

Prospects and clinical effectiveness of remote blood pressure monitoring

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Objective

To assess the clinical effectiveness and prospects of remote ambulatory blood pressure (BP) monitoring in patients with hypertension (HTN).

Materials and methods

The study enrolled 100 patients with uncontrolled HTN who performed self-measured blood pressure monitoring twice daily using the devices with the option of transmitting measurements to the remote monitoring center via a GSM channel. The information was processed and then transmitted to the physician's personal account in order to assist clinical decisions.

Results

Over the 6-month observation period target blood pressure levels of 135/85 mmHg were achieved in 70% of patients. In most cases antihypertensive therapy was corrected by changing the drug dosing or increasing the number of medications.

Conclusion

Remote blood pressure monitoring is an effective and reliable way to control blood pressure.

Keywords: *arterial hypertension, blood pressure, telemedicine, remote monitoring.*

Conflict of interests: None declared.

Blood pressure monitors with GSM communication were provided by LLC 'Remote medicine' free of charge.

Received: 11.04.2020

Accepted: 20.05.2020

Introduction

Hypertension (HTN) is the leading risk factor (RF) of premature death and the main cause of disability worldwide. The prevalence of HTN rises with age and is especially high in older age groups, where HTN co-exists with other comorbidities. Uncontrolled HTN is associated with the development of cardiovascular events such as cerebrovascular events, myocardial infarction and sudden cardiac death [1, 2].

At the same time, according to the results of some epidemiological studies, traditional management of patients with HTN is still insufficient to reach target blood pressure level. According to the study of epidemiology of cardiovascular disease and its risk factors in various regions of Russia (ESSE-RF), only 1/3 of women and 14,4% of men reach target blood pressure level [3]. Data from the outpatient registry of cardiovascular disease in Ryazan Oblast showed that in only 25,6% of patients blood pressure <140/90 mmHg was reached [4]. The similar tendency was noted in other studies [2].

Obviously, the common methods of outpatient HTN management are not effective enough. The reasons of insufficient HTN treatment effectiveness include poor treatment adherence and blood pressure control, irrational utilization of healthcare resources and incomplete outpatient management [5–7]. Today, incorporation of telemedicine technologies in the general medical practice seems like a perspective method of improving the effectiveness of patient management [7, 8]. We suppose that use of the devices with the option of transmitting blood pressure measurements to the remote monitoring center via a GSM channel (tonometers) will improve blood pressure control and reduce the load on medical professionals.

Materials and methods

The study was conducted according to the principles laid down in the Helsinki declaration and Good Clinical Practice standards in Ryazan City Clinical Hospital № 11 and Ryazan State Medical University.

Study protocol was approved by the Ethics Committee of Ryazan State Medical University. Remote blood pressure monitoring was performed according to the protocols accepted by the Ministry of Health of Russian Federation: "The Protocol of Incorporating Remote Blood Pressure Monitoring in Patients with Hypertension in Compulsory Medical Insurance" [9] as well as the guidelines "Outpatient care in chronic non-communicable diseases and in patients with a high risk of its development. Methodology of remote outpatient care" [10].

Telemedical monitoring of patients with HTN was performed with the assistance of LLC "Remote medicine", on site of which the Remote Monitoring Center (RMC) was organized. In the RMC we formed an automated system of telemedical monitoring that included the software-hardware complex. The RMC performed remote monitoring of patients that consisted of blood pressure control, collection, storage and processing of the collected figures, provided round-the-clock informational support of the patients and medical workers as well as online access to the remote telemedical monitoring program for physicians.

Our study included 100 patients with HTN whom LLC "Remote medicine" provided with the blood pressure monitors with GSM communication free of charge. The leading coordinators of the outpatient monitoring were the physician and the RMC operator. The operator worked in the RMC for 24 hours and provided continuous informational phone support for patients and physicians. The physician organized re-

mote monitoring, adjusted the program according to the assigned criteria and then, based on the collected data, decided whether to make any changes in the patient management.

The physician and the operator registered in the RMC Web-interface and gained access to the personal account and a planning tool (planner) before the monitoring started. The planner collected, processed and interpreted any 'events' received from the remote monitors. The events included any medical or non-medical episode that required specific actions determined by the protocol. Medical episodes included any clinically significant events that required actions from the medical workers. Non-medical events included the absence of blood pressure readings. Information about the absence of blood pressure readings was transmitted to the RMC operator's planner and the operator immediately called the patient and recommended resuming blood pressure monitoring.

All medical episodes were divided into three categories based on their urgency. Episodes were assigned to the first category if the blood pressure level increased over 179/109 mmHg or decreased below 80/50 mmHg. If the operator registered such episodes, he contacted the patient and advised him to take the medications that were recommended by the physician or to call the ambulance. The physician, in turn, made decisions concerning the patient's management during the next two days. Target blood levels were from 134/84 mmHg to 110/70 mmHg. Readings between 135/85 mmHg to 179/109 mmHg or from 111/71 mmHg to 80/50 mmHg were considered to be in the "grey zone".

