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Effect of a standardised heart team protocol versus a guideline-based protocol on revascularisation decision stability in stable complex coronary artery disease: rationale and design of a randomised trial of cardiology specialists using historic cases

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ABSTRACT

Introduction A multidisciplinary heart team approach has been recommended by revascularisation guidelines, but how to organise and implement the heart team in a standardised way has not been validated. Inter-team and intra-team decision instability existed in the guideline-based heart team protocol, and our standardised heart team protocol based on a mixed method study may improve decision stability. The objective of this study is to evaluate the effect of the standardised heart team protocol versus the guideline-based protocol on decision-making stability in stable complex coronary artery disease (CAD).

Methods and analysis Eighty-four eligible interventional cardiologists, cardiac surgeons or non-interventional cardiologists from 26 hospitals in China have been enrolled. They will be randomised to a standardised heart team protocol group or a guideline-based protocol group to make revascularisation decisions for 480 historic cases (from a prospective registry) with stable complex CAD. In the standardised group, we will establish 12 heart teams based on an evidence-based protocol, including specialist selection, specialist training, team composition, team training and a standardised meeting process. In the guideline-based group, we will organise 12 heart teams according to the guideline principles, including team composition and standardised meeting process. The primary outcome is the overall percent agreement in revascularisation decisions between heart teams within a group. To demonstrate the clinical implication of decision-making stability, we will further explore the association between decision stability and 1-year clinical outcomes.

Ethics and dissemination The study was approved by the Institutional Review Board (IRB) of Fuwai Hospital (No. 2019-1303). All participants have provided informed consent and all patients included as historic cases provided written informed consent at the time of entry to the prospective registry. The results of this trial will be disseminated through manuscript publication and national/international conferences, and reported in the trial registry entry.

Trial registration number NCT05039567.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is a randomised controlled trial testing an evidence-based standardised heart team protocol covering the whole heart team organisation process with up-to-date information provision against an approach following guideline basic recommendations.

⇒ Randomisation is used in three aspects, stratified randomisation in group allocation, randomisation in heart team membership and randomisation in case allocation, which controls the social factors that may have negative implications for true group decision-making and ensures relatively heart team exposure to case complexity.

⇒ Trial procedures will be carried out remotely, and all heart team meetings will be held via video conference using an online system, enabling full involvement and eliminating the risk of spreading COVID-19.

⇒ The cases discussed are retrospectively instead of prospectively selected, and the study does not investigate the impact of the standardised heart team protocol on true treatment decisions and clinical outcomes in routine clinical care, which is the next step to be tested.

⇒ The intervention in the standardised protocol group is an integrated approach, and the potential differential outcomes associated with its use cannot be attributed to a single point of the process.

INTRODUCTION

The heart team approach has received a class 1C/1B recommendation in European and American guidelines on myocardial revascularisation in patients with complex coronary artery disease (CAD) to optimise the treatment strategies and may lead to better outcomes.[1–5] Clinical guidelines recommend that a heart team, consisting of clinical/non-interventional cardiologists, interventional

cardiologists and cardiac surgeons, should take sufficient time to assess all available information on complex cases. However, there are relatively limited data on the heart team implementation in detail, such as the ideal composition, meeting frequency, the timing of decision-making and outcomes, potentially leading to suboptimal decision-making quality.

Prior efforts have noted insufficient inter-specialist consistency, intra-team reproducibility and inter-team agreement in heart team decision-making. Denvir *et al* found poor agreement existed between cardiac clinical specialists (kappa=0.26).[6] Several studies reported that on re-discussion of the same patient data 9–12 months later, nearly 20%–24% of decisions differed from the original heart team recommendations.[7 8] In our previous work, the agreement between heart teams for revascularisation decision-making was just moderate (kappa=0.58).[9]

Clinical guidelines and previous practice experience from different centres have summarised several critical principles in heart team implementation.[10–12] Guidelines recommend the composition should be at least a cardiac surgeon, an interventional cardiologist and a non-interventional cardiologist.[1 5] Sanchez *et al* summed up the experience of the heart team implementation from their single centre, including team composition, data collection and meeting process.[11] The British Cardiovascular Society, Society for Cardiothoracic Surgery in Great Britain and Ireland and British Cardiovascular Intervention Society set out the principles for the functioning of the heart team across the UK, including composition, frequency and the type of cases discussed.[12] Although these works provided essential experiences for heart team implementation, the protocols were not evidence-based and data regarding how these protocols impact decision-making stability were scarce.[12]

