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Sleep behaviour and cardiorespiratory fitness in patients after percutaneous coronary intervention during cardiac rehabilitation: protocol for a longitudinal study

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ABSTRACT

Introduction Most patients with coronary heart disease experience sleep disturbances and low cardiorespiratory fitness (CRF), but their relationship during cardiac rehabilitation (CR) is still unclear. This article details a protocol for the study of sleep trajectory in patients with coronary heart disease during CR and the relationship between sleep and CRF. A better understanding of the relationship between sleep and CRF on patient outcomes can improve sleep management strategies.

Methods and analysis This is a longitudinal study with a recruitment target of 101 patients after percutaneous cardiac intervention from the Seventh People's Hospital of Shanghai, China. Data collection will include demographic characteristics, medical history, physical examination, blood sampling, echocardiography and the results of cardiopulmonary exercise tests. The information provided by a 6-min walk test will be used to supplement the CPET. The Pittsburgh Sleep Quality Index will be used to understand the sleep conditions of the participants in the past month. The Patient Health Questionnaire and General Anxiety Disorder Scale will be used to assess depression and anxiety, respectively. All participants will be required to wear an actigraphy on their wrists for 72 hours to monitor objective sleep conditions. This information will be collected four times within 6 months of CR, and patients will be followed up for 1 year. The growth mixture model will be used to analyse the longitudinal sleep data. The generalised estimating equation will be used to examine the associations between sleep and CRF during CR.

Ethics and dissemination Ethical approval for this observational longitudinal study was granted by the Shanghai Seventh People's Hospital Ethics Committee on 23 April 2021 (2021-7th-HIRB-012). Study results will be disseminated in peer-reviewed journal articles.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a longitudinal study of patients in cardiac rehabilitation, assessing sleep trajectory and the relationship between sleep and cardiorespiratory fitness.
⇒ The use of cardiopulmonary exercise testing and the 6-min walk test will provide accurate and objective cardiorespiratory fitness outcomes.
⇒ The Pittsburgh Sleep Quality Index and actigraphy will be used to comprehensively assess sleep quality and quantity, improving the power to discover patients with sleep disorders.
⇒ This is a single-centre study, the sample source will only include participants from one tertiary hospital in China.
⇒ The sample has selection bias, as only patients who voluntarily choose to undergo a cardiac rehabilitation programme after the percutaneous cardiac intervention.

INTRODUCTION

Cardiovascular mortality, mostly attributable to ischaemic heart disease (IHD), is expected to increase more dramatically in the next decade globally.[1] According to the 2018 ESC/EACTS Guidelines on myocardial revascularisation, timely percutaneous coronary intervention (PCI) of the infarct-related artery is still the priority treatment of patients with IHD.[2] However, after complete or incomplete revascularisation procedures, patients may still encounter stent thrombosis, angina and symptoms related to psychological and somatic stress. Sleep disturbances such as insomnia, obstructive sleep apnoea are quite common in patients with IHD.[3–5] Evidence from an epidemiological survey demonstrated that over one-third of patients confessed of sleep disturbance post PCI.[6 7] Sleep trait abnormalities include difficulty in falling asleep, periods of breathing cessation or multiple awakenings during the night, which resulted in insufficient sleep durations and poor sleep quality.[3 8] It is established that disturbed sleep is associated with adverse cardiac events after PCI.[9–11] Previous studies have predominantly focused on sleep duration as an isolated risk factor for cardiovascular disease.[12] However,

sleep is multidimensional and multicausal. It is not only associated with cardiovascular outcome but also affects the patient compliance and prognosis during the cardiac rehabilitation (CR) programme.[12–16]

CR is a highly regarded programme of secondary prevention measures, which has been endorsed by the European Society of Cardiology, the American Heart Association and the American College of Cardiology.[17–19] Exercise is a core component of CR.[20] Relevant studies have found that adherence to exercise-based CR can effectively reduce the risk of further cardiac insults, improve sleep quality, enhance cardiorespiratory fitness (CRF) and minimise hospital readmission and mortality.[21–24] In the process of CR, CRF is used to assess the severity of the patient's cardiac limitation and the recovery after a cardiac event, and it is an important independent risk factor for cardiovascular disease.[25 26] Moreover, the risk of long-term major adverse cardiovascular events (MACEs) is further increased when sleep disturbances and decreased CRF co-occur.[27] The number of studies evaluating sleep in relation to CRF is limited, with the majority of research being of cross-sectional design. In a large cross-sectional study of 51 000 participants, peak oxygen uptake (VO_{2peak}) was used to estimate CRF, showing a modest inverse association between having difficulty falling asleep at night and VO_{2peak}.[28] In contrast, another study used a symptom-limited cardiopulmonary exercise test (CPET) to objectively measure CRF and used accelerometry to monitor sleep patterns. The study reported that CRF and sleep characteristics were not significantly correlated in adults with primary hypertension.[29] Lindegård *et al* found similar results in a longitudinal cohort study of women diagnosed with stress-related exhaustion disorder.[30]