The inclusion criteria were:

- (1) Age 25–75 y.o.;
- (2) Assignment to the Ryazan City Clinical Hospital № 11 provided by the Compulsory Medical Insurance;
- (3) Office blood pressure readings > 134/84 mmHg;
- (4) The ability to perform blood pressure measurements using the remote monitors;
- (5) Residence in the area with good GSM signal.

The exclusion criteria were:

- (1) Inability to perform blood pressure measurements due to forms and/or features of the co-existent diseases;
- (2) Absence of blood pressure measurements or contact with the patient;
- (3) Non-compliance to the recommendations given by the physician or operator during telemedical monitoring.

At the first visit all the participants signed informed consent, blood pressure monitor use agreement

and consent to the processing of personal data. The physician explained the need to perform the remote telemedical monitoring, the goals, objectives and expected results of the study in an easily understood form. At the first visit the physician also stated the diagnosis based on the physical exam results, medical history and available medical documents that the patient provided. The antihypertensive therapy was then recommended or corrected. The diagnosis, age and gender were registered in the special form in the physician's personal account using the Web interface. Prior to beginning the study all physicians received detailed instructions on how to use the tonometers with an option of transmitting measurements to the remote monitoring center via a GSM channel.

During the telemedical monitoring all the participants performed three blood pressure measurements twice a day using the provided monitors. Then, all measurements were automatically transmitted to the physician's and operator's planners via the GSM channel.

The patients visited office once in two months. They could also contact their provider any time if they had any complains or questions. Antihypertensive therapy could be corrected both during the office visits and via phone calls. However, medication regimen could be corrected via phone only if the dosages that were corrected were previously prescribed on an in-person visit. Remote blood pressure monitoring was performed for 6 months.

The statistical analysis was performed using the Statsoft Statistica 10.0. Numerical and categorical variables were presented as absolute and relative figures [n (%)], and the relative variables were presented as mean and standard deviation ($M \pm m$). The Shapiro–Wilk test was used for evaluating whether the observations deviated from the normal curve. We used Student's t-test to determine if the means were significantly different from each other. Two unrelated groups of categorical variables were compared using Pearson's χ^2 test and Fisher's exact test. A p-value less than 0.05 was considered statistically significant.

Results

Our study included 100 patients (77 women and 23 men). All patients had hypertension and did not reach the target blood pressure levels with the traditional outpatient management. The mean age was $59,5 \pm 7,8$ years.

The analysis of risk factors and associated clinical conditions showed that 17% (n=17) of the included individuals had objective signs of end-organ damage,

but no symptoms or associated loss of function; 83% (n=83) had both signs and symptoms of end-organ damage. Of all the patients 33% (n=33) had stage 1 hypertension and 54% (n=54) had stage 3 hypertension. Stage 3 hypertension was diagnosed only in 3% (n=3) of the patients included in the study; 10% (n=10) patients had prehypertension (high normal blood pressure) on the first office visit. We stratified all the patients by the cardiovascular risk and found that the majority of patients had high (32%; n=32) or very high (65%; n=65) cardiovascular risk. Three patients (3%) had moderate risk.

During our study period no monitor defects or malfunctions were observed. All patients completed the study.

After 6 months of remote monitoring target blood levels were reached in 70% (n=70) of patients. By the end of the study the number of patients with high normal blood pressure increased from 10% (n=10) to 19% (n=19); $p=0,7$; the number of patients with stage 1 and stage 2 decreased from 33% (n=33) to 7% (n=7); $p<0,001$ and from 54% (n=54) to 3% (n=3); $p<0,001$ respectively. The number of patients with stage 3 hypertension decreased from 3% (n=3) to 1% (n=1); $p=0,6$ (Figure 1).

During the remote monitoring we corrected antihypertensive pharmacological therapy mainly by increasing the number of medications as well as recommending fixed-dose combination. Of note is that this strategy seemed clinically justified. Compared with just increasing the dose of one drug, the use of fixed-dose combination of several antihypertensive medications from the different pharmacological classes decreases adverse effects of each drug in a combination and results in a tighter control of blood pressure. Moreover, the use of combination drugs

significantly improves adherence to therapy and that, in turn, leads to better effectiveness of treatment [2].

After the period of remote monitoring was completed, all patients were offered to continue antihypertensive therapy. The comparison of the number of medications prescribed is presented in Table 1.

Table 1. The number of prescribed medications before and after remote monitoring

Number of antihypertensive drugs	First visit	+ 6 months	p
No medications	7	-	-
1 medication	23	8	0,006
2 medications	45	30	0,03
3 medications	17	38	0,001
4 and more medications	8	24	0,003

As can be seen from Table 1, the number of patients who received 3 and 4 and more medications increased over the 6 months of observation. At the same time, the number of patients receiving 1 or 2 medications decreased.

The pattern of antihypertensive drugs prescriptions is presented in the Table 2.

