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New devices for invasive blood pressure detection and the prototype for a long-term invasive distance control of cardiovascular system

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Abstract
The paper presents an analysis of methods for measuring blood pressure, as well as the latest global development of invasive techniques describing their positive and negative aspects. We have described a prototype of device and multiparametric biosensor that measures systolic and diastolic blood pressure, heart rate and its variability, pulse wave velocity, i.e., indicators that characterize the work of the heart and blood vessels. Invasive microsensor is implanted in the vessel; hence, the risk of any intravascular complications is eliminated. A device is able to transmit information about the state of the cardiovascular system of the person in a real-time mode. In case of critical changes warning, signals of different levels demonstrate the need for medical care. Information about critical changes may come in the appropriate healthcare facilities, e.g., in the nearest ambulance. It is assumed that the device will help to reduce the burden of noncommunicable diseases (morbidity and mortality of the working population).

Keywords: Arterial blood pressure; arterial hypertension; vascular comorbidity; stroke; myocardial infarction; biosensor; implantable device; constant remote monitoring of arterial blood pressure.

Introduction

High blood pressure (arterial hypertension, AH) is a major cause of cardiovascular events which primarily include acute myocardial infarction and acute stroke. According to the WHO contribution of arterial hypertension in the progression of brain and heart diseases ranges from 60% to 95%. By the way more than 10% of the world's population are at risk for hypertension and should always take pills. The epidemiology of arterial hypertension is critical in the Russian Federation, 40% of the adult population suffer from AH, while the effective treatment of hypertension in different regions does not exceed 17% [1]. Violation of pharmacotherapy regimen, interrupted treatment and taking even more than one effective drugs in the absence of continuous monitoring of the blood pressure (BP) do not allow to achieve good results obtained during the conduction of special studies. Circadian rhythms of cardiovascular diseases in which the peaks of the main cardiovascular events strike in the early morning hours largely are the reason for the high prehospital lethality of cardiovascular patients, mainly from stroke and myocardial infarction.

However, an isolated form of arterial hypertension occurs extremely rare. For example, arterial hypertension was the only risk factor only in 3% patients with stroke in Russia, while in 97% of patients with stroke there was a vascular comorbidity that resulted in disability in 45.3% of subjects even before the onset of the stroke [2]. Analysis of the patient data from the Health Search Database in Italy revealed that about 40% of hypertensive patients had three additional factors [3]. As far back as in 2003 the recommendations of the European Society of Hypertension and the European Society of Cardiology emphasized that the diagnosis and treatment of hypertension should be determined from the perspective of the overall risk [4]. Therefore, the study and control over only the blood pressure cannot improve the situation with mortality and disability.

A device with an implanted biosensor for continuous remote blood pressure monitoring in people from the risk groups for developing dangerous socially significant cardiovascular complications can be practically feasible way to solve this global problem.

Methods

Methods for measuring blood pressure are divided into direct and indirect, as well as invasive and non-invasive. Direct measurement of blood pressure (inside the blood vessel) is the most accurate technique, but it is associated with an invasive procedure that determines the risks of vascular complications and limits the scope of the direct method of measurement.

These are mainly external devices – Korotkoff sphygmomanometer that are used at this moment for personal monitoring, allowing to provide only sporadic control carried out in most cases on the initiative of the patient. This indirect noninvasive method was not fundamentally improved during the last hundred years, and its efficiency is low. The number of marketed implantable devices is insignificant at this time, and they are used in clinical medicine in ICU units and during operations on the heart and large vessels, as well as to monitor the effectiveness of professional training of elite athletes. Given the increased interest of physicians and developers, a considerable increase in the production of such devices in the medium term is very likely. This is caused by a permanent reduction of their prices and the possibility of relatively simple improvements of widespread pacemakers and electrocardiographs used for the daily monitoring of heart activity.

Discussion

Developed world solutions for invasive blood pressure diagnostics

The most commonly mentioned among the latest technical developments of the BP measurement is the following device: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients (The CHAMPION) [5]. It measures the level of blood pressure in the pulmonary artery of the patient and transmits the information wirelessly to a centralized database. Doctors get access to this data through a special website [6]. Electromechanical sensor EndoSure of this device is made using the technology MEMS (microelectromechanical systems) and has dimensions of $3.5 \times 2 \times 1.5$ mm. Anchor loops of nitinol (nonmagnetic nickel–titanium alloy) hold the device in the artery where it does not interfere with the blood flow. The main advantage of such device is that it does not require an external power source (it is powered by an external antenna attached to the patient's body). Its implantation is simple using the right heart catheterization allowing the procedure to become generally accepted. In 2010 there was a study of remote monitoring of 1,600 patients with chronic heart failure NYHA III (functional class), and after 6 months there was a reduction in hospital admissions by 30%. However, the decrease in mortality was not achieved. Moreover, authors deliberately avoided data regarding intra-arterial complications. The main disadvantages of the sensor are dependent on the state of the patient (it is necessary to take measurements only in a horizontal position), temperature sensitivity, inaccuracy in over and underweight patients, shortness of breath, etc. The device is unable to register several parameters of the cardiovascular system. In addition, the risk of thrombosis limits the widespread of clinical use of this device (implantation of the sensor into a large vessel, the pulmonary artery, as well as the high price of the device ($15,000 including the cost of hospitalization and implantation).

