BMJ Open Development and validation of a clinical diagnostic model for myocardial ischaemia in borderline coronary lesions based on optical pumped magnetometer magnetocardiography: a prospective Protected by copyright, including for uses related to text and data mining, AI observational cohort study

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ABSTRACT

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Objectives To develop and validate a clinical diagnostic model based on optical pumped magnetometer magnetocardiography (OPM-MCG) for the detection of myocardial ischaemia in patients with borderline coronary lesions prior to invasive coronary angiography (ICA). Design Prospective observational cohort study. Setting Single centre of the China National Clinical Research Centre for Cardiovascular Disease (NCCMRC). Participants Adults with borderline coronary lesions on ICA (n=141).

Interventions Underwent OPM-MCG before ICA and fractional flow reserve measurement.

Results Five parameters were included in the final diagnostic model: MAg_{max} -TT, δDt_{sum} -PN, δAg_{sum} -C, δAr_{sum} -N and δAr_{min} -N. 1000 bootstrap replications showed that the area under the receiver operating characteristic curve and 95% Cl of the diagnostic model were 0.864 (0.803-0.925). with a sensitivity of 79.4%, specificity of 80.8%, positive predictive value of 79.4% and negative predictive value of 80.8%. Decision curve analysis showed a net benefit from the predictive model when the threshold probability of an ischaemic patient was >12%, suggesting the potential utility of the model in the real world.

Conclusions A nomogram based on five OPM-MCG parameters was developed to assess myocardial ischaemia in patients with borderline coronary lesions and has the potential to reduce the need for unnecessary ICA. Trial registration number China Clinical Trial Registry (ChiCTR2300072382).

INTRODUCTION

Borderline coronary lesions are defined as lesions with 40% to 90% stenosis on invasive coronary angiography (ICA). In the fractional flow reserve versus angiography for multivessel evaluation (FAME) study¹, over 80% of lesions fell into this category,

STRENGTHS AND LIMITATIONS OF THIS STUDY

- \Rightarrow As a prospective observational cohort study, this study provides real-world evidence of the diagnostic performance of optical pumped magnetometer magnetocardiography for myocardial ischaemia, enhancing the generalisation of the findings.
- \Rightarrow The study was a single-centre study, which may affect its adaptability to different settings.
- \Rightarrow The clinical diagnostic model did not account for myocardial ischaemia due to coronary microcirculatory dysfunction and did not include evaluations performed with other magnetocardiography devices.

with only 35% of stenoses between 50% and 70% being hemodynamically signifi-cant. Predicting relevance was most accu-rate when estimating coronary artery **g** and diameter over 90%. Therefore, fractional flow reserve (FFR)-guided intervention in S patients with borderline coronary lesions (40%-90% stenosis) has become a recommended treatment strategy in the 2018 European Society of Cardiology (ESC) guidelines on myocardial revascularization² The 2021 American College of **G** Cardiology (ACC)/American Heart Asso- 8 ciation (AHA)/ Society for Cardiovascular Angiography and Interventions (SCAI) Guidelines for Coronary Artery Revascularization³ also provide clear recommendations for managing borderline coronary lesions: FFR and instantaneous wave-free ratio (iFR) are used to assess the need for percutaneous coronary intervention (PCI) in patients without evidence of ischaemia

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but with angina and other equivalent symptoms (class I): PCI is not recommended for stable patients with FFR >0.8 or iFR >0.89 (class III). However, the widespread adoption of FFR in coronary catheter laboratories is hindered by its time-consuming nature, resource consumption and potential adverse effects associated with adenosine application.

Optical pumped magnetometer magnetocardiography (OPM-MCG) measures tiny magnetic fields (10^{-15} Tesla) from the heart using atomic magnetometer technology, without radiation. It is guick, contactless and suitable for diverse populations. Clinical studies have demonstrated that MCG is superior to ECG in detecting early myocardial ischaemia,⁴⁻⁷ and has similar diagnostic effectiveness as single-photon emission CT (SPECT) for coronary artery disease (CAD).⁸⁹ MCG was proven to be precise in diagnosing non-ST-segment elevation myocardial infarction, even in individuals who do not exhibit typical angina symptoms.¹⁰¹¹ However, the parameters and cut-off values of OPM-MCG that indicate myocardial ischaemia in borderline coronary lesion are presently undefined.

Hence, this study aims to investigate the accuracy of OPM-MCG in diagnosing myocardial ischaemia

in patients with borderline coronary lesions, with invasive FFR measurement serving as the reference standard.

