiveness results.

3. RELEVANCE OF THE SELECTED TOPIC

At the family doctor's office, patients with chest pain are frequent visitors and the use of an ECG recording device is a basic aid in their treatment.

The problem with using an ECG is that there are often nonspecific changes that less skilled doctors are not always able to interpret well and therefore refer the patient for treatment either to a hospital in an emergency room or to a cardiologist. An even bigger problem is the misinterpreted ECG result as normal in patients who may be life-threatening. So we face a double problem: the unnecessary sending of healthy patients for additional examinations and the problem of not recognizing the critical situation. It is very important to have enough diagnostic tools available that can be used to treat patients in the family doctor’s office.

Telemedicine offers us a new method in treating patients with suspected or confirmed heart disease. It is a direct link between the patient and the family doctor, in order to obtain a correct diagnosis more quickly and to refer fewer patients to further unnecessary examinations.

Studies have shown that telecardiology can be used to treat patients with specific heart disease (5), also helps better family physician decision-making (6), and reduces unnecessary

hospitalizations without reducing appropriate referral of patients with life-threatening conditions. (7)

3.1. A contribution to science

There has been no protocol found in the literature for the use of the ECG sensor device in the care of patients at the primary level, nor is there any research that would confirm its safe and effective use at the primary level. An important contribution will also be the assessment of the professional effectiveness of the introduction of a new method at the primary level of medical treatment.

4. STUDY DESIGN, PARTICIPANTS, METHODS

4.1. Study design

The research will be quantitative scientific methodologies. It will be a prospective descriptive study. A test and control group will be formed for the study.

4.2. Participants

The observed units will be patients in the family doctor's office with a history of suspected arrhythmia, but without a previously diagnosed arrhythmia for which his treating physician will decide that despite all diagnostic procedures it is not possible to establish an arrhythmia, but he is still suspected of le-to. The sample will include 400 patients aged 18 to 99 years and their doctors, 200 of whom will be included in the test group and 200 in the control group.

4.3. Methods

4.3.1. The course of the research

The research will take place on two levels. The first level will cover patients and the second their doctors. The research will last 24 months, the final phase will last one month.
The first level of the study will cover patients with a history of suspected arrhythmia, but without a previously diagnosed arrhythmia. A 12-channel ECG will be recorded for each patient first, and if I find a rhythm disorder at that time, the patient is treated according to the guidelines and is not included in the study. However, if the diagnosis of arrhythmia cannot be made, the patient is included in the study. In the test or. in the control group patients will be included in order of the visit: the first patient is included in the test group, the next in the control group, the next in the test group, etc. In the test group, the patient receives an ECG sensor, which is installed by a healthcare professional and worn for 3 days. The measurement is then transferred to the computer's memory. After 5 to 10 days, the same patient undergoes a

check-up at the chosen doctor, where he decides to take further action in the event of a recorded arrhythmia. If there is no arrhythmia on the recording, the patient can repeat the whole procedure again, but not more than three times. At the time of placement, the patient receives a questionnaire where he can write down his feelings and give an opinion on the quality and usefulness of the examination. Patients in the control group receive a questionnaire and report to the control of the chosen doctor in 5 to 10 days.

The second level of the survey will include physicians of referred patients who will fill in a questionnaire about the patient at the time of referral, control in 5 to 10 days and in 3 months and a questionnaire for physicians, where he will give an opinion on the quality and usefulness of the examination.

Based on quality indicators, we will assess the number of referrals, measure the frequency of anxiety and palpitations in patients, assess the potential impact on reducing waiting times, and use a patient and physician satisfaction questionnaire.

As far as the economic aspect is concerned, we will initially estimate the cost of the test and control group, monitor it for 2 years and evaluate it at the end of the research using cost indicators that we will set for myself. Based on this assessment, we will try to establish a cost-effectiveness model.

We will assess the safety of using the device with a questionnaire about the patient's problems using the device and the method of examination (installation, handling of the phone, detachment, contact of the device with water).