In 2012 scientists at the Institute of Microelectronics A*STAR (Singapore) developed the wireless passive sensor monitoring of blood pressure [7]. The implant is embedded in the artificial vessel and is powered by a portable external reader that uses an inductive method for wireless power transmission (two miniature coils in combination with an increased sound amplifier). The lack of the battery and low power consumption

(21.6 mW) are the main advantages of the device. Currently, there is a prototype device tested with 5 cm tissue. At the same time, the sensitivity of the mounted sensor to determine the pressure was set with a resolution of 0.17 psi (1172 Pa). In 2014, the start of experimental studies in animals was scheduled [8] since the lack of experimental data does not allow to reveal disadvantages and safety of the method, and the developers say about the possibility to measure blood pressure only alone, with no other parameters of the cardiovascular system.

Another nonstandard solution was a wireless implantable device which is currently being developed at the Stanford University (the Group of Integrated Biomedical Systems). It works without batteries in human blood [9] – autonomous implant sized as a headpin (3 × 4 mm) that has a 2 × 2 mm 2W antenna and the frequency of 1.86 Hz and no battery. This device is able to move inside the vascular bed with a speed of 0.53 cm/s, transmitting data on the status of intravascular homeostasis. The device is still in the process of research [10], so the exact scope as well as its disadvantages has not been established yet.

The other unregistered latest technical solution is an implantable wireless sensor system for monitoring patients with hypertension [11]. This system is a sensor implanted in the femoral artery for the direct measurement of blood pressure and subcutaneous telemetry unit, which is wirelessly connected to a wearable unit that performs the function of reading the information from the sensor, its management, recording and visualization of measurement results and power supply of the whole system. The system allows the direct measurement of blood pressure in the blood flow in the range of 30-300 mmHg with an accuracy of ±1.0 mmHg with a sample frequency of 30 Hz. The device is also able to measure the temperature within the range of 15-45°C and the HR. The main disadvantages of the device are high dimensions of biosensor (5.6 × 0.7 mm), the weight of the wearable unit, short distance of wireless connection (up to 10 cm), inability to assess the state of the vascular wall, the lack of online communication, and most importantly, the risk of intra-arterial thrombosis due to intra-arterial implantation as well as the field of application (urgent medicine) with short-term control over the functioning of the cardiovascular system. At the same time the first successful preclinical studies of this system were successfully conducted (the sensor was implanted to five sheep for 3-5 days).

The most recent work demonstrating the possibility of using indirect (optical) measurement of blood pressure is the paper of Fiala [12]. The structure of an implantable sensor system includes an optical assembly for registration of photoplethysmograms, fitted on the artery and one of the two ECG electrodes positioned subcutaneously near the optical part of the sensor. The physical phenomenon used to record the pressure – the dependence of pulse wave velocity in the vessels on the blood pressure, with the sensor being implanted on the carotid artery with a diameter of 4-5 mm. In addition, the functions of the pressure monitoring the system can measure ECG, heart rate, blood O_2 saturation, concentration of carboxy- and methemoglobin, and changes in pulse wave velocity. The study of this system on a pig being under anesthesia revealed such disadvantages as the need to individually calibrate the sensor after implantation and error in measurement of the blood pressure equal to 6 mmHg. However the main disadvantage of this method is the need for a complex operation to install the optical part of the sensor, site of implantation (carotid artery with the risk of stroke in case of its damage), no possibility of wireless communication with a PC, mobile phone, dependent on the state (no data on the operation of the device in the moving biological objects).

Indigenous development of invasive device for a long-term remote monitoring of the status and critical changes in the cardiovascular system in patients with comorbidities

Close cooperation of the team of doctors of various specialties from different healthcare organizations and manufacturers of various medical devices including pacemakers and cardiac monitors has led to the creation of a prototype of a technical device for a long-term invasive remote monitoring of critical changes in the cardiovascular system in patients with cardiovascular comorbidity. The device has a number of advantages.