METHOD

Study population

This study was a prospective, single-centre, observational, cohort study, which was reviewed by the Ethics rotect Committee of Beijing Anzhen Hospital, Capital Medical University, and registered with the China Clinical Trial Registry (ChiCTR2300072382). All participants signed an informed consent. The methods described in this article **2** follow the standards for reporting of diagnostic accuracy 8 (STARD) 2015 guidelines.

Participants aged 18-80 with typical angina symptoms (CCS class II or higher) or 40%-90% stenosis on coronary CT angiography were scheduled for hospitalisation for ICA. Exclusion criteria included (1) coronary artery stenosis outside of 40%-90% range on ICA; (2) ing acute myocardial infarction; (3) previous myocardial for uses related to text and data mining, AI training, and similar technologies infarction; (4) complex arrhythmias; (5) bundle-branch



Figure 1 Flowchart of the study design. CCTA, coronary CT angiography; MCG, magnetocardiography; ICA, invasive coronary angiography; FFR, fractional flow reserve; OPM, optical pumped magnetometer; PCI, percutaneous coronary intervention.

Table 1 Clinical characteristics (n=14)	41)	
Characteristics	Total (n=141)	
Age (years)	60.64±9.70	
Male, n (%)	109 (77.3)	
BMI (Kg/m ²)	26.15±3.36	
Diabetes, n (%)	47 (33.3)	
Hypercholesterolemia, n (%)	65 (46.1)	
Hypertension, n (%)	82 (58.2)	
Stroke, n (%)	9 (6.4)	
Smoke, n (%)	43 (30.5)	
Systolic blood pressure, mm Hg	128.69±15.54	
Diastolic blood pressure, mm Hg	75.15±10.79	
Heart rate	73.81±10.38	
Medication, n (%)		
Aspirin	129 (91.5)	
Statin	137 (97.2)	
ACEI/ARB	45 (35.6)	
SGLT2 inhibitors	22 (16.7)	
Nicorandil	23 (16.3)	
Admission lab results		
Low-density lipoprotein cholesterol (mmol/L)	1.82±0.69	
hs Tnl (pg/ml)	3.5 (2.5,5.8)	
Brain natriuretic peptide (pg/ml)	29.00 (14.75,48.25)	
Blood glucose (mmol/L)	5.52 (4.82,7.33)	
HbA1c (%)	6.25 (5.7,7.1)	
ICA and FFR characteristics		
1-vessel disease	50 (35.5)	
2-vessel disease	43 (30.5)	
3-vessel disease	48 (34.0)	
Number of patients with FFR ≤ 0.8	68 (48.2)	
Number of vessels with FFR	157	
Number of vessels with FFR ≤0.8	74 (47.1)	
Left anterior descending artery with FFR	97 (68.8)	
Left circumflex artery with FFR	25 (17.7)	
Right coronary artery with FFR	35 (24.8)	
Interval between MCG and FFR	2 (1,7)	

ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; FFR, fractional flow reserve; ICA, invasive coronary angiography; MCG, magnetocardiography; SGLT2, sodium-glucose transport protein 2.

block; (6) pacemakers, metallic implants in trunk and (7) claustrophobia.

This study was based on a prospective cohort design, the sample size of which was calculated by power analysis and sample size (PASS) 2021 software using the area under the receiver-operating characteristic (ROC) curve (AUC). The significance level (α) was 0.025 and the degree of certainty (1- β) was 0.90, combining the results of the literature review of related studies as well as the statistics of the small sample in the previous period, and calculating according to the FFR-positive (ischaemic)/FFR-negative (non-ischemic)=2:3. The sample size was calculated as 138.

A total of 163 patients from 30 June to 30 November 2023 were consecutively enrolled, and 22 patients were excluded, of which 11 patients with stenosis >90%, 7 patients underwent direct PCI without FFR testing, 4 patients with poor-quality MCG imaging and finally, 141 patients with borderline coronary lesions underwent MCG and FFR sequentially (figure 1). In this study, the cardiologists were not aware of the MCG results at the time of the FFR examination, and the MCG parameters were determined before the FFR examination (online supplemental figure 1).