4.3.2. Instrument description

V raziskavi bom uporabila naslednje instrumente:

a. ECG sensor
b. ECG sensor record
c. Structured questionnaire for patients
d. Structured questionnaire for doctors: (so far summarized after the pilot study of ZD Ljubljana: Use of a personal meter in the family doctor's office)
   i. doctor's questionnaire about the patient;
   ii. doctor's questionnaire about doctor and patient.

Ad a. With the help of an ECG sensor reading, we will obtain data on the heart rhythm of 200 patients and on possible arrhythmias.

2. Ad b. Using a structured questionnaire for 400 patients, we will obtain the following data:
    1. Demographics (gender, age, education, employment)
    2. Reason for coming to the doctor
    3. Opinion on the usability and comfort of the installed sensor
    4. Opinions and experiences on this method of diagnostics.

Ad c. With the help of a structured questionnaire for doctors, we will obtain the following information:

Ad i .: doctor's questionnaire about the patient, which is divided into 3 parts and the doctor enters data about the patient before placement - part 1, at the first control - part 2 and at the second control - part 3.

Part 1: Chronic Patient Illness, Regular Therapy, Smoking Status, Alcohol Drinking, Blood Pressure, BMI, Cause of ECG Sensor Installation, Working Diagnosis, and Additional Investigations.

Part 2: Diagnosis based on reading, action

Part 3: Diagnoses and additional investigations, referrals or medications

Ad ii .: doctor's questionnaire about the doctor, where the doctor enters the following information about himself.

1. Demographic data (gender, age, years of service, specialization)
2. Opinion on the usability and comfort of the installed sensor
3. Opinions and experiences on this method of diagnostics.

5. ANALISYS

Analysis a: When reading ECG recordings, we will obtain data on the patient's basic rhythm, average heart rate, whether the day-night rhythm is maintained, data on the frequency and type of SVES (supraventricular extrasystole) and VES (ventricular extrasystole) and possible arrhythmias. We will use univariate analysis in this.

By comparing the records in the patient's diaries and the recording, we will get information on whether the patient is just feeling a rhythm disorder or whether it is an actual disorder. We assume that when patients feel the disorder they will actually have a rhythm disorder, that the difference between these groups of patients will be statistically significant, for this we will use Pearson's Hi-square test (or correction for smaller samples - Fisher's exact test).

Analysis b: When processing patient questionnaire data, we will compare the test with the control group. To compare each factor between the groups, we will use the Mann-Whitney test for independent samples or the chi-square test (depending on whether the factor is categorical or numerical - Likert scale).

Analysis c: When processing the Structured questionnaire for doctors questionnaire data, we will compare the test with the control group. To compare each factor between the groups, we will use the Mann-Whitney test for independent samples or the chi-square test (depending on whether the factor is categorical or numerical - Likert scale).
We will use univariate analysis when processing the questionnaire data.

Numerical variables will be expressed as mean ± and range and compared using the t-test or Mann-Whitney test, as appropriate. Categorical variables will be presented as percentages or frequencies, and the differences were compared using Pearson's chi-square test. A P-value ≤ 0.05 was considered statistically significant in all tests. All analyses will be performed using the SPSS® Statistical Program version 26 (SPSS Inc., Chicago, IL, USA) for Windows®.

6. EXPECTED RESULTS

We expect to describe and develop and validate a protocol for the use of the ECG sensor in primary care patients, which would be a safe, reliable and high-quality device at work, with the help of the ECG sensor device and its readings, and completed questionnaires by patients and doctors. primary care physician in treating a patient with suspected cardiac arrhythmia. We will also assess the financial benefit of introducing a new method at the primary level.

7. APPROVAL OF THE MEDICAL ETHICS COMMISSION

Patients who will meet our criteria will be invited to participate in a study that was approved by the Ethics Committee of the Republic of Slovenia (number 0120-299/2017-7,), and written informed consent will confirm their participation. The study will be conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

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