Effect of Eye Acupuncture with Needle-Retained Exercise on Postoperative Heart Rate Variability and Prognosis in Patients Undergoing Percutaneous Coronary Intervention: Postprint

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Abstract

Background: Heart rate variability (HRV) is a non-invasive indicator for evaluating cardiac autonomic nervous function and is commonly used to assess the short-term prognosis of coronary artery disease. Percutaneous coronary intervention (PCI) is a common surgical modality for coronary artery disease; however, malignant arrhythmias, recurrent myocardial infarction, and other major adverse cardiovascular events (MACE) frequently occur postoperatively. While dual antiplatelet therapy (DAPT) can reduce the incidence of MACE to some extent, it is prone to gastrointestinal bleeding complications and cannot continuously and effectively improve PCI prognosis. Eye acupuncture can effectively reduce the duration and frequency of chest pain, while exercise therapy can enhance cardiac and vascular function. The application of combined eye acupuncture with needle-retained exercise following PCI remains to be explored.

Objective: To investigate the effects of eye acupuncture with needle-retained exercise on heart rate variability and prognosis in patients with coronary heart disease after percutaneous coronary intervention.

Methods: Thirty-two postoperative patients with intermediate-low risk stratification were randomly allocated in a 1:1 ratio to either an eye acupuncture with needle-retained exercise group or a medication group. The eye acupuncture with needle-retained exercise group received eye acupuncture with needle-retained exercise in addition to dual antiplatelet therapy, whereas the medication group received dual antiplatelet therapy alone. All subjects completed the 2-week intervention and pre- and post-treatment assessments. Twenty-four-hour ambulatory electrocardiography was employed to monitor heart rate variability (HRV) for evaluation of autonomic nervous system function. The prognosis of PCI was

assessed through major adverse cardiovascular events recorded in a specially designed adverse event diary. All outcome measures were evaluated within 24 hours after PCI and on the day of completion of the 2-week intervention.

Results: Following the intervention, significant statistical differences were observed between the two groups in LF/HF, SDNN, SDANN, and CRP ($P< 0.05$). Compared with the medication control group, the eye acupuncture with needle-retained exercise group exhibited a lower incidence of major adverse cardiovascular events ($P=0.016$), which demonstrated a significant negative correlation with SDNN, SDANN, and LF/HF ($P< 0.05$).

Conclusion: Eye acupuncture with needle-retained exercise is more effective than dual antiplatelet therapy alone in improving heart rate variability in patients with coronary heart disease after coronary intervention, with a lower incidence of major adverse cardiovascular events and better short-term postoperative prognosis.

Full Text

Ocular Acupuncture and Exercise Combination Therapy on Post-Surgery Heart Rate Variability and Prognosis of Patients Undergoing Percutaneous Coronary Intervention

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Abstract

Background: Heart rate variability (HRV) is a well-established non-invasive indicator of cardiac autonomic function commonly used to evaluate short-term prognosis in coronary artery disease. Percutaneous coronary intervention (PCI) is a standard surgical treatment for coronary lesions, but postoperative complications such as malignant arrhythmias and recurrent myocardial infarction contribute to major adverse cardiovascular events (MACE). While dual antiplatelet therapy (DAPT) can reduce MACE incidence to some extent, it carries risks of

gastrointestinal bleeding and cannot consistently improve PCI outcomes. Ocular acupuncture effectively reduces chest pain duration and frequency, while exercise therapy enhances cardiac and vascular function. The combined application of ocular acupuncture with exercise after PCI warrants investigation.

Objective: To investigate the effect of ocular acupuncture and exercise combination therapy (OAECT) on heart rate variability and prognosis in coronary heart disease patients after PCI.

