The Effect of Ambulatory Blood Pressure Monitoring on Sleep Disturbance

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(EMBED Research)

Research plan

1. Research Background

Ambulatory blood pressure monitoring (ABPM) is an ideal tool for the diagnosis and evaluation of hypertension. It can show the degree of blood pressure variability, blood pressure load and nighttime blood pressure reduction, and better evaluate the diurnal blood pressure of antihypertensive drugs. It has a guiding significance for the reasonable control of day and night hypertension, thus protecting target organs and preventing target organ damage. At the same time, ABPM is the only non-invasive method for nighttime blood pressure monitoring. However, ABPM frequently measures the tightening feeling, buzzing and other factors when the blood pressure cuff is inflated at night, which can cause the patient to wake up easily during sleep, which will affect the sleep of the human body and affect the quality of life of the patient. At the same time, improper waking of the patient from sleep can significantly increase the patient's blood pressure and affect the accuracy of ABPM monitoring. Different patients have different tolerances, and sleep should be affected by ABPM. There are few related studies.

2. Research purposes

Observe whether ABPM tests affect sleep, as well as the relationship and influencing factors of sleep and ambulatory blood pressure monitoring results, and screen for people who are susceptible to ABPM testing.

3. Research design and methods

3.1 Design type and method of study: Subjects who underwent ABPM monitoring during the continuous study period were followed by pre-sleep control studies;

3.2 Study period of the entire project: 24 months.

3.3 Start time: From the date of ethics adoption, the end time: twenty-four months after the date of ethical adoption.

3.4 Inclusion criteria

① gender is not limited, age 18-80 years old, undergo ABPM in the Second Affiliated Hospital of Zhejiang University School of Medicine;

② Capable of understanding the test and cooperating with the questionnaire.

3.5 Exclusion criteria

① History of psychosis, including schizophrenia, bipolar disorder, depression, anxiety, obsessive-compulsive disorder, phobia, somatoform disorder, stress-related disorders

② History of insomnia, currently with medication

③ History of obstructive sleep apnea (OSA)

④ History of other sleep disorders, including narcolepsy/hypersomnias, circadian rhythm sleep disorder, parasomnias, sleep-related dyskinesia

⑤ History of heart failure, that is New York heart association (NYHA) Class III-IV

⑥ History of atrial fibrillation and frequent atrial or ventricular extrasystoles

⑦ Ongoing substance or alcohol abuse

⑧ Currently receiving sedative hypnotic medication within 1 week

⑨ Pregnant women

⑩ Ongoing involvement in night-shift work (22:00-6:00) within 1 week
⑪ Ongoing need of care of families at home that wake during the night within 1 week
⑫ Incomprehensible or unwilling to fill in informed consent or questionnaire.

3.6 Exit criteria

① found that does not meet the test program;
② refused to continue to participate in the test;
③ lost to the visitor;
④ unauthorized use of sedative hypnotic drugs during the test.

3.7 Specific research options

① Sign the informed consent form, collect the subject's name, gender, age, contact information, height, weight, education, ethnicity, occupation, past history, family history and drug history, and fill out the STOP-BANG evaluation form. If the patient is unclear about his or her own hand condition, fill in the hand test form for testing. If there is obvious symptoms of upper respiratory tract infection, the symptoms will disappear after the symptoms disappear.

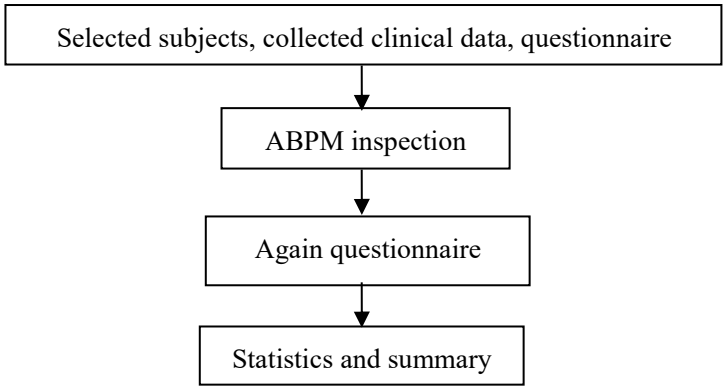
② to conduct blood pressure measurement in the office, standardize the instructions for filling out the form, complete the Generalized Anxiety Disorder Scale (GAD-7), the Depression Screening Scale (PHQ-9), the State-Special Anxiety Questionnaire (STAI), and the Ford Stress Insomnia Response Test (FIRST) scale, Pittsburgh sleep quality index scale (PSQI scale), St. Mary's Hospital Sleep Questionnaire and pain assessment scale for cuff inflation;

③ ABPM examination, if the patient agrees, the external electrocardiograph also performs ECG monitoring;

④ Fill in the St. Mary's Hospital Sleep Questionnaire and pain assessment scale again at the end of the examination;

⑤ Statistical analysis of St. Mary's Hospital Sleep Questionnaire results before and after ABPM examination, correlation analysis with basic patient status, scale scores and ambulatory blood pressure test results, statistics related factors and susceptible subjects with sleep susceptible to ABPM, and sleep quality and The possible relationship between ambulatory blood pressure test results.

3.8 Flow chart of the research steps;



3.9 The study does not involve vulnerable groups.

4. Sample size calculation

According to the existing literature reports and the number of previous dynamic blood pressure examinations in our hospital, with an enrollment rate of 30% and a rate of loss of 10%, an estimated 1700 cases were screened and 500 cases were enrolled, with an effective rate of about 450 cases.

5. Data management and confidentiality

5.1 After the database is established, the entered data is strictly checked, and the database is strictly managed and kept confidential.

5.2 All records relating to the identity of the subject are kept confidential and are not made public as permitted by applicable laws and/or regulations.

6. Informed consent

6.1 Informed consent is obtained by the investigator in the dynamic blood pressure room working time specification after the subject is explained and written by the subject.

6.2 The study does not involve patients, especially inpatients with mental illness, mental illness and incapacity; the study does not involve illiterates, prisoners, pregnant women, mentally handicapped and other individuals who may be disadvantaged economically and educationally; the study does not involve children. The study did not involve patients with mental/cognitive impairment.

6.3 If the study involves students, staff of the Institute, etc., participation in research conducted by their management personnel has no additional benefits and will not be forced to participate.

7. Reporting adverse events

Part of the study involved subjects with informed consent, questionnaires, and routine ambulatory blood pressure measurements. There were no additional risks associated with the study measures. If an adverse event occurs, take timely measures to deal with it and record it in the case report form. Serious Adverse Events (SAE): Take timely action measures, record in the case report form, immediately report to the ethics committee, drug clinical trial institutions and sponsors, and report to the national and provincial food and drug administration within 24 hours. The SAE is reported to the “Intranet Inadequate Incident and Approximate Error Responsibility Reporting System”. The specific process: see the figure below.