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Research Article

Digital Model's Structure Andremote Patient Monitoring in Respiratory Medicine

Vitaliy Mishlanov[1]*, Alexander Chuchalin[2], Valeriy Chereshnev[3], Ekaterina Koshurnikova[1], Ksenia Bekker[1], Veronique Emelkina[1] and Igor Shubin[2]

[1]E.A. Vagner, Perm State Medical University, Perm, Russia

[2]N.I. Pirogov National Research Medical University, Moscow, Russia

[3]Institute of Physiology and Immunology, Ural Branch of the Russian Academy of Science, Ekaterinburg, Russia

Summary

Digital regression models based on an interactive questionnaire and objectively measured results were used for the investigation of new objective methods of remote monitoring of respiratory patients. 43 patients with COPD and 26 with bronchial asthma were examined in a retrospective-prospective observation study before and after exacerbation in the hospital (the first observation). After that, theywere monitored by a digital system with an interactive questionnaire including results of Smart Watch use and a velometric test at home for at least 6 months. The effectiveness of remote patient monitoring was achieved by changes in the treatment program and rehabilitation. An integrative scale for patient monitoring effectiveness evaluation was used for a comparison study before and after remote monitoring wasstarted (historical control). The results of correlation, regression analysis, and OR calculation showed that new monitoring parameters: velometric test distance, daily steps count, night sleep duration, and the number of night awake ups were dependent on the dyspnea score and FEV1. The system of remote patient monitoring based on a digital model decreased the number of calls for emergency medical care, hospitalizations, and increased the effectiveness score of patient monitoring.

More Information

***Address for correspondence:** Vitaliy Mishlanov, E.A. Vagner, Perm State Medical University, Perm, Russia, Email: permmed@hotmail.com

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Keywords: Respiratory disease; Digital models; Regression analysis; Interactive questionnaire; Smart watch; Velometric test; Effectiveness score of patient monitoring

Introduction

Digital models have become very popular in different fields of medicine. We can subdivide medical tasks to be solved by using digital models into two main groups: diagnostic and prognostic ones. From the mathematical point ofview, they correspond to regression models and network models. Multilayer, deep networks and recurrent neural network-based models are effective inimage diagnostics, treatment planning, and othermedical tasks solving based on a prognostic approach, but not so well in clinical diagnostic ones [1-5]. A lot of publications have confirmed the diagnostic accuracy of regression models [6-11]. It was early postulated that more than 200 parameters are needed for an accurate diagnostic model, and the accuracy can reach up to 95% - 96%, but not in all studies[12]. In 2011, we constructed a PC program for diagnostic purposes, which includes 6 different modes, and the respiratory one among them [13]. The whole program consists of more than 20,000 coefficients. The program was approved for more than 11,000 patients of respiratory, cardiovascular, nephritic, gastroenterological, hematological, and oncologic branches [14-21]. The principle of decision making consists of an interactive questionnaire, a personal patient's model constructedin parallel to the process of questionnaire using, and an automatic comparison of the patient's model to the disease model. The result is the ratio of compared signs in percent. The system can analyze both subjective clinical signs and objective ones, for example, spirometry data or X-ray data, or others [18,22,23]. But remote patient monitoring requires a new approach to patient status examination, excluding such methods as ultrasound, CT, MRI, and even spirometry at home. A physician needs new criteria for patient status evaluation. Some of them were suggested duringthe last decades, for example, daily step count, regular pulse oximetry, sleep quality parameters, and others.The question is whetherwe can include some new parameters in the diagnostic digital model for remote patient monitoring? What is the clinical significance of them, and what coefficient can we use in a regression model?

The study aimed to incorporate new parameters, registered by a smart watch and exercise bike, into a remote patient monitoring system based on digital models.

Material and methods

There were 69 patients with chronic obstructive pulmonary disease (COPD, 43 patients) and bronchial asthma (BA, 26 patients). The study was conducted in the pulmonological department of the Perm clinical hospital №4 (Perm, Russia), which has 50 hospital beds, and about 20 of them are for patients with bronchial obstructive diseases. We included patients with special criteria for 6 months, and the total number of examined patients was 134 (56% of patients with bronchial obstruction, and 87% of patients with spirometric criteria of COPD or BA).