Methods: Thirty-two postoperative patients with low-to-moderate risk stratification were randomly assigned in a 1:1 ratio to either the OAECT group or the medication group. The OAECT group received ocular acupuncture with exercise in addition to DAPT, while the medication group received DAPT alone. All participants completed a 2-week intervention with pre- and post-treatment assessments. Autonomic nervous system function was evaluated through 24-hour ambulatory electrocardiogram monitoring of HRV. PCI prognosis was assessed via major adverse cardiovascular events recorded in a specially designed adverse event diary. All outcome measures were obtained within 24 hours post-PCI and immediately after the 2-week intervention.

Results: After intervention, statistically significant differences between groups were observed in LF/HF ($1.42\$\pm0.72, P = 0.044$), $SDNN(118.60\pm24.92, P = 0.045)$, $SDANN(107.60\pm25.75, P = 0.049)$, $andCRP(4.06\pm\$3.70,$ P=0.047). The OAECT group demonstrated a lower MACE incidence compared to the medication group (25% vs. 75%, P=0.016), which was negatively correlated with SDNN (t=-3.714, P=0.002), SDANN (t=-3.553, P=0.003), and LF/HF (t=-2.225, P=0.043).

Conclusions: OAECT is more effective than DAPT alone in improving HRV and reducing MACE incidence, resulting in better short-term prognosis for patients after PCI.

Keywords: ocular acupuncture and exercise combination therapy; heart rate variability; major adverse cardiovascular events; percutaneous coronary intervention; randomized clinical trial

Introduction

Coronary heart disease (CHD) represents the leading cause of cardiovascular mortality, posing a serious threat to public health. According to the 2019 China Cardiovascular Health and Disease Report, the ratio of CHD to cardiovascular disease patients in China is 1:30. Percutaneous coronary intervention (PCI) is an effective treatment for improving myocardial perfusion in CHD patients. However, ischemia-reperfusion injury following PCI frequently leads to major adverse cardiovascular events (MACE), including malignant arrhythmias, recurrent myocardial infarction, repeat PCI, chest discomfort, and even cardiac or all-cause death, resulting in poor prognosis.

Heart rate variability (HRV) serves as a non-invasive indicator of cardiac autonomic function and provides evidence of myocardial ischemia and arrhythmias, making it valuable for evaluating short-term prognosis in coronary artery disease, where lower values typically indicate worse outcomes. Currently, dual antiplatelet therapy (DAPT) with aspirin and oral P2Y12 inhibitors remains the cornerstone of post-PCI care for preventing thrombotic complications. However, premature discontinuation is associated with stent thrombosis and adverse outcomes including death, while long-term use increases bleeding risk, limiting its ability to consistently improve PCI prognosis. The optimal duration of postoperative pharmacotherapy remains controversial, necessitating better approaches to avoid or reduce drug-induced stent thrombosis or bleeding events.

Ocular acupuncture with exercise is an emerging integrative rehabilitation approach combining ocular acupuncture needle retention with exercise training. Ocular acupuncture is a micro-acupuncture technique based on the "eight-region theory" in traditional Chinese medicine meridian theory, involving needle insertion at the orbital rim to unblock meridians, activate blood circulation, relieve pain, and regulate organ function. According to traditional Chinese medicine, periorbital tissues are closely related to organ function, and ocular acupuncture at the "upper jiao region" and "heart region" can effectively reduce the duration and frequency of angina in CHD. Exercise therapy enhances cardiac and vascular function, reduces MACE incidence after PCI, and improves muscle strength, endurance, balance, coordination, and quality of life, earning Class I evidence recommendations from the American Heart Association and European Society of Cardiology for cardiac rehabilitation programs.

Currently, ocular acupuncture with exercise is primarily applied in post-stroke rehabilitation and was promoted nationwide by the National Administration of Traditional Chinese Medicine in 2018 as an appropriate technique, though its application in other fields requires further exploration. Based on these considerations, we conducted a randomized controlled trial to investigate the effects of ocular acupuncture with exercise on HRV and prognosis in CHD patients after PCI, aiming to develop a more effective and safer therapy to reduce medication-related MACE or postoperative complications and expand cardiac rehabilitation options after PCI.