To determine the potential factors influencing heart team decision-making comprehensively and explore an evidence-based heart team protocol, we conducted a sequential explanatory mixed method study and summarised 3 themes (specialist quality, team composition and meeting process) and 10 subthemes of potential factors. In addition, nine recommendations for heart team implementation were derived based on qualitative and quantitative data, and a standardised heart team protocol was developed based on the previous experience, recommendations and guidelines, covering the whole procedure of heart team implementation.

However, the practical effect of the standardised protocol versus the guideline-based protocol on decision-making stability and clinical outcomes remains unknown, and a randomised trial for validation is warranted. Therefore, we designed this pivotal randomised trial.

METHODS AND ANALYSIS
Study design
The current study is a randomised, controlled, two-arm trial involving 84 cardiac specialists from 26 hospitals in China. Eligible specialists have been randomised to a standardised implementation protocol group or a guideline-based group to establish 24 heart teams and make revascularisation decisions for 480 stable complex
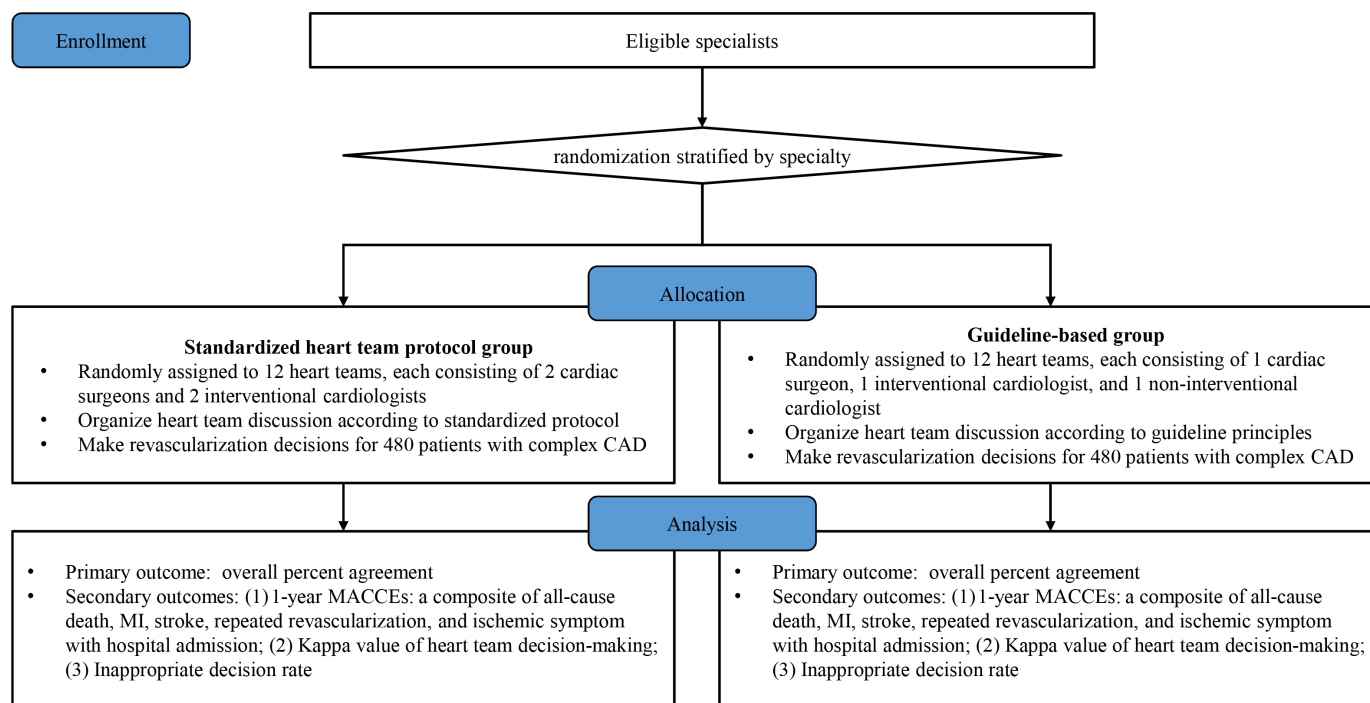
Figure 1 Study flow chart. Eligible specialists will be randomised to a standardised heart team protocol group or a guideline-based group and established 12 heart teams in each group to make revascularisation decisions for 480 historic cases (from a prospective registry) with stable complex CAD. CAD, coronary artery disease; MACCE, major adverse cardiovascular and cerebrovascular event; MI, myocardial infarction.