First, it was decided that the measurement of blood pressure only is insufficient. The analysis of the physical principles of hemodynamics and physiology has revealed that full control of the activity of the cardiovascular system should include the dynamic monitoring of at least the systolic and diastolic blood pressure, pulse and heart rate, pulse wave velocity, i.e. indicators that characterize the work of both heart and vessels. These figures, along with other derivate indicators are excellent markers of the treatment efficacy, as well as the assessment of the cardiovascular system and the prediction of cardiovascular events. Furthermore, a large number of parameters increase the limited understanding of the physiology and reduce the possibility of errors, including fatal ones. Thus using the technique of MEMS, allowing miniaturization of all components used, we have created a solid, multiparametric microsensor monitoring cardiovascular system with the maximum dimensions of 5 mm. Due to its size this device can ensure the requirements of the minimally invasive method of implanting with the minimal surgical intervention.

Second, the microsensor is designed for fixing on the vessel (outside) that completely eliminates dangerous cardiovascular complications and allows to operate for a long-term basis (for at least 5 yrs).

Third, the high degree of biocompatibility is developed due to the unique biomaterials.

Fourth, it is easy-to-use because the external device operating as a power supply and an information reader is connected periodically (no more than once per day) and does not require the patient to wear it all the time.

Fifth, there is a system for remote monitoring, transmitting digital data in a real time. An element sensitive to any changes is connected to the module for instant transmission and recording of data.

Thus, the information on the state of the person's cardiovascular system will be continuously received in a real time. In case of critical changes visual, auditory and sensory stimuli (alerts) will turn on indicating the need to provide emergency care. The information on these critical changes will also be transmitted to the appropriate healthcare facilities, for example, to the nearest ambulance.

Conclusion

Creation of implantable devices for comprehensive diagnosis of the heart work, blood pressure, ischemic disorders is the most recent promising method of the control and prevention of cardiovascular diseases.

The developed device which has no direct analogues in the world will help to reduce burden of noncommunicable diseases (morbidity and mortality of the working population). In addition, the full duration of the continuous monitoring of the cardiovascular system will allow the patient to monitor the implementation of therapeutic measures. It will also allow the doctor to determine the effectiveness of the prescribed treatment and perform pharmacological correction in time.

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References

1. Oganov RG, Timofeeva TN, Koltunov IE, Konstantinov VV, Balanova YuA, *et al.* (2011) Arterial hypertension epidemiology in Russia: The results of 2003-2010 federal monitoring. Cardiovascular Therapy and Prevention 10(1): 3-7.

2. Rumyantseva SA, Oganov RG, Silina EV, Stupin VA, Bolevich SB, *et al.* (2012) Modem treatment strategies in patients with vascular comorbidity Part 1. Correcting tissue energy deficiency. Cardiovascular Therapy and Prevention 11(6): 44-49.

3. Sturkenboom MCJM (2005) Prevalence and treatment of hypertensive patients with multiple cardiovascular risk factors in Italy. Pharmacoepidemiology and Drug Safety 14(2): 48-49.

4. Guidelines Committee (2003) European Society of Hypertension – European Society of cardiology guidelines for the management of hypertension. Journal of Hypertension 21: 1011-1053.

5. St. Jude Medical acquires CardioMEMS and announces FDA approval of heart failure (HF) monitoring technology. (Date Views 10.06.2014, www.cardiomems.com/content.asp?display=news&view=20).

6. The CardioMEMS Champion™ HF Monitoring System for Patients with NYHA Class III Heart Failure Executive Summary for the Circulatory Systems Device Panel Advisory Committee, December 8, 2011. (Date Views 25.06.2014,

www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM281514.pdf).

7. No batteries required. Microscale medical sensors inserted under the skin can be powered wirelessly by an external handheld receiver, Published online 27 March 2013. (Date Views 25.08.2014, www.research.a-star.edu.sg/research/6651).

8. Cheong JH, Ng SS, Liu X, Xue RF, Lim HJ, *et al.* (2012) An inductively powered implantable blood flow sensor microsystem for vascular grafts. IEEE Transactions on Biomedical Engineering 59(9): 2466-2475.

9. Myslewski R (2012) Boffins build blood-swimming medical microbot set for a fantastic voyage through your veins, Feb 25, 2012. (Date Views 21.08.2014, www.theregister.co.uk/2012/02/25/autonomous_implantable_robot).

10. Pivonka D, Yakovlev A, Poon F, Meng T (2014) A mm-Sized Wirelessly Powered and Remotely Controlled Locomotive Implant. (Date Views 17.08.2014, www.stanford.edu/~adapoon/papers/tbcas12.pdf).

11. Cleven NJ, Müntjes JA, Fassbender H, Urban U, Görtz M, *et al.* (2012) A novel fully implantable wireless sensor system for monitoring hypertension patients. IEEE Transactions on Biomedical Engineering 59(11): 3124-3130.

12. Fiala J (2013) An implantable optical blood pressure sensor based on pulse transit time. Biomedical Microdevices 15: 73-81.