All included patientswere examined first in the hospital during 5-7 days after admission, with moderate exacerbation. The treatment program included NIV or oxygen therapy in addition to short-acting beta2-agonists, systemic corticosteroids, and, in some cases, antibiotic therapy was administered.Following examination was performed distantly bythe severity of patient status: more severe patients were examined every week, moderate ones were examined every 1 - 3 months,and not severe ones were examinedin 6 months. The age of the patients was 45 - 85 years. 43 men and 26women were included. The prospective-retrospective observation design of the study was used (Figure 1).

Traditionally patients with COPD were administered systemic corticosteroids (SCS) up to two weeks after hospital discharge withdrawn slowly in the next 2 - 4 weeks bythe severity of patient status and they were under the triple inhaled therapy (inhaled CS + Long acting beta2-agonist + Long acting anticholinergic drug), then we tried to reject ICS and prolong double bronchodilatatorintake plus physical rehabilitation. Patients with BA were discharged with a recommendation of SCS use and triple inhalation treatment, with slow abolishment of SCS bythe severity of the patient's status.

Retrospective and prospective comparison analysis

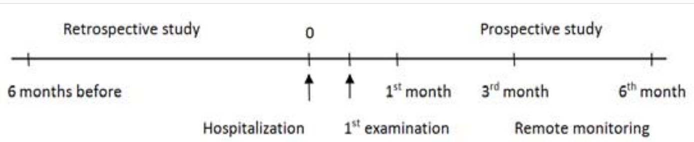

Figure 1: Design of the study.

included results of several polyclinic or ambulatory visits, several ambulance calls, several hospitalizations, and cases of fatal end.

Including criteria: moderate or severe COPD in the phase of moderate exacerbation, moderate, severe or very severe BA in the phase of moderate or severe exacerbation, age of 45 - 85 years, with presence of comorbidities including arterial hypertension of the 2^{nd} stage, 1-2 grades of blood pressure increasing, or/and coronary heart disease with coronary stenting in the past with chronic heart failure (CHF) of the stage "C" by classification of the American College of Cardiology (ACC) and the American Heart Association (AHA)), with preserved ejection fraction of Left ventricle, and 1-4 function class (FC).

Excluding criteria: negative criteria for COPD or BA, cognitive deficit, brain stroke in the past, psychiatric diseases, myocardial infarction in the past year, arrhythmic disorders, refractory arterial hypertension (AH), chronic kidney disease, diabetes mellitus, refusal to participate or to write down the informed consent.

Special examination program included: interactive questioning (IQ), spirometry, Echocardiography, proBNP test, 6-minute walk test (6-MWT), pulse oximetry, smart watch usage, velometric test (VMT).

IQ consists of a PC program "Electronic Polyclinic" using [13], which is placed on the Internet. Secondary testing takes about 5 minutes. We used coded access to the personal data and a depersonalized approach to store the results. The PC program constructs personal digital model at the time of testing based on subjective and objective data (more than 200 parameters are analyzing at the first time and more than 30 every secondary testing) then it compares this model with syndrome and nosological digital model and presents results in the form of a table to compare previous and last results,so called personal clinical register. The patient can view only the result of testing and automatically constructed recommendations. A physician can view the result and a table of questions and answers for a patient. A teleconsultation was performed after IQ finished to explain further the clinical tactic.

Spirometry with a salbutamol test was performed with Microlab spirometry.

6-MWT [24] was performed only oncebefore patient discharge to compare the data with the results of VMT and smart watch use.

Smart watch (AmazfitBip U Pro A2008) allows to analyze the number of meters in the 6-MWT as well as daily work distance, the number of steps in the 6-MWT and in 24 hours, the sleep time at night and during the day, sleep phases time, the number of night wake-ups, and tissue oxygen saturation.

A pulse oximeter (*Fingertip Pulse Oximeter LK87*) was used to evaluate the accuracy of smart watch testing.

VMT was performed using velotrainer Thera-trainer Mobi, which is compact, perfect to patient physical rehabilitation at home and contents monitor to visualization of the results which stimulates a patient to reach more in his perfect status. We used Bluetooth to transfer the results of the training from velotrainer to the Smartphone.

We evaluate the usefulness and applicability of the patient monitoring system using the System Usability Scale (SUS) [25].

To evaluate the results of remote patient monitoring we used integrative scale of dyspanser effectiveness which was calculated by the next equation E = P + 3A + 5H + 10L, were: E – effectiveness of remote patient monitoring (dyspanser monitoring effectiveness), P – some polyclinic or ambulatory visits per year, A – several ambulance calls per year, H – several hospitalizations per year and L – a case of fatal end.

