

Review Article

Chinese Consensus Statements on Remote ECG Monitoring-Methods and Equipment (CCS-ON-RECGM)

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Abstract

On the 21st of August to November, 2014, experts met at Beijing China, under the Professional Committee of Cardiac Monitoring, China Medical Information Association (CMIA-PCCM) with the aim of establishing a round table that would allow specialists to consider the most appropriate current general actions to be taken when diagnosing and making appropriate treatment evaluation on patients who need to receive remote ECG monitoring. The 2016 Chinese Consensus Statements and Recommendations for Remote ECG Monitoring Instruments and Equipment is jointly drafted and modification by former and current chairman, secretary-general and expert committee members nationwide, also get CMIA-PCCM approval.

The core contents of CCS-ON-RECGM include: Progress of remote ECG monitoring, patient indications, appropriate instruments selection, the frequency of monitoring, ECG monitoring leads selection as while transmission mode consideration. briefly introduces the benefits and associated risks of remote ECG monitoring. Data storage, **access, comparison, analysis permission**, electronic signature, confidentiality and other issues. We believe that with the CCS-ON-RECGM clinical practice and technological development, further additions and modifications will be made to make contributions to remote ECG monitoring.

Keywords: Chinese; Consensus Document; ECG; Monitoring; Remote

Introduction

Population aging is a global phenomenon. Aged society has been posing not only medical, nursing and welfare problems, but also complex problems closely associated with economy, industry and culture. Older people often suffer from many diseases. Prevention and control of chronic diseases accounted for 80% of China's health care costs. An effective screening system carried out by a primary-care doctor, and privacy-preserving medical data sharing among hospitals and clinics are needed [1]. China has vast territory, accounting for 22% of the world's population, while medical and health resources accounts for only 2% of the world's 80% of hospital medical resources has been distributed in the city, while only 20% in rural areas. To reduce the length of stay in acute hospitals, to reduce the physical burden of health-care professionals working at acute hospitals and to meet the demand of older people who prefer to remain in their own homes, fostering of medical professionals' technical personnel and Family care who can provide Remote ECG monitoring especially for the oldest, Chronic disease surveillance and Health care population as while further promotion of home-based care is needed [2-5].

Through the telemedicine health management mode, the use of limited economic resources and expert resources is maximized, the advantages of information science and technology and ECG diagnosis technology are given full play, diagnosis and treatment training specifications as well as shared equipment standards for China's cardiac monitoring industry are established. Its purpose is to promote the prevention and early diagnosis of cardiovascular diseases, the rehabilitation and treatment of chronic cardiovascular diseases in China so as to strive for China's telemedicine and people's health undertaking. Remote cardiac monitoring course is rising all around the world and has been promoted to be used by communities, families and individuals [6]. In China, remote

cardiac monitoring course is thriving and developing rapidly by taking the technology express of Internet, big data and cloud platforms. Remote ECG monitoring makes Chinese high quality medical resources reasonable allocation as well helps to adjust the traditional hospital medical care to the community and family medical care transformation. CMIA-PCCM is an academic organization engaged in cardiac monitoring. It is dedicated to Chinese academic seminars, exchanges and cooperation, regulating cardiac monitoring level, vigorously developing new technologies, guiding and promoting the technicalization and standardization of cardiac monitoring and converting cardiac monitoring research findings to clinical applications. Experts and scholars are extensively contacted to comprehensively promote the theoretical research, technical innovation, standards establishment, application practice and international exchanges of cardiac monitoring [7]. On the 21st of August to November, 2014, experts met at Beijing China, under the Professional Committee of Cardiac Monitoring, China Medical Information Association CMIA-PCCM with the aim of establishing a round table that would allow specialists to consider the most appropriate current general actions to be taken when diagnosing and making appropriate treatment evaluation on patients who need to receive remote ECG monitoring. CMIA-PCCM drafted modified and approved CCS-ON-RECGM in 2016. We believe that with the CCS-ON-RECGM clinical practice and technological development, further additions and modifications will be made to make contributions to the clinical application of remote ECG monitoring [8-10].

Party I Monitoring Equipments

Instruments and equipment are the basis to carry out remote ECG monitoring, whose performance can directly influence the capability and quality of remote ECG monitoring service. While carrying out remote ECG monitoring, various medical units and medical experts shall select appropriate instruments and equipment according to different application scenarios and

service objects. It is worth to note that “monitoring” referred to here can mean “detection”, “monitoring” or “guardianship” in different applications. A complete set of remote ECG monitoring system is generally comprised of monitoring terminal, monitoring server and monitoring center. Based on our own knowledge and application experience, this chapter will make some suggestions on requirements for the above three equipment for your discussion and reference [11-15].