ICA and FFR procedures

ICA and FFR measurements were performed on the vessels according to the 2021 ACC/AHA/SCAI Guidelines for Coronary Artery Revascularization and Expert consensus on the clinical pathway for FFR measurement in China. After the administration of nitroglycerin, a pressure monitoring guidewire was advanced through ē the stenosis. Hyperaemia was attained by the administration of intravenous adenosine $(140 \mu g/kg/min)$. The FFR pressure wire was positioned a minimum of 20 mm distal to the stenosis in vessel segments $\geq 2 \text{ mm}$. The presence of an FFR ≤ 0.80 was considered a positive indicator ല ā of functional ischaemia in patients and was defined as the FFR-positive group. ata m

MCG imaging

The MCG recordings were conducted using a 36-channel OPM-MCG system (Miracle MCG), featuring OPM ⊳ sensors sourced from Beijing X-Mag Technologies' mature commercial product. The OPM sensor is based on the spin-exchange relaxation-free technology, with alkali metal atoms as the core sensitive element. The OPM sensor has a sensitivity below 30 fT/Hz^{1/2}, a recording bandwidth of 1 Hz-40 Hz, a sampling frequency of 200 Hz and a noise baseline not higher than 15fT. The OPM-MCG residual magnetic field is kept below 1.5 nT, and the data acquisition mode is analogue signal acquisition nolog (online supplemental figure 2). Each subject had a 90s continuous recording at 36 locations (6×6 grid) above the lles chest using an arrayed sensor grid.

MCG signal analysis and statistical analysis

After MCG data acquisition, the software automatically post-processes the signals to generate magnetic field and current density maps and output 65 parameters (online supplemental table 1). The 65 parameters we output characterise the stability of the current dipole in the TT segment (the position from one-third of the T max amplitude (T onset) to T max (T peak)) according to the previous studies of Park et al and Pena et al (see supplementary material for post-processing steps).

Statistical analysis was performed with SPSS V.25.0 and R V.4.3.2 (http //www.R-project.org/). Counting data were presented as numbers and percentages, while normally distributed measurement data were shown as mean \pm SD. Continuous variables that were not normally distributed were presented using median and quartile values. Statistical significance was determined for all analyses with a p value <0.05. Based on this cohort and the principle of at least 10 events per variable, we considered the rationality of the parameters included in the diagnostic model and evaluated the number of parameters. The 65 potential predictor variables were assessed through univariable logistic regression, and only those with p-values <0.1 were selected. These variables were then subjected to the Least Absolute Shrinkage and Selection Operator (LASSO) regression, ultimately identifying the most impactful predictors. Continuous variables representing the amount of change were transformed into ordered categorical variables based on IQR. Continuous variables representing absolute values were converted into dichotomous variables by grouping their upper and lower quartile values into extreme categories, while middle-range values were grouped and incorporated into the model. The final model was developed using multivariate logistic regression with a backward selection approach. The model's predictive performance was assessed using the enhanced bootstrap method, and clinical benefit was evaluated using the decision curve analysis (DCA). The nomogram was used to report scores for assessing myocardial ischaemia with OPM-MCG parameters.

Patient and public involvement

Patients make more people aware of the clinical use of OPM-MCG and how it is examined by sharing news and information about clinical studies with others.

RESULT

Clinical characteristics

The study included 141 patients, mostly male (77.3%) with an average age of 60.64±9.70 years. After MCG scans, all patients underwent ICA and FFR examination, with 48.2% having positive FFR (FFR ≤ 0.8). A total of 157

vessels were examined, with 47.1% having FFR ≤ 0.8 . Interval between MCG and FFR <30 days, median 2 days. Most patients had FFR measurements primarily done on the left anterior descending artery. See table 1 for patients' clinical characteristics.

Selection of parameters and development of the diagnostic model

50 variables that were statistically significant (p<0.1)in univariable logistic regression were included in the LASSO regression (online supplemental table 2 and online supplemental figure 3), and 8 variables were selected based on the reasonableness of the parameters selected to reduce the model overfitting and covariance through LASSO regression. By using the backward 2 approach, 5 parameters were included in the final diagnostic model: MAg_{max} -TT, δDt_{sum} -PN, δAg_{sum} -C, δAr_{sum} -N and δAr_{min} -N (table 2 and figure 2). The model AUC obtained from multivariate logistic regression analysis was 0.864, with a sensitivity of 79.4%, specificity of 80.8%, positive predictive value of 79.4% and negative predictive value of 80.8% (See online supplemental figure 4) ğ for the confusion matrix of the diagnostic model). The uses related to text nomogram (figure 3) provides a graphical overview of the diagnostic model using multivariate logistic regression analysis (online supplemental table 3).