Although prior observational evidence exists, none included the prospective, multitime assessment of sleep and CRF during the CR programme of patients post-PCI. There is still limited information on the relationship between patients' sleep traits and the joint effects of CRF. Moreover, subjective reports are used to assess perceptions of sleep quality in most studies, but they may not accurately measure sleep duration and efficiency. Within this context, clinicians cannot provide targeted guidance for patients undergoing CR after PCI.

Therefore, the purposes of this study are to: (1) investigate the sleep quality and efficiency of patients undergoing CR for the first time after PCI; (2) determine the sleep trajectory and influencing factors of patients undergoing CR for the first 6 months after PCI; and (3) investigate the longitudinal correlation between objectively measured sleep quality and CRF in patients undergoing CR after PCI.

METHODS

Patient and public involvement

Based on literature review in related fields, the research questions and outcome measures were evaluated and discussed by researchers. Patients were not involved in the design of the study, but their cooperation was required during the implementation phase of the study, and their needs and preferences were fully taken into account. Test results will be communicated verbally or in writing to participants.

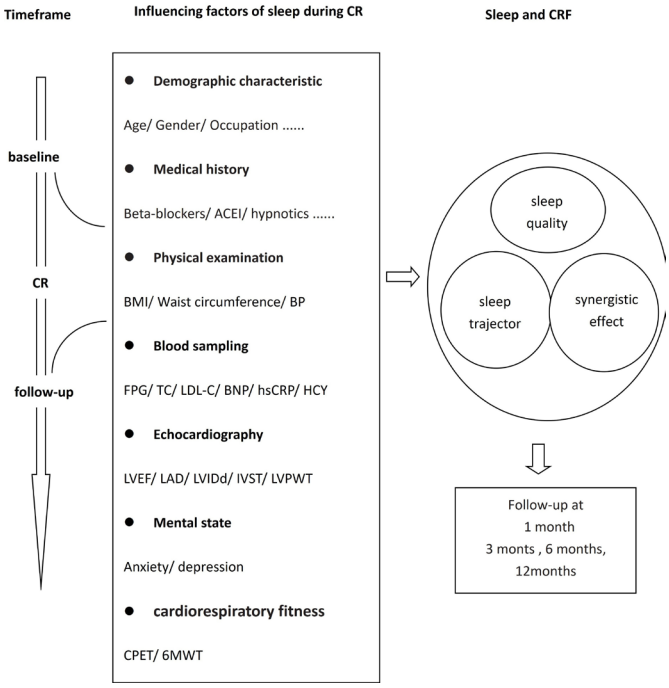

Figure 1 Study framework. BMI, body mass index; BNP, B-type natriuretic peptide; BP, blood pressure; CPET, cardiopulmonary exercise testing; CR, cardiac rehabilitation; CRF, cardiorespiratory fitness; FPG, fasting plasma glucose; HCY, homocysteine; hsCRP, serum high-sensitivity C-reactive protein; IVST, interventricular septal thickness; LAD, left atrium diameter; LDL-C, low-density lipoprotein cholesterol; LVEF, left ventricular ejection fraction; LVIDd, left ventricular internal diameter at end-diastole; LVPWT, left ventricular posterior wall thickness; 6MWT: six-minute walk test; TC, total cholesterol.

Study design

This is a longitudinal study of patients in CR, which collects data at five-time points as follows: (1) T1, patients will have completed the first CPET 1 month after PCI and will have begun CR programme, based on the risk evaluation by the physicians; (2) T2, 1 month after the beginning of CR programme; (3) T3, 3 months after the beginning of CR programme; (4) T4, 6 months after the beginning of CR programme; and (5) T5, 12 months after the beginning of CR programme. This study explores the time-varying effects of sleep structure in patients after PCI during CR and the potential relationship between sleep and CRF. The data will be collected in person at the time of the four scheduled visits. Twelve months after the start of CR, the disease prognosis will be followed up over the phone. The study framework is shown in figure 1.