1.1 Trial Design

Thirty-two low-to-moderate risk CHD patients who underwent PCI at the Hospital of Chengdu University of Traditional Chinese Medicine between September 2021 and August 2022 were enrolled. Participants were randomly assigned in a 1:1 ratio to either the ocular acupuncture with exercise group (n=16) or the medication group (n=16) using computer-generated random sequences. The study was approved by the Hospital Ethics Committee of Chengdu University of Traditional Chinese Medicine in July 2021 (2021KL-028) and registered with the Chinese Clinical Trial Registry in July 2021 (ChiCTR2100048960). The trial followed the SPIRIT guidelines for interventional trial protocols and reported

results according to CONSORT standards.

1.2 General Information

Inclusion criteria: (1) Confirmed CHD with stable angina, NSTEMI, or STEMI; (2) Age 45-80 years; (3) Low-to-moderate risk stratification after PCI (see Table 1); (4) Within 24 hours post-PCI with stable vital signs.

Exclusion criteria: (1) Unstable vital signs; (2) Severe complications including malignant tumors, heart failure, respiratory failure, or shock; (3) Cognitive impairment or severe hearing/vision deficits; (4) Severe hepatic, renal, or immune dysfunction; (5) Pregnancy or lactation; (6) Contraindications to acupuncture; (7) Conditions deemed unsuitable for exercise.

All participants provided informed consent before enrollment.

1.3 Randomization and Blinding

A dynamic block randomization method generated the allocation sequence through an online application system. Researchers sent text messages containing participants' initials, gender abbreviations, and birth dates to the central randomization system, which automatically replied with a random number and group assignment. The study implemented triple separation of researchers, operators, and statisticians to maintain blinding. Researchers remained unaware of individual treatment assignments; operators implemented treatments according to the centrally determined protocol; participants were blinded to treatment options; and statisticians were blinded to group allocation and treatment details. A separate investigator managed group assignments, which were concealed on a computer and disclosed only to operators. Both statisticians and participants remained blinded until study completion.

1.4 Treatment Methods

Medication group: Participants received conventional perioperative and postoperative antiplatelet and anticoagulant therapy for 2 weeks according to the 2016 Chinese PCI guidelines: (1) Aspirin enteric-coated tablets: 100-300mg preoperatively, then 100mg daily for 2 weeks postoperatively; (2) Clopidogrel bisulfate tablets: 300-600mg at least 6 hours preoperatively, 600mg at 2-6 hours preoperatively, then 75mg daily for 2 weeks postoperatively. Cardiology specialists could add antihypertensive, lipid-lowering, or glucose-lowering medications as needed, with continued treatment after study completion.

Ocular acupuncture with exercise group: In addition to the medication regimen, participants received continuous ECG monitoring for 24 hours, followed by 2 weeks of ocular acupuncture with exercise therapy after vital signs stabilized. Using specialized ocular acupuncture needles, practitioners inserted needles 2mm outside the orbital rim at specific points: "upper jiao region"

(ACU1) and "heart region" (ACU2). Point location followed the *Chinese Ocular Acupuncture* standard [Figure 1: see original paper]. The operator fixed the periorbital skin with the pressing hand, grasped the needle handle with tweezers, and inserted the needle at a 15° angle along the skin from the starting to ending point of the acupoint region, reaching the dermis and subcutaneous tissue to a depth of 5-8mm. After obtaining the needling sensation, the needle handle was secured with adhesive tape. Exercise therapy commenced immediately, including warm-up, training (aerobic, resistance, flexibility), and cool-down exercises, with specific protocols detailed in Table 2 . Ocular needles were retained once daily for 60 minutes of exercise, 5 days per week for 2 weeks, with 2 rest days. Exercise intensity was adjusted in real-time based on patient sweating, respiration, pulse, and blood pressure.

Exercise therapy protocol:

1. Warm-up training: Respiratory muscle relaxation training. Participants lay supine with hips and knees flexed, feet flat on the bed surface. Therapists instructed relaxation using abdominal breathing, placing thumbs approximately 1cm below the xiphoid process. At the end of deep inhalation, before exhalation began, therapists pressed firmly on the rectus abdominis then quickly released. Protocol: 30 seconds per set, 10 sets per session, once daily, 5 minutes total duration.