To estimate factors of medical service to mortality, 30 electronic patient cards of not monitored and died patients with COPD (5 – GOLD stage II, 29 – III, and 6 – of the IV stage) of equal characteristics of age, sex, dyspnea severity, and comorbidities were analyzed.

Statistics were performed using the program packages Statistica 10.0, SPSS, and MedCalc. Examinant data were presented as Mean and standard deviation (M ± σ), Median, 10% and 90% of the variable range. The significant difference was approved by Chi square, Mann-Whitney, and McNemar tests when p was < 0,05. Spearman correlation test, regression analysis, classification tree analysis, and OR calculation were used,and OR was presented as Me value and confidence intervals (CIs).

Results

83% of included patients with bronchial obstructive diseases had arterial hypertension, 26% - ischemic coronary disease complicated by CHF with certain changes of EchoCG parameters. Patients examined before hospital discharge had a restricted 6-minute work distance at 378,5 ± 110,06 (Me = 390,0; 10% = 210,0; 90% = 530,0) m. In the whole group 3% had 0 f.c. of chronic heart failure (CHF), 33% - 1 f.c., 44% - 2 f.c., 16% - 3 f.c., and 4% - 4 f.c. Mean proBNP level consisted of 159,3 ± 213,24 (Me = 61.0; 10% = 13,0; 90% = 404,0).

Smart Watch registered compared results in metersin 6-MWTwith the traditional method,with a correlation coefficient r = 0,9475 (p < 0,0001). The number of steps was correlated with 6-MWT distance (r = 0,9155, p < 0,001) as well as the 24-hour count of steps (r = 0,5426, p = 0,0002). Moreover over all these parameters were correlated with the severity of dyspnea calculated asmMRC score, not only in hospital but also at home, taken into account by IQ (Table 1). The forced expiratory volume in 1 second (FEV1) measured after salbutamol was taken was correlated with the result of 6-MWD as well as with 24-hour meters of work distance and count of steps (Table 2). Regression analysis confirmed the influence of the dyspnea severity and FEV1 on the 6-MWD and 24-hour count of steps. The mean value of the SUS test related to Smart Watch use was 66,7 ± 16,63 (the maximum is 100) due to poor vision and complicated choosing of the window with needed information.

IQ with a regression digital model of data analysis demonstrated good results,adjusted for patient distant monitoring. They help a physician to reveal some unfavorable symptoms needed in not unplanned patient examination to register mild exacerbation (fever, increased cough, sputum production, dyspnea,fatigue, exercise intolerance, chest pain, and some others). The period of testing was variable by patient health status (oncein 6 months in stable status of mild disease, up to once a week just after exacerbation in severe or moderate patients). Results of reviewing more than 1000 distant COPD patient monitoring using the PC program “Electronic polyclinic”, which contained positive results on exacerbation recurrence and patient mortality,were published previously [20,26,27]. But in this study, we have used SUS to evaluate the patient point of view on this method and unfortunately did not excellent result. The mean value of the SUS test was 76,1 ± 12,15.

VMT was comfortable and usable for patients. It helped the patient training quadriceps and diaphragm muscles and to improve himself status (decreasing a dyspnea), then a patient viewed his best result of regular testing and was stimulated to compliance with a physician and participation in the treatment program. The SUS mean value was 74,9 ± 18,73 (Me = 75,0; 10% = 68,0, 90% = 78,0).

We had compared the results of 6-MWT and VMT in patients with different CHF f.c. (Table 3).

Table 1: Correlation coefficients of different tests with the mMRC characteristic of dyspnea.

Parameters	r	p
6-MWT (m)	-0,5017	0,0005
6-MWT (steps)	-0,4249	0,0036
24-hour work distance (m)	-0,4166	0,1084
24-hour work distance (steps)	-0,5504	0,0001

Table 2: Correlation coefficients of different tests with the FEV1 absolute value after salbutamol taken.

Parameters	r	p
6-MWT (m)	-0,3993	0,0288
6-MWT (steps)	-0,5106	0,0039
24-hour work distance (m)	-0,7945	0,0035
24-hour work distance (steps)	-0,5381	0,0026

Table 3: The comparison results of 6-MWT and VMT in patients with different CHF f.c.