Participants

This study will be conducted at the Seventh People's Hospital of Shanghai, China. A convenience sampling

method will be used to recruit patients after PCI in the rehabilitation department. We hope to recruit at least 101 patients who meet the eligibility criteria. We plan to recruit patients in CR over an 18-month period beginning in May 2021.

General inclusion criteria

The inclusion criteria are as follows: (1) diagnosed with coronary heart disease and underwent PCI; (2) clinically stable; (3) aged 18–75 years; (4) no contraindications to exercise rehabilitation; and (5) capable and mentally able to communicate with the investigator in verbal or written form and provide written informed consent.

General exclusion criteria

The exclusion criteria are as follows: (1) unable to participate in regular exercise training on time; (2) have a cardiogenic shock or severe arrhythmia; (3) have severe lung diseases; and (4) have severe liver and kidney dysfunction, infection, tumour or anaemia.

Recruitment

Recruitment posters with research details will be placed at the front of the rehabilitation clinic. Medical staff will introduce this study to eligible patients undergoing CPET. Patients who are post PCI will be invited to participate in this study after signing a written informed consent form.

Study procedures

At the baseline selection prior to the study, subjects provided a self-report of demographic characteristics and medical history. The medical staff will conduct clinical examination including physical examination, blood sampling, echocardiography, as well as CPET results. Body mass index and waist circumference were determined during physical examination. The fasting serum of each subject was collected in the morning, the measurements of fasting plasma glucose, total cholesterol and low-density lipoprotein cholesterol were recorded. Cardiac biomarkers including B-type natriuretic peptide, serum high-sensitivity C-reactive protein and homocysteine were measured in a laboratory. Data from echocardiography examination were collected, including left ventricular ejection fraction, left atrium diameter (LAD), left ventricular internal diameter at end-diastole (LVIDd), interventricular septal thickness (IVST) and left ventricular posterior wall thickness (LVPWT).

CPET will be assessed by a physician, focusing on recording peak oxygen uptake (VO_2 peak), oxygen consumption divided by heart rate (known as the oxygen pulse: VO_2/HR), metabolic equivalents, minute ventilation divided by carbon dioxide production (VE/VCO_2 slope), oxygen uptake efficiency slope, anaerobic threshold (AT), heart rate recovery at 1 min after exercise (HRR 1 min) and maximal heart rate reserve (HRR Max).

The baseline assessment will also include the Pittsburgh Sleep Quality Index (PSQI) to understand the sleep conditions of the participants in the past month. The mental states of depression and anxiety will be assessed with the Patient Health Questionnaire (PHQ-9) and the General Anxiety Disorder Scale (GAD-7), respectively. The scales are in the Chinese version. All enrolled participants will be required to wear an actigraphy on their wrists for 72 hours to objectively monitor sleep conditions. The physical therapist will prescribe a personalised exercise programme for each participant, based on the CPET result and the patient's disease state. Then the patient will undergo a CR exercise programme three times a week in the rehabilitation clinic for a total of 6 months. Patients perform 40 min of aerobic training on a treadmill or bicycle each time and use a heart rate monitor and Borg ratings of perceived exertion scale to assess exercise intensity. During the CR process, data (physical examination, echocardiography, blood sampling, actigraphy for the assessment of sleep, PSQI, PHQ-9 and GAD-7) will be collected again in the first, third, and sixth months. In addition, CEPT will be performed again in the sixth month of the CR programme and the 6-min walk test (6MWT) will be performed in the first and third months of the CR programme to supplement the CPET. Except for this, other assessment contents will be the same as those listed in the baseline assessments. At the 12th month, a telephonic follow-up will also be required. The follow-up content includes MACEs and the number of rehospitalisations. Table 1 shows the data collection details.

Sample size

The calculations of the sample size were based on an estimate of the correlation coefficient between sleep quality and CRF in participants from previous studies.[31] With a two-sided significance level of 5% and a minimum correlation coefficient of 0.37 between sleep quality and CRF, 84 patients after PCI would be included. Considering an attrition rate of 20%, the final total sample size will be at least 101 patients.