2. Exercise training: Combined aerobic, resistance, and flexibility training.

2.1 Aerobic training: (1) Walking training: Participants performed bedside standing warm-up, maintained standing position, and walked slowly in the ward for 15-25m at 5 minutes per session, once daily, totaling 5 minutes. (2) Cycling training: Using the Shandong Zepu intelligent exercise rehabilitation machine for lower limb active/passive cycling, the system automatically adjusted based on muscle strength—providing passive motion when no active movement was detected, assisted motion based on residual strength, resistance for stronger patients, and automatic stop during spasms. Protocol: 15 minutes per session, once daily, totaling 15 minutes.

2.2 Resistance training: Using Thera-Band red-level resistance bands for biceps, triceps, forearm muscles, pectoralis major, trapezius, quadriceps, gastrocnemius, and calf muscles, performing flexion, adduction, and abduction exercises with attention to breathing regulation to avoid breath-holding or Valsalva maneuvers. Protocol: 30 repetitions per movement in 3 sets with 1-minute rest intervals, once daily, 20 minutes total (10 minutes each for upper and lower limbs based on individual capacity).

2.3 Flexibility training: Focused on shoulders, waist, and legs with slow, controlled movements gradually increasing range of motion. Each stretch held 6-15 seconds, progressing to 30-90 seconds, at intensity producing a pulling sensation without pain, repeated 3-5 times per movement. Once daily, 10 minutes total duration.

3. Cool-down training: Repeated respiratory muscle relaxation training as in warm-up, once daily, 5 minutes total duration.

1.5 Observation Indicators

Baseline indicators: Demographic data including height, weight, gender, age, marital status, education, medical history, and family history, plus coronary lesion characteristics (location, severity, complete revascularization status, and complications).

Primary indicators: 24-hour ambulatory ECG assessed HRV at 24 hours post-PCI and immediately after the 2-week intervention. Parameters included SDNN, SDANN, SDNN index, RMSSD, PNN50, HF, LF, and LF/HF to evaluate cardiac autonomic function and prognosis. MACE was assessed at 2, 4, and 8 weeks post-intervention via telephone and outpatient consultations, recording cardiac or all-cause death, malignant arrhythmias (ventricular tachycardia, ventricular fibrillation), severe heart failure, recurrent myocardial infarction, repeat PCI, and chest pain.

Secondary indicators: Fasting blood samples obtained at 24 hours post-PCI and the morning after intervention completion assessed cardiac biomarkers: CRP, NT-proBNP, CK-MB, and hs-TnI levels to evaluate myocardial function.

Safety indicators: Post-PCI complications including subcutaneous hematoma, skin lesions, muscle soreness, abnormal respiration, and stroke were documented.

1.6 Statistical Analysis

One researcher collected all data using case report forms (CRF) recorded in a specialized Excel database, with a second researcher performing double-checking. Paper and electronic data were stored at the Hospital of Chengdu University of Traditional Chinese Medicine and an independent network drive for ten years.

SPSS 23.0 software performed statistical analyses. Descriptive statistics assessed demographic and general characteristics. Continuous variables were analyzed using t-tests or Kruskal-Wallis tests based on distribution, while categorical variables used chi-square or Fisher' s exact tests. Multiple linear regression explored correlations between MACE and HRV between groups, calculating mean differences or odds ratios with 95% confidence intervals. $P<0.05$ indicated statistical significance.

All 32 participants completed the 2-week intervention without dropout. At baseline, both groups showed similar demographic and clinical characteristics . Mean age was 68.31$±$13.17 years, with 14 males (43.75%). Education level was relatively low (61.11% with junior high school or less), and 24 participants were non-manual laborers (75%). All patients had coronary artery disease, with 26 (81.25%) involving two or more vessels. Additionally, 68.75% had two or more chronic comorbidities: hypertension (26.47%), hyperlipidemia (23.53%), diabetes (26.47%), and other diseases (23.53%).