CHFf.c.	6-MWT (M±σ)	3-minute VMT (M ± σ)
1	485,0 ± 31,23	1700,0 ± 49,9 м
2	346,3 ± 33,51	1200,0 ± 101,1 м
3	248,5 ± 43,21	1140,0 ± 272,64 м
4	94,0 ± 29,66	933,3 ± 331,16 м

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VMT demonstrated poor results in differential diagnosis between 2nd and 3rd f.c. as well as 3rd and 4th f.c. of CHF, but had good correlation with 6-MWT (*r* = 0.4668, *p* = 0,0247). Mean value of VMT in the whole group was 1260,9 ± 334, 38 (Me = 1300; 10% = 750, 90% = 1700) m.

Using Classification tree analysis, we constructed a classification of 3 groups of FC of exercise intolerance based on VMT results (Table 4).

Table 4: Classification of VMT classes of exercise intolerance.

FCofexerciseintolerance	Distance of velotrainer performance (m)
I	1500 m and more
II	from 1200 up to 1499 m
III	1199 m and less

All patients were monitored for at least 6 months. We calculated the number of physicians' visits, calls for emergency medical care, hospitalizations, and cases of death. We had any cases of patient death?To calculate the effectiveness of patient monitoring, we suggested a scale that includes all medical events in a year and used special coefficients: for a physician visit, 1, for a call for emergency medical care, 3, for hospitalization, 5, and 10 was used for the case of death. Then the sum of scores was calculated for every patient. We found that the main significant factors influencing the effectiveness of monitoring were: mMRC score, FEV1% after salbutamol intake. Regression analysis showed b = 0,17, *p* = 0,0039 and b = -0,32, *p* = 0,0001, correspondently. Secondary monitoring evaluation demonstrated the same data with the correlation of dyspnea severity, mMRC score, Borg score, as well as the number of steps in 24 hours and duration of night sleeping, the number of night awake ups, and the result of 6-MWT in steps with the sum score of monitoring effectiveness and the number of hospitalizations per year.

All the parameters presented above were input into a digital model of regression analysis. As well as in our previous studies, the digital model mostly consisted of subjective data froma questionnaire. A patient chose, as usual, his traditional characteristics (about 35 by the nosological form), but in every case, he can include other clinical signs (up to 250) which can help a physician to suppose other complications, side effects of the drug, or comorbidities. In this study, the system was added by VMT result, daily step count, duration of sleep time and sleep phases, night awake ups, and others. Remote patient monitoring after hospital discharge aimed to check the time point when a patient's health status would rather best to change the long-term treatment program to exclude SCS first and to change the triple COPD inhalation therapy program todouble bronchodilator in the progress of positive dynamics. In a patient who doesn't have positive dynamics, the aim of remote patient monitoring consists of early patient examination to correct the diagnosis and to choose a proper treatment. The final aim of the presented monitor system is to prevent patient death and to reduce the number of exacerbations and hospitalizations.

In the monitored group, the number of calls for emergency was 0,1 ± 0,18 and the number of hospitalizations – 0,2 ± 0,32. We hadn't fatal cases in our group of monitored patients in 6 6-month period. The integrative score of monitoring effectiveness was 2,6 ± 1,35 (Me = 2,0; 10% = 0,0, 90% = 6,0). Retrospective analysis showed a decreaseincalls for emergency medical care by twice, a significant decreasing number of hospitalizations,but not inpatients' visits to a physician. The design of the study can't reveal the influence of remote patient monitoring on lethal cases.

Toestimatefactors of medical serviceto mortality, 30 electronic patient cards of not monitored and died patients with COPD (5 – GOLD stage II, 29 – III, and 6 – of the IV stage) of equal characteristics of age, sex, dyspnea severity, and comorbidities were analyzed.Patients were characterized by frequent calls to an ambulance and hospitalizations. The doctor's visits were 7,9 ± 7,51 (Me = 7,0; 10% = 0, 90% = 15,5); calls for emergency medical care – 6,5 ± 14,2 (Me = 2,0; 10% = 0, 90% = 14,5); hospitalizations – 2,1 ± 1,81 (Me = 2,0; 10% = 0, 90% = 4,0). The integrative score of monitoring effectiveness was 37,9 ± 47,1 (Me = 22,0; 10% = 8,0, 90% = 77,5). The most crucial risk factors for mortality were the number of calls for emergency therapy, more than 2, and the number of hospitalizations, more than 2 per year. 2 or more calls for emergency care per year increased mortality by 3,4 times (CI:1,8; 5,0) and 2 or more hospitalizations by 4,8 times (CI:2,4; 6,3).