Table 1 Inclusion criteria for heart team specialists

Disciplines	Inclusion criteria
Interventional cardiologist	1. Annual PCI volume ≥200[16] 2. Annual LM-PCI volume ≥25[1] 3. CTO PCI total volume ≥10 4. Clinical researcher experience in coronary revascularisation 5. Proficient in clinical guidelines
Cardiac surgeon	1. CABG total volume ≥200[17] 2. Proficient in both on-pump and off-pump CABG 3. Clinical researcher experience in coronary revascularisation 4. Proficient in clinical guidelines
Non-interventional cardiologist	1. Proficient in clinical guidelines

CABG, coronary artery bypass grafting; CTO, chronic total occlusion; LM, left main; PCI, percutaneous coronary intervention.

CAD cases retrospectively enrolled. We will evaluate the decision-making stability (figure 1). Standard Protocol Items: Recommendations for Interventional Trials,[13] Consolidated Standards of Reporting Trials[14] and Template for Intervention Description and Replication[15] checklists are mentioned in online supplemental file 1. The study start date is 4 January 2022 and the anticipated end date is 31 January 2023.

Objective and hypothesis

The primary objective of this study is to evaluate the effect of the standardised heart team protocol versus the guideline-based protocol on the stability of decision-making in stable complex CAD. The primary hypothesis is that heart teams organised on the standardised protocol will result in better decision-making consistency compared with those based on guideline principles. The secondary objectives of this study are to (1) evaluate the association between decision-making stability and 1-year composite of death, myocardial infarction (MI), stroke, repeated revascularisation and re-hospitalisation due to ischaemic symptoms; (2) assess the appropriateness of heart team decision-making.

Participants and recruitment

To have access to enough experienced specialists, we will enrol eligible specialists from hospitals with (1) annual volume of percutaneous coronary intervention (PCI) ≥500; (2) annual volume of coronary artery bypass grafting (CABG) ≥200[1]; (3) have at least two interventional cardiologists, two cardiac surgeons and one non-interventional cardiologist meeting the inclusion criteria and agreeing to participate in the study. The inclusion criteria for the heart team specialists differ from specialties and require specified operator volumes and experience (table 1). The interventional cardiologist is required to have an annual PCI volume ≥200,[16] an annual left main (LM)-PCI volume ≥25[1] and is capable of chronic total occlusion (CTO)-PCI. The cardiac surgeon must have a total CABG volume ≥200[17] and be proficient in both on-pump and off-pump CABG. We have contacted all the potential participants via emails or telephones to get their information confirmed and obtained their content from 1 December 2021 to 10 January 2022. All participating specialists have provided written informed consent for enrolment (online supplemental file 2).

Randomisation

Randomisation is stratified by specialties and conducted by a data manager using random number generation in SAS. We have randomised 36 cardiac surgeons and 36 interventional cardiologists in a 2:1 ratio to the standardised protocol group (24 surgeons and 24 interventional cardiologists) or the guideline-based group (12 surgeons and 12 interventional cardiologists). Twelve non-interventional cardiologists have been randomly selected and allocated to the guideline-based group. After the randomisation, each group of specialists will be randomly assigned to 12 heart teams and perform heart team meetings according to corresponding protocols. Research staff will be informed of the randomisation and organise the allocated specialists to establish heart teams. Participating specialists are unaware of the implementation conditions (online supplemental figure 1).