Monitoring Terminal Monitoring terminal is the “sensor” of remote ECG monitoring system and also the information provider of service. The followings shall be paid close attention to when selecting a monitoring terminal

Equipment Function

To understand whether the equipment is used for detection, monitoring or guardianship. Remote cardiac monitoring technology has been developed from remote ECG monitoring to remote blood pressure, remote blood sugar, remote blood oxygen, remote sleeping, remote respiration monitoring, remote cardiac failure, remote arrhythmia, remote pacemaker monitoring, etc.; Currently, there are common equipment such as ECG detection terminal (also called electrocardiographs), dynamic ECG monitor (Holter), real-time ECG monitor, etc. [16].

Number of Lead

To understand the number of lead. Single lead, double lead, 3-lead, 5-lead, 7-lead or 12-lead, 15-lead and 18-lead equipment shall be selected according to the application [17].

Monitoring Electrode

Currently, commonly seen monitoring electrodes for ECG monitoring terminals include patch electrode, suction ball electrode, clip-on electrode, wearable electrode, dry electrode, etc. Different monitoring electrodes shall be selected according to application scenarios (medical diagnosis, health monitoring), monitoring object, monitoring time, etc. [18].

Storage Time

There are various equipment on current market with tens of seconds of segment monitoring, tens of minutes of short-time monitoring, 24-hour monitoring and several days of continuous monitoring. Monitoring equipment with corresponding storage time shall be selected according to different application purposes [19].

Transmission Mode

Remote transmission function is a unique function of remote ECG monitoring terminals different from traditional ECG monitoring terminals. At present, there are many communication modes. Wired ones include USB, telephone transmission, local area network, broadband network; wireless ones include Bluetooth,

WIFI, GPRS/3G/4G, etc. Terminal equipment with different transmission functions shall be selected according to the actual operating environment, transmission distance, etc. [20].

Importance Indicators of ECG Monitoring Terminals

As apparatus and instruments, ECG monitoring equipment must meet requirements for equipment performance and safety prescribed in relevant national and industrial standards. The followings are important technical performance indicators worth paying attention.

Sensitivity: An important indicator measuring the capability of the equipment to respond to ECG signals. ECG signals are weak; therefore, monitoring equipment must be highly sensitive to be able to record distinguishable waveforms for signals of $50\mu\text{V}$ at least.

Noise level: An indicator reflecting the noise level of equipment, the lower the better. When the input end of ECG monitoring equipment has a short circuit, it is generally required that the noise level shall not exceed the peak value of $50\mu\text{V}$.

Frequency response: An importance indicator reflecting the passing capacity of signals. Considering baseline drift, power frequency, myoelectricity and other high- and low-frequency interference existed in the process of ECG monitoring process, high- pass and low-pass filter must be designed to filter out interference. However, the filter may also result in ECG signal distortion. For example, over high-pass cut-off frequency may result in ST waveform distortion; while below high-pass cut-off frequency may result in baseline drift and failure of filter. Similarly, over low low-pass cut-off frequency may result in passivation and distortion of R wave and other waveforms; while over low-pass cut-off frequency may result in high-frequency interference and failure of filter. In actual use, the high- frequency and low-frequency cut-off frequency of monitoring terminals for detection and diagnosis (such as electrocardiographs) shall be widened as much as possible, e.g. 0.05-120Hz; the high- frequency and low-frequency cut-off frequency of monitoring terminals for dynamic monitoring and real-time monitoring equipment shall be narrowed as much as possible, e.g. 0.05-35Hz [21].

Common mode rejection ratio: An important indicator reflecting the capability of equipment to reject common-mode signal and enlarge different-mode signal. Reducing noisy signal is very important in signal transmission. Common mode rejection ratio is the larger the better. For ECG monitoring equipment, the common mode rejection ratio is required to be larger than 80dB [22].

Input impedance: To reflect the equivalent impedance of circuit input end of equipment. Considering the relatively weak organism signal and high equivalent impedance, therefore the input impedance of equipment detection circuit is the higher the better.

For ECG monitoring equipment, the input impedance shall be at least larger than 3M.