Measurements

Cardiopulmonary exercise testing

The CPET will be performed by professional physicians with operating qualifications using COSMED S.R.L Pulmonary Function Equipment (The Metabolic company, Guangzhou, China). Patients will not need to stop cardiovascular drugs (including β-blockers) on the day of the CPET test and must avoid drinking caffeine beverages and smoking 2 hours before the test. According to the American Thoracic Society (ATS) guidelines, CPET uses a continuous load escalation programme for symptomatic self-limiting cycling exercise.[32] The patient sits on a cycle ergometer and first rests for 3 min and then performs a zero-load idling warm-up for at least 1 min, followed by the load-increasing exercise phase with an incremental power of 10 W/min or 20 W/min, so that the patient can reach maximum exercise intensity for self-limiting symptoms. The speed of the treadmill is maintained at 55–65 r/min throughout the test. ECG, blood pressure and respiratory status will be continually monitored during the recovery period for at least 3 min after

Table 1 Data collection in the study

Items	T1	T2	T3	T4	T5
Demographic characteristic	✓				
Medical history	✓				
Physical examination	✓	✓	✓	✓	
Blood sampling	✓	✓	✓	✓	
Echocardiography	✓	✓	✓	✓	
CPET	✓			✓	
6MWT		✓	✓		
Actigraphy	✓	✓	✓	✓	
PSQI	✓	✓	✓	✓	
PHQ-9	✓	✓	✓	✓	
GAD-7	✓	✓	✓	✓	
MACEs					✓
Rehospitalisations					✓

T1: baseline assessment and enrolment; T2: 1 month after the beginning of CR programme; T3: 3 months after the beginning of CR programme; T4: 6 months after the beginning of CR programme; T5: 12 months after the beginning of CR programme. Physical examination: BMI, WC, BP; blood sampling: FPG, TC, LDL-C, BNP, hsCRP, HCY; echocardiography: LVEF, LAD, LVIDd, IVST, LVPWT.
BMI, body mass index; BNP, B-type natriuretic peptide; BP, blood pressure; CPET, cardiopulmonary exercise testing; CR, cardiac rehabilitation; FPG, fasting plasma glucose; GAD-7, General Anxiety Disorder Scale; HCY, homocysteine; hsCRP, serum high-sensitivity C-reactive protein; IVST, interventricular septal thickness; LAD, left atrium diameter; LDL-C, low-density lipoprotein cholesterol; LVEF, left ventricular ejection fraction; LVIDd, left ventricular internal diameter at end-diastole; LVPWT, left ventricular posterior wall thickness; MACEs, major adverse cardiovascular events; 6MWT, 6-min walk test; PHQ-9, Patient Health Questionnaire; PSQI, Pittsburgh Sleep Quality Index; TC, total cholesterol; WC, waist circumference.

the loading exercise stops, until the end of the test. The main measured outcomes include the AT, peak oxygen uptake, peak oxygen pulse, minute ventricular load and maximum exercise load. The V-slope method will be used to calculate the AT.

6-minute walk test

Functional exercise capacity is objectively evaluated by the 6MWT. This test records the distance that a patient can quickly walk along a long and flat corridor in 6 min. During this test, patients are permitted to decide their walking speed but are still required to walk as far as possible for 6 min. Every minute, physiotherapists will call out a standardised phrase of verbal encouragement. The 6MWT process is based on guidelines from the ATS.[33]

Actigraphy for the assessment of sleep

Actigraphy (Respironics, Murrysville, America) will be continuously monitored for 24 hours to analyse patients' sleep and waking data. The recording frequency interval for actigraphy will be 30 s/frame, and the recording time will be 3 days. The exported sleep report will comprise daily sleep data and average sleep data. Sleep data will include: (1) sleep time and wake-up time; (2) time in bed; (3) actual sleep time; (4) sleep latency; (5) sleep efficiency; and (6) the number of minutes and times of awakening after the start of sleep. Finally, the averaged sleep data will be included in the statistical analysis.

Pittsburgh Sleep Quality Index

The PSQI is a sleep self-rated questionnaire designed and revised by scholars including Buysse *et al*.[34] In this study, the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI) was used to measure the sleep quality of patients in the past month.[35] The questionnaire has a total of 18 items, which are used to measure the following: (1) subjective sleep quality; (2) sleep latency; (3) sleep duration; (4) sleep efficiency; (5) sleep disturbances; (6) use of sleeping medication, and (7) daytime dysfunction.

Patient Health Questionnaire

The PHQ-9 is a reliable and effective indicator for measuring the severity of depression, and its items correspond to the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depression.[36] In this study, the Chinese version of the PHQ-9 was used to assess the severity of depression in patients in the last 2 weeks through nine questions.[37] The PHQ-9 total score ranges from 0 to 27 points, and the scores 5, 10 and 20 are the cut-off values for mild, moderate and severe depression, respectively.