Case selection and preparation

Selection of cases to be discussed

Adult cases with stable CAD according to the National Cardiovascular Data Registry (NCDR) CathPCI criteria[18] (stable angina, no or silent myocardial ischaemia) and angiographically confirmed 3-vessel disease or LM disease are eligible for inclusion in the study. We have randomly selected eligible cases from a prospective registry of consecutive patients who underwent coronary angiography between August 2016 and August 2017 (online supplemental figure 2).[19] All cases provided written informed consent at the time of registration and agreed to use their data for subsequent approved cardiovascular-related medical research. Definitions and inclusion/exclusion criteria of cases can be seen in online supplemental methods.

Structured patient information

Patient data will be presented in a structured information form on an electronic meeting support system by non-clinical coordinators (online supplemental table

1). The structured information includes (a) demographics; (b) medical histories and clinical risk factors; (c) medical treatment histories and CVD symptoms of the index hospitalisation; (d) laboratory results; (e) non-invasive testing results (eg, ECG, echocardiogram, stress testing results); (f) diagnostic angiogram images and quantitative flow ratio (QFR)[20]; (g) clinical risk scores (ie, Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery (SYNTAX) score,[21] SYNTAX II score,[22] SYNTAX II 2020 score,[23] Society of Thoracic Surgeons (STS) score,[24 25] the European System for Cardiac Operative Risk Evaluation (EuroSCORE) II[26] and SinoSCORE II).[27] All the clinical information has been obtained from medical records according to the NCDR CathPCI data definitions.[18] An independent angiographic core laboratory takes responsibility for all angiogram image screening and risk score evaluation by using a computer-based automatic calculator.
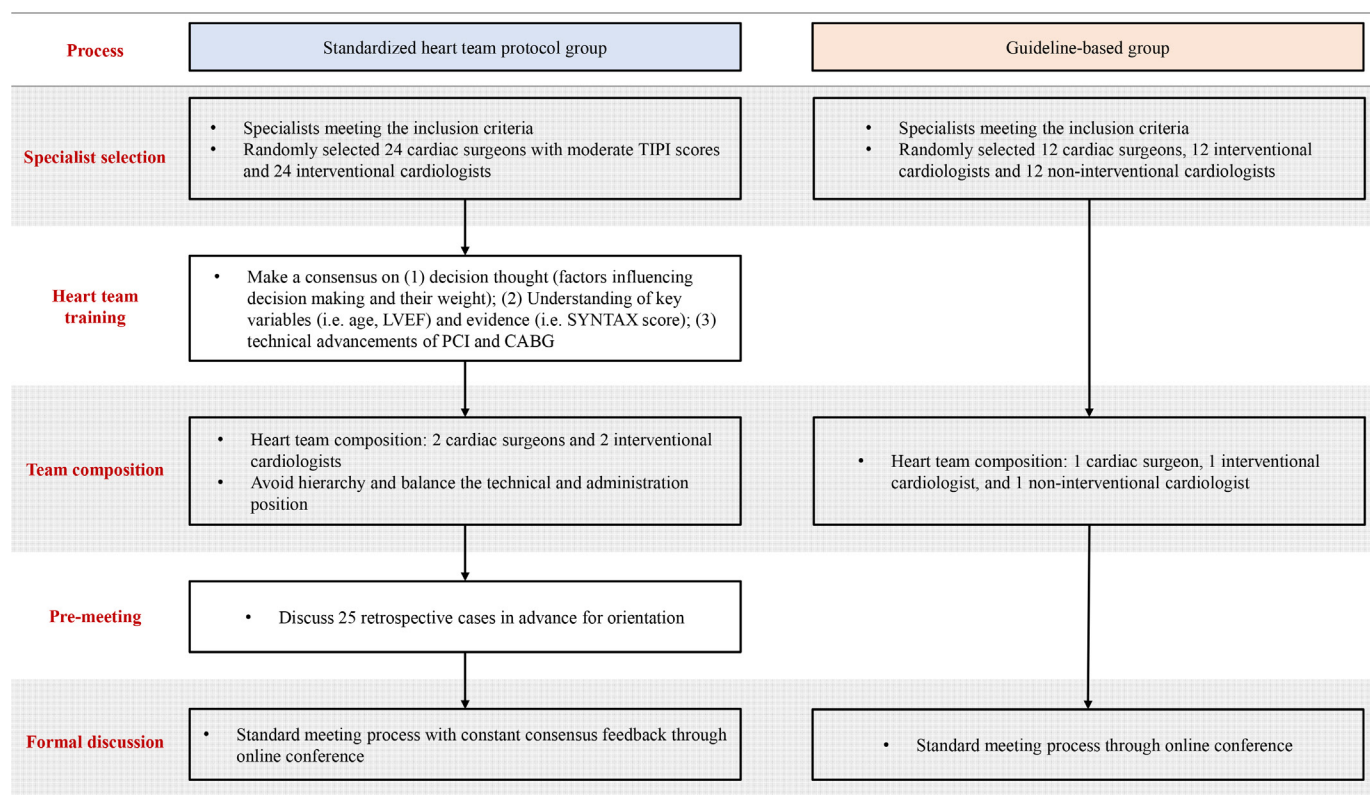
Case assignment