Communication speed: An important indicator reflecting the data transmission capability of equipment. The communication speed is the higher the better. However, in actual use, appropriate transmission mode and communication speed shall be selected according to the volume of data to be transmitted and the service charge of telecommunication operator.

Safety performance: In addition to meeting general safety requirements in GB9706.1-2007, different types of ECG monitoring equipment shall also meet corresponding national and industrial safety requirements. The followings are parts of the national and industrial standards related to ECG monitoring equipment.

- GB9706.1-2007 Medical Electrical Equipment-Part 1: General Requirements for Safety;
- (2) GB9706.25-2005 Medical Electrical Equipment-Part 2-27: Particular Requirements for the Safety of Electrocardiographic Monitoring Equipment.
- GB10793-2000 Medical Electrical Equipment-Part 2: Particular Requirements for the Safety of Electrocardiographs.
- YY 0782-2010 Particular Requirements for the Safety of Single-lead and Multi-lead Electrocardiographs.
- YY 1139-2000 Single-lead and Multi-lead Electrocardiographs.
- YY 0828-2011 Cable and Lead Wire of ECG Monitor.

Part II Monitoring Methods

- Expert Suggestions and Purposes of Remote ECG Monitoring These suggestions set forth issues related to the methods of remote ECG monitoring, clinic application, precautions as well as instruments and equipment. Standardized suggestions are made for various chronic diseases affecting the heart, electrocardiographic abnormality endangering the heart, rehabilitation needs and clinical needs of electrocardiogram monitoring. They are intended to help doctors reasonably select remote ECG monitoring instruments, apply correct application methods, determine monitoring frequency and confirm analysis results; help patients save medical cost, improve capital efficiency and provide basis for medical insurance.
- Definition of Remote ECG Monitoring Remote ECG monitoring applies modern transmission technology to realize long-distance transmission of ECG information recorded by an electrocardiogram machine to the ECG diagnosis center, where the information is analyzed in real-time and then the result is sent back to the patient and doctor in charge, so that

electrocardiographic abnormality can be found timely and subsequent treatment can be contacted when needed.

- Process and Method of Remote ECG Monitoring Remote ECG monitoring needs to set up the remote ECG monitoring center, lay several ECG monitoring channels and terminals and install the ECG monitoring system.

Monitoring Server Monitoring server is the “communication center” and “data center” of remote ECG monitoring system and also the bridge of service. Monitoring server generally consists of communication server, data processing server, WEB server, database, file server, etc. The communication server is mainly responsible for data receiving and forwarding; the data processing server is mainly responsible for data processing; the database and file server are mainly responsible for the storage of various information and data; WEB server is responsible for the alternative access of user information. High working stability, high communication load capacity, high information process capability and large storage capacity are importance indicators of a monitoring server that worth paying attention [23].

ECG Monitoring Center Monitoring center is the “processing center” of data of remote ECG monitoring system and also the service provider. Generally, monitoring center consists of various ECG analysis workstation, guardianship workstation, etc. With the help of computer software, ECG analysts and experts can measurement, analysis, guardianship, statistics, report ECG datas. The accuracy of automatic measurement, analysis and guardianship of computer program, convenience of man-machine interactive editing, standardization and diversification of report output, etc. are performance indicators that the monitoring center needs to pay attention. There shall be medical personnel on duty for 24 hours, including doctors, technicians or nurses to make sure real-time reception of ECG information, make judgment of result timely and send the diagnosis report to the patient and doctor in charge. Specific rules and regulations shall be established to ensure safety and quality. Excellent equipment, instruments and servers shall be installed to ensure strong ECG monitoring signals, smooth information delivery and datas safety. There shall be necessary follow-up support to contact for first-aid, hospitalization and consultation when patients needed.

ECG monitoring terminals: As required by the patient, the doctor in charge shall evaluate patient’s condition, apply for allowing the local medical personnel to conduct subsequent checks, upload ECG information to the remote ECG monitoring center and be responsible for receiving the diagnosis report. The doctor in charge shall also conduct clinical diagnosis and treatment [24].

Transmission Long-distance transmission can be done through wire telephone, wireless mobile phone, public broadband network, special local area network, wireless Wi-Fi, etc.