Internal validation and net benefit of the model

The model performance for the diagnosis of myocardial ischaemia in borderline coronary lesions of the OPM-MCG was evaluated by bootstrap replications. 1000 bootstrap replications showed that the model AUC and a 95%CI of 0.864 (0.803–0.925) (figure 4). 1000 bootstrap replications showed that the mean absolute error was 0.017 (figure 4). The DCA for the diagnostic model showed that if the threshold probability of patients is >12% (figure 4), screening strategies based on the OPM-MCG diagnostic model resulted in superior net benefit than screen-none or screen-all strategies.

DISCUSSION

training, and similar technologies CAD is presently characterised by an epicardial vascular lesion with stenosis exceeding 50% in the ICA. Frequently, the degree of stenosis indicated by ICA is

Table 2 The definitions of MCG parameters	
MCG parameters	Definitions
MAg _{max} -TT	The maximum magnetic field angle at intervals of a certain time τ within TT segment
δDt _{sum} -PN	The sum of changes in magnetic pole distance at intervals of a certain time τ within TT segment
δAg_{sum} -C	The sum of changes in current angle at intervals of a certain time τ within TT segment
δAr _{sum} -N	The sum of changes in negative pole area at intervals of a certain time τ within TT segment
δAr _{min} -N	The minimum value of changes in negative pole area at intervals of a certain time τ within TT segment

Ag, Angle; Ar, Area; C, Current; DT, Distance; M, Magnetic Field; N, Negative Pole; PN, Positive Pole to Negative Pole; TT, from T onset to T peak; δ , Change value; τ , one-tenth of the time interval between TT segment.

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data

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C OPM-MCG scan and ICA (<70%) in FFR-positive (FFR ≤ 0.8) 70-year-old male



D OPM-MCG scan and ICA (>70%) in FFR-negative (FFR > 0.8) 67-year-old male



Figure 2 Schematic diagram of OPM-MCG scan. (A) Schematic diagram of MAg_{max} -TT and current angle. In magnetic field distribution maps and current density maps, the definition rule for angle values is based on the horizontal axis, with counterclockwise angles being negative and clockwise angles being positive. MAg_{max} -TT is the maximum angle between the line connecting the maximum positive and negative magnetic poles and the horizontal axis in the TT segment. δAg_{sum} -C is the sum of changes in current angle at intervals of a certain time τ within TT segment (B) Normal OPM-MCG scan. The OPM-MCG scan showed no evidence of ischaemia or obstructive coronary artery disease, as demonstrated by the lack of significant current deviations within the myocardium and absence of angle shift between the positive red pole and negative blue pole between T-onset and T-peak. (C) The OPM-MCG scan of a patient in his 70s showed magnetic field angular deflection and abnormal magnetic field distribution of the positive and multipolarisation of negative poles, suggesting significant myocardial ischaemia, and the ECG showed no significant abnormality. The ICA showed two lesions: 60% stenosis of the D1 and 50% stenosis of the R-PDA. The FFRs were 0.77 for the R-PDA. (D) The OPM-MCG scan of a patient in his 60s showed no myocardial ischaemia, ECG showed no significant abnormalities and echocardiography showed widening of the ascending aorta and aortic sinus. ICA showed 75% stenosis of the LAD and 60% stenosis of the RCA, and the FFR value of the LAD was 0.88. D1, diagonal branches; FFR, fractional flow reserve; ICA, invasive coronary angiography; LAD, left anterior descending artery; MCG, magnetocardiography; OPM, optical pumped magnetometer; RCA, right coronary artery; R-PDA, posterior descending artery.

used as a reference standard for myocardial revascularisation. Moreover, FFR can be used to evaluate the existence of myocardial ischaemia, with a threshold of 0.8. However, as illustrated in figure 2, the coronary stenosis identified in ICA may not precisely align with the FFR results. This observation is in line with the conclusions drawn in the 2019 ESC Guidelines for Chronic Coronary Syndromes,^{12 13} emphasising that the accuracy of



Figure 3 Nomogram of the diagnostic model. The nomogram graphically demonstrates the diagnostic model of OPM-MCG. Points for MAg_{max} -TT, δDt_{sum} -PN, δAg_{sum} -C, δAr_{sum} -N and δAr_{min} -N can be obtained using a point calliper and then summed to obtain a total score that can be measured by diagnosing myocardial ischaemia in patients with borderline coronary lesions.