Four hundred and eighty cases will be randomised into 6 sets of 80 cases each, using a stratified randomisation procedure to ensure relatively equal heart team exposure to case complexity and a similar ratio of actual treatment strategies (CABG, PCI or medication therapy).

Intervention

Standardised heart team protocol

Eligible specialists randomised to this group will establish 12 heart teams and conduct heart team meetings based on the standardised heart team protocol[9] (figure 2).

i. *Specialist selection*: all the cardiac surgeons are required personality tests by Ten-Item Personality Inventory in China (TIPI-C)[28] and 24 surgeons with moderate scores will be randomly selected (online supplemental table 2). Twenty-four interventional cardiologists will be randomly selected without personality selection.

ii. *Specialist training*: all heart team members must undergo unified training to achieve a consensus on the potential factors influencing revascularisation decisions. The training will be conducted and recorded by well-prepared coordinators. Consensus view should include clinical considerations on the essential characteristics (eg, age, left ventricular ejection fraction (LVEF) and body mass index (BMI)) and their weightage, interpretation of evidence (eg, SYNTAX trial, Evaluation of XIENCE vs Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularisation trial and the International Study

Process	Standardized heart team protocol group	Guideline-based group
Specialist selection	• Specialists meeting the inclusion criteria • Randomly selected 24 cardiac surgeons with moderate TIPI scores and 24 interventional cardiologists	• Specialists meeting the inclusion criteria • Randomly selected 12 cardiac surgeons, 12 interventional cardiologists and 12 non-interventional cardiologists
Heart team training	• Make a consensus on (1) decision thought (factors influencing decision making and their weight); (2) Understanding of key variables (i.e. age, LVEF) and evidence (i.e. SYNTAX score); (3) technical advancements of PCI and CABG	
Team composition	• Heart team composition: 2 cardiac surgeons and 2 interventional cardiologists • Avoid hierarchy and balance the technical and administration position	• Heart team composition: 1 cardiac surgeon, 1 interventional cardiologist, and 1 non-interventional cardiologist
Pre-meeting	• Discuss 25 retrospective cases in advance for orientation	
Formal discussion	• Standard meeting process with constant consensus feedback through online conference	• Standard meeting process through online conference

Figure 2 Implementation strategies for the standardised protocol group and guideline-based group. In the standardised protocol group, the heart team will be implemented based on an evidence-based protocol including specialist selection, specialist training, team composition, team training and a standardised meeting process. In the guideline-based group, the heart team will be implemented according to the key principles mentioned in clinical guidelines, including team composition and standardised meeting process. CABG, coronary artery bypass grafting; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery; TIPI, Ten-Item Personality Inventory.

of Comparative Health Effectiveness with Medical and Invasive Approaches results). Additionally, the latest technical advancements in PCI and CABG will be discussed, especially for PCI, to narrow cognitive gaps among specialists of different expertise. The consensus view document will be recorded and put onto the electronic meeting support system for reference at any time. To maintain fidelity to the consensus view, we will present each bullet point of the consensus view as a footnote under the corresponding variable.

iii. *Team composition*: all specialists selected will be randomly assigned to 12 heart teams consisting of 2 cardiac surgeons and 2 interventional cardiologists. Non-interventional cardiologist or other disciplinary specialist is not required in the routine heart team unless necessary. Moreover, the technical level and administration position will be balanced in each team.