Table 2. The pattern of antihypertensive drugs prescriptions

Antihypertensive drugs	First visit	+ 6 months	p
Angiotensin-converting-enzyme inhibitors	53	53	1,0
Angiotensin II receptor blockers	35	33	0,8
Diuretics	38	59	0,001
Calcium channel blockers	36	52	0,001
Beta-blockers	28	53	0,001
Other classes	10	14	0,9

As can be seen from Table 1, after the 6-month monitoring period was completed, the number of patients receiving angiotensin-converting-enzyme in-

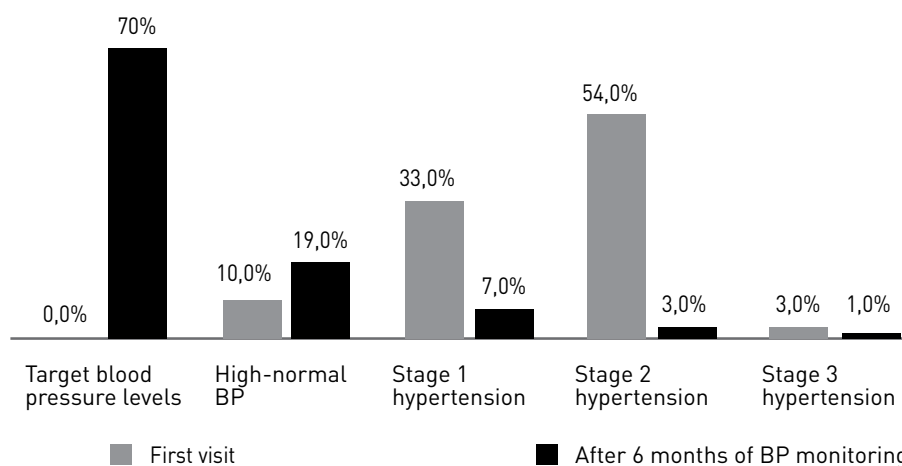


Figure 1. Blood pressure levels at the first office visit and after 6 months of monitoring

hibitors and angiotensin II receptor blockers stayed the same but more patients were prescribed diuretics, calcium channel blockers and beta-blockers.

At 6 months of remote monitoring the number of patients receiving fixed-dose combinations significantly increased from 19% (n=19) to 33% (n=33), $p=0,02$.

Of all the patients, 30% (n=30) didn't reach target blood pressure levels. Adverse effects occurred in 13% (n=13) and included dizziness and hypotension. We decided to change target levels to high normal blood pressure in these patients with the plans to reach normal blood pressure in the future. In 17% of patients target blood pressure levels were not reached despite the use of three or more drugs. Considering that these patients were fully compliant and followed all recommendations given by their provider, they can have refractory hypertension.

Discussion

After a 6-month period of remote blood pressure monitoring 70% (n=70) of patients reached target blood pressure levels (<135/85 mmHg). The use of telemedical technologies offered the opportunity to correct antihypertensive therapy according to the latest clinical guidelines and resulted in better blood pressure control. Also, over the monitoring period, the number of antihypertensives prescribed (both separate medications and fixed-dose combinations) markedly increased.

There are some earlier studies of telemedical blood pressure control in the Russian Federation. In one study, the patients sent their blood pressure readings via text messages that were further processed by a special software [11, 12]. In other studies, the patients sent their blood pressure readings via e-mails or text messages for a year [13].

The method of remote blood pressure monitoring that we used in our study uses the device that sends blood pressure figures automatically and doesn't require the patients to know how to write and send e-mails or text messages. That alleviates all the incon-

veniences for the patient and is crucial for effective management of older patients. Moreover, according to the conditions of the current study, an operator who controlled blood pressure changes, managed the complete absence of blood pressure readings and contacted the patients by phone also took part in the remote monitoring. This allowed to decrease the load on physicians who only had to make decisions concerning any changes in the patient's management. The operator also contacted the patients if he identified high blood pressure levels and recommended to take the prescribed medications or to call for an ambulance. Together it all helped to avoid disturbing the physician when he/she was off work but at the same time the patients were provided with medical help.

One specific feature of telemedical monitoring is that the patient doesn't need to decide to contact the physician himself/herself, but the physician chooses how and when to contact the patient based on the objective monitoring results. As such, the tactics for decision making concerning the 'physician-patient' contacts changes significantly. Usually the patient himself determines whether he/she needs to see the doctor, and the remote monitoring made it possible for the physician to determine the need of the visit and that, in turn, helps to provide more effective blood pressure control. Obviously, the incorporation of telemedical monitoring will offer the opportunity to decrease the cardiovascular disease prevalence and mortality and help reduce the load on medical workers.

Conclusion

Remote blood pressure monitoring in patients with hypertension for a 6-month period helped to reach target blood pressure levels in 70% of patients. This method of remote blood pressure monitoring using the blood pressure monitors with GSM communication is easy to use both for patients and physicians.

Conflict of interest: Blood pressure monitors with GSM communication were provided by LLC 'Remote medicine' free of charge.

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