determining CAD solely based on angiographic stenosis was as low as 64% when compared with flow reserve fraction. The positive mismatch rate, where lesions with <50%stenosis may demonstrate an FFR ≤ 0.8 , was 19%, while the negative mismatch rate, where lesions with over 50% stenosis may result in an FFR value >0.8, reached up to one-third. Numerous studies 1415 have consistently demonstrated that FFR-guided stenting leads to superior immediate outcomes and long-term prognosis. Therefore, FFR has a Class I recommendation, Level of Evidence A value in guiding revascularisation in angiographically borderline coronary stenoses in patients with stable angina. The feasibility of diagnosing myocardial ischaemia in patients with borderline coronary lesions using OPM-MCG was shown in our study, when compared with invasive FFR. The collective diagnostic potential of MCG parameters in detecting myocardial ischaemia in borderline coronary lesions resulted in an AUC of 0.864 (95% CI 0.803 to 0.925). Due to factors such as time consumption, costs, patient-related discomfort, contraindications and a lack of reimbursement, the current rate of FFR utilisation in catheterisation laboratories in China is <6%.³ OPM-MCG allows ischaemia assessment in patients with borderline coronary lesions prior to ICA and has a good concordance with FFR.

In comparing our MCG results with those reported by Park *et al*¹⁶, it is clear that FFR, serving as the reference standard, evaluates ischaemia through direct measurement of pressure beyond the coronary lesion. In contrast, the 5 parameters of our OPM-MCG, along with the ST-segment fluctuation scores (AUC=0.835) and Bull's eye analysis (AUC=0.914) employed by Park, offer a non-invasive alternative. According to Park *et al*, the TT segment, defined as the interval from T onset to T peak, is a more effective parameter for analysing MCG signals due to its superior signal-to-noise ratio for reflecting

for uses rela ventricular repolarisation electrical activity.¹⁷ In terms of the selected parameters, consistent with earlier literature,¹⁸ we focused on assessing the overall homogeneity of the repolarisation process, including spatial structural similarity and smoothing of current changes. Park et al used ST-segment fluctuation scores and Bull's eye analysis đ to evaluate the uniformity of the repolarisation process in e relation to current variations and spatial distribution variances for ischaemia assessment. In our study, we further characterised the images by incorporating the δAg_{sum} -C, cnaracterised the images by incorporating the δAg_{sum} -C, ΔAr_{sum} -N and δAr_{min} -N, δDt_{sum} -PN parameters of the model to analyse changes in currents, pole areas and distances. Additionally, describing the images using the parameters of the three different angular points provided a comprehensive description and response to the images. In terms of image feature discrimination, the ischaemia-positive features of the OPM-MCG (pole multipolarisation and magnetic field angle deflection) initially are consistent with the FFR (figure 2). For practical clinical application, Park et al used a 64-channel axial gradiometer system, which offers greater channel capacity and higher sensitivity for positional discrimination. However, this approach required patients to complete two MCG testsone during stress and one at rest-in a shielded room. Comparatively, OPM-MCG is equipped with a shielding barrel that can effectively diagnose myocardial ischaemia caused by borderline coronary lesions at rest, without **3** the need for a specially constructed shielding room. This enhances the practicality and universality of its clinical application.

Non-invasive methods like positron emission tomography/CT (PET/CT), SPECT and cardiovascular magnetic resonance (CMR) are accurate for assessing myocardial ischaemia, but their use is limited due to cost, long wait times and radioactive substances.¹⁹ In a prospective study done by Roel *et al*,²⁰ which included 189

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Figure 4 Accuracy and internal validation of the diagnostic model. (A) OC curves for the diagnostic model. After 1000 bootstrap replications, the area under the curve and 95% CI for receiver operating characteristic is 0.864 (0.803–0.925). (B) Calibration curve for the diagnostic model. Calibration curve for the borderline lesion ischaemia diagnostic model was established by comparing the actual and predicted probability of a positive FFR in patients with borderline lesions of the coronary arteries. The smaller the distance of the scatter from the dashed line, the better the calibration. (C) Decision curve analysis (DCA) for diagnostic models of ischaemia in borderline coronary lesions. Treat none: net benefit when it is assumed that no patients with borderline lesions of the coronary arteries would have the outcome (FFR-positive). Treat all: net benefit when all patients with borderline coronary lesions are assumed to have an outcome (FFR-positive). Diagnostic model: net benefit of managing borderline coronary lesions with a diagnosis of myocardial ischaemia based on the diagnostic model estimate. The strategy with the highest net benefit at any given threshold is the preferred strategy.