iv. *Team training*: before the formal heart team meeting, a pilot discussion (25–50 retrospective cases) will be performed following the standard meeting procedure to reinforce the practice of the former consensus view for a more solid team consensus.

v. *Standardised meeting process*: heart team meetings will be conducted standardly in both groups according to the procedure widely used in the previous studies.[10–12] Each heart team independently evaluates a set of cases (80 cases) through the heart team assistance system using structured online case presentations, with the members blinded to the other heart teams and the decisions of other heart teams. All specialists are required to make decisions independently among five treatment categories (PCI, CABG, PCI/CABG equipoise, medical therapy or further testing) before (round I) and after (round II) the heart team discussion. The heart team member only has access to the responses of the other heart team members after all members have submitted their independent decisions. The final treatment strategy is determined by a majority decision (online supplemental figure 3).

Guideline-based protocol

We will randomly assign eligible specialists randomised to this group to 12 heart teams based on the principles of guidelines (figure 2). Each heart team consists of one interventional cardiologist, one cardiac surgeon and one non-interventional cardiologist. This group does not require premeeting training on consensus view and pilot discussion. Formal meeting procedures follow the standardised meeting process as the other group.

All heart team meetings will be held through video conferencing, and a quiet environment will be required. For each heart team, the frequency of meetings is one or two times per week and lasts 1.5–2 hours at a time.

Outcomes

The primary outcome is the overall percent agreement (OPA),[29] defined as the proportion of patients who received coincident decision recommendations from paired heart teams. The secondary outcomes include:

1. One-year major adverse cardiovascular and cerebro-vascular events (MACCEs): a composite of all-cause death, MI, stroke, repeated revascularisation and re-hospitalisation due to ischaemic symptoms.
2. Kappa value of heart team decision-making: Fleiss's (>2 raters) and Cohen's (2 raters) kappa coefficients to evaluate inter-team, intra-team, inter-specialist, intra-specialist and inter-round agreement for treatment decisions. To evaluate the reproducibility, all assigned cases will be re-discussed with the same clinical data but not in the same order 1 month after the completion of the initial discussion, with the heart team blinded to the outcome of the initial meeting.
3. Inappropriate decision rate: the final heart team recommendations will be adjudicated for appropriateness using the American College of Cardiology/American Association for Thoracic Surgery/American Heart Association 2017 Appropriate Use Criteria (AUC) and the Chinese AUC for coronary revascularisation for each case.[30 31] Two investigators who do not participate in data collection will take responsibility for reviewing the team decisions and adjudicating the decision appropriateness independently. Any disputes will be settled via review by a third investigator, with a decision by consensus.

Data management and monitoring

Our IRB-approved protocol specifies plans for data entry, coding, security and data storage on a secure server. For retrospective data, all data will be double-checked or assessed by two independent coordinators. For prospective data on heart team meetings, the online meeting supporting system included several mechanisms to protect data integrity and promote data quality (eg, warning of missing values and preventing duplicate team participation). The data manager will maintain detailed data management procedures. Coordinators will report to and discuss with the principal investigator about the study progress, including participant recruitment, data collection and analysis and heart team meeting conductions. Any protocol modifications will be discussed with and approved by the IRB. Any significant changes in methods will be reported to the project's programme officer and updated on the registration site https://ClinicalTrials.gov. This study does not need a data monitoring committee because all the cases discussed are retrospectively selected. Their revascularisation strategies would not be influenced by heart team recommendations and will be no risk for cases. As for participating specialists, heart team discussion will not interfere with their routine clinical work. The principal investigator and approved study team members will have access to the final trial datasets.