Results

2.1 Comparison of HRV Between Groups

At baseline, mean heart rate was within normal range in both groups, while HRV parameters (SDNN, SDANN, SDNN index, RMSSD, PNN50, HF, LF, LF/HF) were below normal values. After 2 weeks, the OAECT group showed significant increases in LF/HF, SDNN, SDANN, and SDNN index approaching normal levels, while the medication group showed slight decreases. No differences were observed in LF, HF, RMSSD, or PNN50. Statistically significant differences between groups were found in LF/HF, SDNN, and SDANN ($P<0.05$), but not in SDNN index ($P>0.05$) .

2.2 Comparison of Myocardial Function Between Groups

After 2 weeks , both groups showed decreased cardiac biomarkers (CRP, NT-proBNP, CK-MB, hs-TnI) approaching normal ranges, with more pronounced reductions in the OAECT group. Significant between-group differences were observed in CRP values ($P<0.05$), while other parameters showed no statistical significance ($P>0.05$).

2.3 Comparison of MACE and Adverse Reaction Rates

The OAECT group demonstrated significantly lower MACE incidence (25%) and adverse reaction rates (12.5%) compared to the medication group ($P<0.05$). The OAECT group reported only one case of subcutaneous hematoma, while the medication group reported three gastrointestinal adverse reactions and one inflammatory reaction . No participants withdrew from either group.

2.4 Correlation Analysis Between MACE Incidence and HRV

Multiple regression analysis revealed that MACE incidence was negatively correlated with SDNN, SDANN, and LF/HF ($P<0.05$), but not with SDNN index, RMSSD, or PNN50 ($P>0.05$).

Discussion

After the 2-week intervention, nearly all HRV parameters (except HF) that were below normal values in the OAECT group increased toward normal ranges, while the medication group showed slight decreases. Significant between-group differences in indices reflecting sympathetic function (SDNN, SDANN) and autonomic balance (LF/HF) ($P<0.05$) were observed. The OAECT group showed significantly lower MACE incidence (25%) compared to the medication group ($P<0.05$), with multiple linear regression confirming negative correlations between MACE incidence and SDNN, SDANN, and LF/HF ($P<0.05$).

These findings demonstrate that OAECT is superior to medication alone in reducing post-PCI MACE incidence and improving prognosis, primarily by re-

ducing sympathetic activity and promoting autonomic balance to regulate heart rate variability. HRV parameters include frequency-domain measures (LF, HF, LF/HF) and time-domain measures (SDNN, SDANN, SDNN index, RMSSD, PNN50), which reflect cardiac autonomic activity. SDNN, SDANN, and SDNN index are important indicators of sympathetic activity, with decreases reflecting increased sympathetic tone. RMSSD, PNN50, and HF primarily reflect vagal activity, with decreases indicating reduced vagal tone. LF is sensitive to both sympathetic and vagal activity, while LF/HF reflects sympathetic/vagal balance. Myocardial ischemia causes cardiac autonomic dysfunction with excessive sympathetic activation and diminished vagal activity, leading to reduced HRV in CHD patients. Conventional post-PCI DAPT can increase HRV, particularly parameters representing sympathetic function such as SDNN, SDANN, SDNN index, and LF, which are protective factors against MACE and reflect short-term prognosis after PCI. Although studies show HRV increases significantly at 24 hours and 6 months post-PCI compared to preoperative values, with higher values at 6 months than at 24 hours, early transient autonomic dysfunction due to endothelial cell injury, thromboembolism, and inflammatory responses from PCI causes a temporary HRV decline during the first postoperative week. This aligns with our baseline findings of below-normal HRV parameters within 24 hours post-PCI, indicating persistent sympathetic dominance and parasympathetic deficiency. The post-treatment increases in SDNN, SDANN, SDNN index, RMSSD, PNN50, LF, and LF/HF, along with decreased HF, and the significant between-group differences in SDNN, SDANN, and LF/HF demonstrate that OAECT exerts more pronounced effects on autonomic activity than medication alone, significantly reducing MACE risk and attenuating sympathetic activity.