patients in a head-to-head comparison, it was found that using FFR as the gold standard, the sensitivity of SPECT, PET/CT and CMR was only 67%, 81% and 66%, and the specificity was only 61%, 65% and 62%. The diagnostic accuracy of PET/CT was not statistically different from that of SPECT and CMR. Recently, CT-derived FFR (CT-FFR) has emerged as a non-invasive test for detecting myocardial ischaemia, with a sensitivity of 89% and specificity of 91% according to a multicentre study.²¹ The widespread use of CT-FFR has limitations including the

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microvascular and diffuse lesions.²² ECG is widely used in the clinic as the fastest and low-cost test. ECG uses a two-dimensional linear approach to record cardiac radial currents to detect ischaemia, but it can be affected by body tissues or fluids and has low spatial resolution. MCG detects and measures weak magnetic fields generated by the electrical activity of the heart, and the waveform of the MCG waveform is similar to that of the ECG signal. However, MCG is less affected by changes in conductivity

and does not suffer from skin electrode contact problems. In addition, MCG is more sensitive to magnetic fields generated by tangential currents that are more affected by myocardial ischaemia, and MCG detects eddy currents that are not apparent with ECG.¹⁸ Thus, previous studies have demonstrated that MCG has a higher sensitivity to early myocardial ischaemia.^{23 24} In most studies of MCG detection of myocardial ischaemia, researchers have categorised the analysis of MCG into morphological and quantitative data analyses.²⁵ Morphological analysis often focuses on amplitude, non-dipole phenomena and current or magnetic field angle. Quantitative data analysis is mostly based on changes in the magnetic field during ventricular repolarisation, usually at the end of the ST segment (before the T wave) and/or during the T wave, and partially measured during the OT and ORS segment. These parameters describe the poles, the angles of the magnetic and current fields and the waveform amplitude by extrema, dynamics and ratios. Current studies analysing MCG at rest for the detection of myocardial ischaemia use a variety of methods, including dichotomous classification methods based on MCG parameters, quantification of abnormal MCG parameters, creation of composite indices using MCG parameters and the application of machine-learning methods.²⁶

This is similar to our finding that a positive OPM-MCG scan was demonstrated by one or more abnormalities in the TT segment, including changes in TT segment parameters and the changes in image (non-dipole phenomena and angular deflection of currents or magnetic fields). Different MCG parameters and their combinations can provide more incremental information on cardiovascular disease. In addition, studies have shown that MCG is capable of accurately diagnosing myocardial ischaemia resulting from epicardial CAD as well as effectively detecting myocardial ischaemia caused by coronary microvascular dysfunction (CMD). The accuracy of MCG identification of CMD is 94.8%, sensitivity of 100% and specificity of 93.3%²⁶. In our study, we also found a small number of FFR-negative patients with positive MCG scans as described above and considered the possibility of CMD. In the future, we will summarise the characteristic images of patients with CMD and further explore the incremental information provided by the MCGs for these patients.

The difference between superconducting quantum interference device (SQUID)-based and OPM-based MCG systems lies in their sensor technology. SQUID-based MCGs were developed earlier and offer high sensitivity. But their reliance on liquid helium refrigeration for achieving low-temperature superconductivity, as well as the high maintenance costs associated with them, have hindered their widespread adoption and utilisation. In contrast, the OPM-MCG operates at room temperature without liquid helium cooling and offers comparable sensitivity, as it is easier to use and less expensive to operate.^{27 28} However, OPM-MCG is also unsuitable for claustrophobic patients. Furthermore, as a result of

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its late development, there is a lack of established guidelines for analysing MCG parameters. As such, we intend to conduct further exploratory studies on OPM-MCG in various clinical settings.

LIMITATION

The study is a single-centre registry study with some limitations. We are aware that the current diagnostic model may suffer from potential overfitting and therefore the conclusions of this study require further validation in multicentre studies. In addition, the definition of positive and negative poles we currently use differs from the Rome Biomag Conference in 1981 standard, and there are currently multiple types of MCGs globally, and the current methodology for analysing myocardial ischaemia has not been compared head-to-head with other MCG devices.

CONCLUSION

MCG shows excellent sensitivity, specificity and diagnostic accuracy in identifying significant myocardial ischaemia when compared with FFR. MCG can provide evidence of a precise diagnostic strategy in patients with borderline coronary lesions before ICA, reducing unnecessary invasive examination.

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Competing interests None declared.

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

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Ethics Committee of Beijing Anzhen Hospital, Capital Medical University (KS2023008). Written informed consent was required for participation in the study. Participants gave informed consent to participate in the study before taking part.

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