Discussion

COPD and uncontrolled asthma remain life-limiting factors. They are characterized by comorbidities and are frequently associated with CHF. Remote patient monitoring suggested as a technique for exacerbation and hospitalization prevention. Many studies confirmed positive results of remote monitoring, but mostly due to the rehabilitation program. The questions for medical care development include the discussion of methods of monitoring, criteria for medical decision making, and recommendations for long-term treatment and rehabilitation programs.

Our study aimed to investigate new parameters registered by a smart watch and exercise bike in a remote patient monitoring system based on digital models.

Digital models are not traditional in clinical practice, but have been proposed for many years.In our previous publications, the sensitivity of syndrome and nosological diagnostics,which was performed by IQ, was revealed as 82% - 87% and itsspecificitywas 76% - 96% for different pathologies [26]. The system is based on regression models and isn't recommended for the prognosis of the disease progression or treatment effectiveness. It includes only treatment recommendations from the National ClinicalGuidelines as a help system for clinical decision-making. This system helps us to compare the effectiveness of different clinical criteria and treatment programs. It was published before that this monitoring system, added by analysis of patients' electronic medical card (in Russia, the Unique State information digital medical system is used) and remote video consultations on demand, reduced mortality in the Perm region up to 15% - 35%in the group of COPD patients severity [27,28].

This study revealed high practicability ofsuch new monitoring parameters using including a result of VMT, daily step count, night sleep duration, the number of night's awake ups, as well as analysis of every call for emergency care, every hospitalization that suggestsan ineffective long-term treatment program. Some of listed above methods were presented before, for example: reducing the number of steps taken less than 5000 per day [29,30], the ratio of time spent in bed or chair to walking time, the duration of night sleep, the number of awake ups, the ratio of the phase of shallow and REM sleep, respiratory rate, oxygen saturation in tissues and its dynamics during sleep, under the influence of physical activity, heart rate and respiratory rate, etc. [9,31-36], decrease in total nighttime sleep or frequent awake ups due to shortness of breath [37-39], an increase in REM sleep [40], a decrease in oxygen saturation in tissues less than 93% at rest or more than 50% of observation time, or 50% of sleep time were suggested as additional criteria for remote patient monitoring too [41].

The restriction of the study may be caused by the limited number of included patients for remote monitoring. But most of the suggested criteria were used in other studies before, and the novelty of this study consisted in the method for evidence, first of all in the mathematical method (regression model), where each of the diagnostic criteria has a specific coefficient. Additionally, we suggested a new integrative scale for patient monitoring effectiveness evaluation,which included the number of polyclinic or ambulatory visits per year, the number of ambulance calls per year, the number of hospitalizations per year, and the incidence of fatal end.

We can also confirm that the specificity and number of monitoring parameters are very significant for the result. The retrospective comparison analysis showed that the best results had been achieved if the number of registered parameters was 30-50 [26].

Conclusion

The study was devoted to investigating new objective parameters as a component for regression patient model construction for patients with chronic obstructive pulmonary disease and bronchial asthma.Assumed regression digital models consisted of subjective and objective data,and demonstrated a perfect result in remote patient monitoring. Among other subjective data, the characteristics of severity and specificity of dyspnea were the most favorable, and such objective data as a result of velometrictest distance, daily step count, night sleep duration, and the number of night awake ups were very important in monitoring patients with bronchial obstructive diseases. Two or more calls for emergency medical care and two or more hospitalizations per year increased the risk of mortality in 3,4 (CI: 1,8; 5,0)and 4,8 (CI: 2,4; 6,3)times correspondingly.

Author contributions

Mishlanov V. Ju suggested the design of the study, analysis of the results, and paper writing, the author of the velometric test;

Chuchalin A.G. – General planning and conclusion making; Chereshnev V.A. – Consultation for the use of electronic devices and digital model construction; Koshurnikova E.P. – Patient examination; Bekker K.N. – Analysis of the clinical register of monitored patients; Emelkina V.V. – Patient's examination; Shubin I.V. – Retrospective analysis of electronic medical records.

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