General Anxiety Disorder Scale

The GAD-7 is used to determine whether the patients have psychological symptoms of anxiety and their frequency within 2 weeks.[38] The Chinese version of GAD-7 showed good reliability and validity in cardiovascular patients.[37] This scale includes seven items, each with a score of 0–3 points for a total score of 21 points, of which a score of 10–21 points denotes having an anxious mental state.

Statistical analysis

The results will be statistically analysed using SPSS V.25.0 software (SPSS, Chicago, Illinois, USA) and Mplus V.7.1 software (Muthén & Muthén, Los Angeles, USA). Continuous variables are expressed as mean±SD and categorical variables as proportions. We will use the growth mixture model (GMM) to analyse the participants' longitudinal sleep data and identify the longitudinal development trajectory of sleep during CR. And we will explore the characteristics of sleep trajectory in the sample population over time based on the consideration of population heterogeneity. GMM combines aspects of latent growth curve modelling and finite mixture modelling to identify discrete trajectories in longitudinal data.[39 40] The generalised estimating equation will be used to examine the association between sleep and cardiopulmonary function during CR, adjusting for potential covariates which include age, sex, education, socioeconomic status, comorbidities, drug use and psychological status. Cox regression

model was used to calculate HRs and 95% CI for the incident of MACEs after 12 months of CR in relation to sleep.

DISCUSSION

Sleep disturbance after PCI can cause both acute and chronic physiological and psychological burdens to patients. Following PCI, patients must reduce their risk of cardiac events and sleep disturbance through secondary prevention strategies.[41] CR is helpful for reducing the deleterious effects of sleep disorders and improving CRF. This protocol describes a longitudinal observational study to explore the time-varying effect of sleep structure and the potential relationship between sleep and CRF in patients after PCI and during CR. Compared with the longitudinal study by Mazaki *et al*, the sleep data collected by actigraphy and PSQI are more extensive and comprehensive.[11] Moreover, multi time-point sleep data can display the dynamic changes of sleep in patients after PCI during CR, helping patients to implement effective sleep management during the CR period. Additionally, given the importance of CRF for cardiovascular disease, a key strength of this study is addressing the longitudinal underlying relationship between sleep and CRF. As far as we know, this is the first longitudinal study to explore the trajectory of patients' sleep structure changes after PCI and during CR. The advantages of this study include the use of the PSQI and actigraphy to comprehensively assess sleep quality and quantity. Actigraphy is an objective sleep measure that improves data accuracy. CPET will also be used to non-invasively monitor the ECG, pulse oximetry (SpO_2), O_2 inhalation, and CO_2 output at rest and during exercise. Cardiopulmonary reserve function and exercise tolerance will be analysed by combining multiple indicators.

There are some limitations to this study. First, the sample source will only include participants from one hospital in China. Due to the limitations of research sites and recruitment strategies, our sample may be prone to selection bias and random-sampling recruitment may be difficult. Second, the study will only include patients who voluntarily choose to undergo a CR programme after PCI. Patients who meet the conditions but have a fear of exercise will be excluded. This part of the patient information may have an impact on the study results. Finally, we did not use the gold standard sleep assessment technique, polysomnography (PSG). PSG is difficult and expensive due to the fact that the patient is out of hospital for a long period of time and the CR takes place in a rehabilitation clinic. Although actigraphy cannot replace PSG in terms of diagnostic accuracy and reliability, it has shown good performance for tracking sleep and wakefulness.[42 43]

Poor CRF is considered a possible adverse health outcome associated with poor sleep. This study aims to investigate the sleep conditions of patients during CR and the relationship with CRF as the preliminary basis of clinical intervention. The exploration of the dynamic fluctuations of sleep and its relationship with CRF may provide useful reference for targeted CR management. During CR management, medical staff can timely detect and adjust the patient's adverse state through objective sleep and CRF monitoring, and speed up the recovery process.

ETHICS AND DISSEMINATION

This article describes a prospective, longitudinal study protocol to assess sleep trajectory and the relationship between sleep and CRF for patients in CR. Ethical approval for this observational longitudinal study was granted by the Shanghai Seventh People's Hospital Ethics Committee on 23 April 2021 (2021-7th-HIRB-012). All participants will be provided with a full understanding of the study and will be made aware that participation is strictly voluntary. Informed consent and information sheets will be provided for patients before the onset of this research. The study results will be disseminated in peer-reviewed journal articles.

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Contributors LH is the principal investigator of the study and is responsible for protocol design, data collection and analysis and presentation of findings. She was also responsible for drafting this manuscript. JW obtained funding. JZ, HL and YW participated in data collection and analysis. XW and JW contributed to the protocol design and revisions of the manuscript. All authors have read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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