Clinic Application of Remote ECG Monitoring

- Monitoring of cardiovascular related symptoms to discover the close connection between electrocardiographic abnormality and symptoms.
- The observation of basic heart rate during the treatment process of chronic cardiovascular diseases such as coronary heart disease and hypertension as well as the observation of electrocardiographic changes in daily life and when doing sports.
- Heart rate and ECG rhythm monitoring and regular check during the rehabilitation process of other chronic diseases, e.g. diabetes.
- Long-time home monitoring of high-risk patients with apychia and sudden death endangering life and continuous monitoring during the first-aid process.
- Capture of paroxysmal heart arrhythmia, such as home monitoring of paroxysmal atrial fibrillation or post-operation atrial fibrillation recurrence.
- Heart rate or ECG monitoring for other diseases endangering cardiac function, e.g. hyperthyroidism, etc.
- Heart function evaluation of sub-healthy adults and indirect evaluation of autonomic nervous function;
- ECG self-inspection of health persons and evaluation of data collection.
- Monitoring during field work or traveling.
- Necessary monitoring for public vehicle drivers.

Lead Selection Remote ECG Monitoring is Conducted in the Form of single-lead, double-lead and multi-lead

- The single-lead recorder can be selected in priority when monitoring heart rate changes and screening arrhythmia. It is convenient and has good patient dependency.
- The double-lead recorder can be selected in priority when confirming ventricular tachycardia and serious arrhythmia. It can avoid misdiagnose or missed diagnosis caused by interference.
- The multi-lead recorder can be selected in priority if there is myocardial ischemia when judging symptoms. Multi-position synchronous monitoring is easy to discover ST-T changes at different positions and conduct analysis and assessment.

Selection of Monitoring Time Remote ECG Monitoring Time Can be Tens of Seconds, Tens of Minutes, 24 Hours and Several Days of Continuous Monitoring

Tens of seconds of monitoring: Mainly used to record heart rate, compare heart rate changes, screen whether there is arrhythmia at the time of symptom onset. Handheld, single-lead and dry electrode recorders for tens of seconds of monitoring can be selected in priority. These recorders are at low cost, convenient to use, portable and free from the influence of time, occasion and climate. Repeated recording is available [25].

Tens of minutes of monitoring: Mainly used to screen ECG abnormality at the time of symptom onset and to observe heart rate changes when doing sports. The double-lead electrode patch recorder able to monitor for tens of minutes shall be selected in priority. The single-lead electrode patch recorder can also be used. The recorder involves with relatively low cost and is convenient to use and portable. It is suitable for patients with premonitory symptoms or onset symptoms lasted for some time. Repeated recording is available.

24-hour monitoring: Used to observe the 24-hour electrocardiogram situation during first visit, analyze the evolution status of each hour and arrhythmia or myocardial ischemia related to daily activities; used for comparison and quantitative analysis of curative effect after treatment. The multi-lead recorder for continuous 24 hours can be selected in priority. The recorded data is complete, convenient for comprehensive analysis, quantitative determination, risk assessment and judgment of autonomic nervous function. However, the cost is relatively high.

Several days of continuous monitoring: Used to make a definite diagnosis for electrocardiographic abnormality found in serious syncope, amaurosis, etc. in low onset frequency; and to observe the curative effect of drugs. The multi-lead electrode patch recorder able to monitor for several continuous days shall be selected in priority mainly to record rapid arrhythmia and chronic malignant arrhythmia.

Priority Selection of Different Monitoring Purposes

Monitoring basic heart rate changes: ECG can be recorded before getting up each morning. ECG before and after the afternoon nap of the same day, before going to bed at night can be recorded and compared. The single-lead, handheld and dry electrode recorders can be selected in priority. They are convenient and efficient. Short-time monitoring lasts from 30 seconds to 60 seconds.

Observing heart rate changes during sports: ECG before, during and after doing sports everyday can be recorded continuously to confirm the exercise heart rate variability and screen whether arrhythmia is occurred. The single-lead or double-lead patch electrode recorders can be selected in priority. They are convenient for upper limb movement to avoid erroneous judgment caused by movement interference. The monitoring process lasts from 30 minutes to 2 hours [26].

Monitoring electrocardiographic changes of special type of works: e.g. driver and pilot. ECG is recorded continuously before, during and after work to confirm heart rate variation degree during work and screen whether arrhythmia and myocardial ischemia are occurred. The double-lead or multi-lead patch electrode recorder can be selected in priority to avoid erroneous judgment caused by movement interference. The wearable and dry electrode recorder or single-lead patch electrode recorder can be selected for convenient screening. The monitoring process lasts from 12 hours to 24 hours.