Statistical analysis

The pairwise comparison between the heart team decisions in each case provides data on the agreement (online supplemental table 3). The inter-team, intra-team, inter-specialist, intra-specialist and inter-round agreements will be assessed using OPA and Cohen's κ coefficient, whenever applicable. Mean decision time will also be calculated. Cox proportional hazards models will be used to analyse whether the treatment decision adhering to the heart team recommendations is associated with better outcomes. Categorical variables will be expressed as frequency and percentage. Continuous variables will be expressed as mean±SD, or median and IQR. Categorical variables will be analysed with the likelihood ratio χ^2 test or Fisher's exact test if >25% of the cells have an expected frequency smaller than 5. Continuous variables will be computed with the two-sample t-test when data follow a normal distribution and will be compared with the Wilcoxon rank sum test for non-normal distribution; 95% CIs will be computed for all measurements. All the analyses will be performed at a significance level of two-sided 0.05. All tests will be performed using SAS software, V.9.4 (SAS Institute, Cary, North Carolina, USA).

Sample size

Number of assessments necessary to evaluate decision-making agreement

The primary end point of this study is to compare the OPA between the standardised protocol group and the guideline-based group. In our previous study, heart teams were established based on guidelines, and it was estimated that the OPA was 66.3% (unpublished data), serving as the reference rate of the controlled group in this study. We assumed that inter-team agreement is similar to or no better than intra-team reproducibility rate. According to relevant literature,[7][8] it is estimated that the OPA of the standardised protocol group is 76% (the minimum estimate of previous literature). Under this circumstance, the standardised protocol group has a minor effect on improving decision consistency compared with the guideline-based group. Using a 5% level of two-side significance and a confidence level of 90%, it was estimated that a total number of 454 pairwise comparisons for each group would be necessary to meet the study acceptance criterion. For the convenience of case assignment, we adjusted the sample size to 480 cases.

Number of heart teams needed

Considering the feasibility of implementation and a good representation of both samples and heart teams, it was decided that 24 heart teams are needed with 12 in each arm. Teams in each group will be divided into 6 pairs randomly, and each pair of heart teams will evaluate the same randomly assigned 80 cases independently to provide inter-team agreement data, generating 480 pairwise comparisons in each group.

Number of heart team specialists

The heart team in the standardised group consists of two interventional cardiologists and two cardiac surgeons and that in the guideline-based group consists of one interventional cardiologist, one cardiac surgeon and one non-interventional cardiologist. With 12 heart teams in each group, a minimum of 36 cardiac surgeons, 36 interventional cardiologists and 12 non-interventional cardiologists are needed in the final study in total.

Subgroup analysis

The primary and secondary outcomes will be analysed in prespecified subgroups, including specialties and professional status. The analysis will also be conducted according to different cases stratified by age, LVEF, BMI, degree of the stenosis, calcified lesion, stenosis severity, tandem and bending/tortuous lesion, LM, SYNTAX stratification, SYNTAX II recommendations and SinoSCORE stratification. The comparisons in these analyses may be not powered for hypothesis testing but are descriptive in nature.

Current status

Thirty-six cardiac surgeons, 36 interventional cardiologists and 12 non-interventional cardiologists from 26 eligible hospitals agreed to participate in this study and have provided informed consent. Four hundred and eighty cases with stable complex CAD have been randomly selected for discussion. Specialist and patient baseline data are shown in tables 2 and 3.

Patient and public involvement

None.

Ethics and dissemination

Ethics

The study was reviewed and approved by the Ethics Review Committees of Fuwai Hospital (2019–1303) on 2 August 2021; subsequent amendments have been approved. All participants have provided informed consent and all patients included as historic cases provided written informed consent at the time of entry to the prospective registry.

Safety

All the eligible cases were retrospectively selected and underwent coronary angiography between August 2016 and August 2017. Heart team decisions do not affect patients' actual treatments. There will be no adverse event or serious adverse event relating to this study.

Dissemination

The results of this trial will be reported to the participating specialists, disseminated through manuscript publication and national/international conferences, and reported in the trial registry entry.