Beyond HRV effects, OAECT also reduced elevated myocardial function biomarkers and improved myocardial function to some degree. However, except for CRP ($P<0.05$), improvements in CK-MB, hs-TnI, or NT-proBNP values were not statistically significant compared to medication alone, possibly reflecting different pathophysiological significance of each marker. CK-MB, primarily composed of cardiomyocytes, rises 3-6 hours after acute myocardial infarction, peaks at 12-24 hours, and normalizes within 2-3 days, serving as the "gold standard" for diagnosing acute MI. hs-TnI, existing as a complex in cardiomyocyte cytoplasm, is released into circulation during myocardial injury, providing early and sensitive detection of minor myocardial damage and serving as a crucial diagnostic criterion recommended by European and American cardiovascular societies as the preferred cardiac injury marker. NT-proBNP is synthesized and released in response to increased ventricular volume or pressure load, primarily diagnosing acute and chronic heart failure and playing an irreplaceable role in management and outcome assessment. CRP, a marker of myocardial cell injury synthesized by hepatocytes during inflammation (such as microbial invasion or tissue injury), is closely associated with the acute phase of cardiovascular endothelial injury and serves as an independent and powerful predictor of cardiovascular events. CRP begins rising within

hours of inflammatory stimulation and normalizes with lesion resolution and functional recovery. Studies show significantly elevated CRP levels in post-PCI angina patients correlate closely with inflammatory response severity. Based on these pathophysiological relationships and our findings, OAECT appears more effective than medication in anti-myocardial inflammatory responses, and equally effective in promoting myocardial injury repair and reducing ventricular load.

As a randomized controlled study examining HRV and prognosis in CHD patients undergoing PCI (including unstable angina, STEMI, and NSTEMI), the acute nature of these conditions precluded preoperative 24-hour Holter monitoring in most patients, particularly those undergoing emergency PCI. Therefore, this study only compared post-PCI HRV parameters, MACE incidence, cardiac function indices, and adverse reactions between groups; differences between pre- and post-PCI values remain unknown. Future studies with stricter inclusion criteria recruiting elective PCI patients could address this limitation. Additionally, while the between-group difference in CRP confirms the anti-inflammatory efficacy of OAECT, the negative findings regarding myocardial injury repair and ventricular load reduction warrant attention. With larger sample sizes, these conclusions may change. Future studies incorporating imaging modalities such as Doppler echocardiography, cardiac PET-CT, or cardiac MRI could provide more direct myocardial function indices to clarify OAECT' s therapeutic effects on myocardial function.

Limited by sample size, correlation analysis between MACE incidence and HRV could only be performed using multiple linear regression. With expanded sample sizes, future studies could employ multiple logistic regression to identify the most dangerous HRV parameters for MACE development and further explore the relationship between OAECT' s effects on autonomic function and myocardial function and their underlying mechanisms.

In conclusion, ocular acupuncture with exercise is more effective than dual antiplatelet therapy alone in regulating HRV, reducing major adverse cardiovascular events, and improving prognosis in CHD patients after PCI. These advantages are achieved by inhibiting sympathetic activity, enhancing vagal tone, maintaining autonomic balance, and improving myocardial function through anti-inflammatory effects and promotion of cardiomyocyte repair.

Author Contributions: Author 1 conceived the study, drafted the manuscript, and was responsible for quality control and final approval. Authors 2 and 3 collected and organized case data. Authors 4 and 5 managed patient diagnosis and treatment. Author 6 performed statistical analysis. Author 7 revised the manuscript. Author 8 supervised medication guidance and vital sign monitoring. All authors approved the final manuscript.

Conflict of Interest: The authors declare no conflicts of interest.

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Note: Figure translations are in progress. See original paper for figures.