ECG Result Description, Report Mode and Diagnostic Terminologies the ECG result description various with different recording duration and number of lead. The report mode includes name, gender, clinic diagnosis or clinical symptom, recording duration and place. Diagnostic terminologies are the same as the diagnostic standard terminologies of ECG and dynamic ECG.

Single-lead electrocardiogram with recording duration from 10-60 seconds: offering heart rhythm and heart rate report to judge whether arrhythmia is existed. If arrhythmia is existed, it is suggested to go to hospital for treatment.

Multi-lead electrocardiogram with recording duration from 10-60 seconds: offering heart rhythm and heart rate report and the nature of arrhythmia to judge whether ST-T abnormality is existed. If serious ST-T abnormality is existed, it is suggested to go to hospital for treatment.

12-lead electrocardiogram with standard recording duration and long-distance transmission: making diagnosis according to the routine ECG report format.

Dynamic ECG with 24 hours of recording duration and long-distance transmission: making diagnosis report according to the routine dynamic ECG report format.

Risk Assessment and Warning Before network access of remote ECG monitoring, clinical physicians shall conduct basic inquiry, physical examination, chemical examination, imaging examination, etc. to make risk assessment. Grading administration is carried out by judging as healthy, sub-healthy and ill states

- the monitoring result shows normal ECG or heart rate variation and arrhythmia by respiratory, kindly reminders explanations can be offered.
- If the monitoring result shows accidental or single ventricular premature beat, kindly reminders explanations can be offered.
- If the monitoring result shows frequent or repetitive ventricular

premature beat, a reminder to seek for treatment at the hospital shall be given. Further examinations shall be done, and a new risk assessment shall be conducted.

- The monitoring result shows other serious arrhythmia, e.g. paroxysmal atrial tachycardia, ventricular tachycardia, transient whole heart arrest, etc, a warning shall be given and suggestions shall be made to seek for medical treatment at the hospital. When necessary, subsequent emergency aid and treatment shall be offered, e.g. dialing 120 emergency call.
- Subsequent Treatment Services and Suggestions If any abnormality is found through remote ECG monitoring, doctors in the remote ECG diagnosis center shall provide follow-up diagnosis and treatment counseling to the patient. The remote ECG monitoring report shall be sent to the patient and the patients' doctor or the medical institution. When necessary, the public emergency call shall be dialed to help the patient with follow-up treatment or first-aid.
- Quality Control, Supervision, Code of Ethics and Legislations Comparisons are made according to dynamic electrocardiogram standards to realize quality control. Existing industrial standards in China can be referred to. Professional societies and expert committees conduct supervision by periodical random inspection and evaluation. Code of ethics and legislations are carried out according to relevant laws and existing medical standards established by the health administration department.

Part III Problems and Development

Current Problems Existed in Remote Cardiac Monitoring Devices

High price, small product variety and quantity (remote blood sugar and blood fat monitoring technologies are especially urgent to be developed), complex operation and incapability of meeting the demands of medical institutions at all levels, patient rehabilitation, health and health care monitoring. There is no unified standard for the communication interface of various equipment manufacturers. They set their own exclusive passwords, which renders the application in a unified network impossible. With the extended coverage of remote ECG information monitoring and the establishment of international remote ECG monitoring platforms, the research and development of computer software to accurately analyze and diagnose remote ECG information becomes extremely urgent [27].

China's Remote Cardiac Monitoring Development and Suggestion

- To perfect the leading registered expert database consultation system of China's remote ECG monitoring.

- To build an international and domestic regional, inter-hospital and in-hospital remote ECG monitoring network consultation cloud computer platform, unify the data interface and password of remote cardiac monitoring devices, achieve sharing of disease resources, training resources, data resources and results as well as common use of outcomes, truly realize effective redistribution of expert resources with the least cost and offer the maximum benefit to patients.
 - To establish a database for remote cardiac monitoring system, which can be used to make development plans and offer scientific basis for prevention and scientific researches.
 - To establish a remote cardiac first-aid system is a promising project of great importance. The application of relevant 120 first-aid system in ambulance before sending to hospital emergency rooms could save a lot of critical cardiac patients. To enhance remote consultation, remote monitoring and rescue technologies in ambulance is a very promising research project [28-30].
 - To support and step up domestic and international academic exchange activities about cardiac remote monitoring, publish magazines, books and popular science books concerning cardiac remote monitoring.
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