DISCUSSION

The optimisation of heart team implementation including team composition, operation, distribution of

Table 2 Specialist baseline characteristics

Characteristics	Overall (n=84)	Cardiac surgeon (n=36)	Interventional cardiologist (n=36)	Non-interventional cardiologist (n=12)
Male	71 (84.5)	35 (97.2)	34 (94.4)	2 (16.7)
Status				
Chief specialist	46 (54.8)	21 (58.3)	19 (52.8)	6 (50.0)
Associate specialist	34 (40.5)	15 (41.7)	13 (36.1)	6 (50.0)
Attending specialist	4 (4.8)	0 (0.0)	4 (11.1)	0 (0.0)
Personality (TIPI)*	5.20 (4.80–5.70)	5.20 (4.90–5.50)	5.20 (4.60–5.80)	5.45 (4.80–5.60)
Extraversion	4.50 (4.00–5.00)	4.50 (4.00–5.50)	4.50 (4.00–5.00)	4.50 (4.00–5.00)
Agreeableness	5.50 (4.50–6.00)	5.00 (4.50–5.50)	5.75 (4.50–6.50)	5.75 (5.00–6.00)
Conscientiousness	5.50 (5.00–6.50)	6.00 (5.00–6.50)	5.50 (5.00–6.50)	5.75 (5.00–6.00)
Emotional stability	5.00 (5.00–6.00)	5.00 (5.00–5.50)	5.00 (4.50–6.00)	6.00 (5.00–6.00)
Openness to experiences	5.00 (4.50–5.50)	5.00 (4.50–5.50)	5.00 (5.00–5.50)	4.75 (4.50–5.50)

Data presented as n (%) and median (IQR).
*Personality was evaluated by the TIPI scale in Chinese.[28]
TIPI, Ten-Item Personality Inventory.

responsibilities and other issues still lacks verification by evidence-based trials. The present study is the first trial focusing on the heart team implementation quality assessment and improvement by evaluating the effect of the standardised heart team protocol compared with the guideline-based protocol on decision-making stability for stable complex CAD.

Stability is a potential metric of decision-making quality. As the expertise of individual specialists is specific to their professional training and experience, cardiologists and surgeons prefer PCI or CABG, respectively.[10] Prior data showed that 18.1% of the overall decision-making for patients with stable angina was classified as inappropriate based on a single disciplinary decision, especially among patients undergoing PCI.[32] The heart team, a medium of communication to integrate the input of numerous specialists, can help to minimise fragmented communication between specialists and eliminate specialist bias in the decision-making process. It was reported that heart team recommendations differed from those of the original treating interventional cardiologist in approximately one-third of cases.[33] Sanchez *et al* convened 301 heart team meetings for complex CAD from 2012 to 2015 and reported the concordance of the heart team to appropriate use criteria was up to a 99.3% appropriate primary indication for coronary revascularisation.[34] Therefore, qualified heart teams perform more evidence-based and neutral in revascularisation decision-making. The success of the heart team approach is apparent in a growing number of optimal revascularisation decisions made according to professional guidelines.

Notably, a dedicated and structured heart team has a potential benefit for patient survival. Sardari Nia *et al* reported patients treated for mitral valve disease based on a dedicated heart team decision have significantly higher survival than a general heart team, which illustrated the establishment of a dedicated heart team consisting of experienced specialists with adequate procedure volume benefits patient survival.[35] In addition, appropriate revascularisation is associated with improved 1-year outcomes in patients with appropriate indications and has no benefit in those with uncertain or inappropriate indications.[19] Thus, we assume that revascularisation recommendations of dedicated heart teams organised by the standardised heart team protocol would be more stable and appropriate compared with those of general heart teams based on guideline principles, which leads to better clinical outcomes.

Making the heart team approach well-structured and efficient contributes to a better quality of cardiovascular care. The current study is essential to answer the following questions: (1) Is it feasible to establish and organise heart team meetings with the guidance of the standardised heart team protocol? (2) Will the standardised heart team protocol improve the decision-making stability in patients with stable complex CAD compared with the fundamental principles of heart team organising in guidelines? Moreover, it will enhance educational opportunities for all team members involved and provide experience in the practice of heart team meetings in prospective clinical scenarios.

Several novel designs underlie the strength of this study. First, we use a randomised controlled design to demonstrate the structure and effect of an evidence-based standardised heart team protocol on decision-making stability against the controlled approach based on guideline principles, which fills the gap with no randomised data currently available in optimal heart team implementation.[12 33] Second, the study applies randomisation three times. Eligible specialists are first randomly selected and

Table 3 Demographic and clinical characteristics of retrospective patients

Characteristics	Patients for discussion (n=480)
Demographics	
Age, years	62.0 (55.0–67.5)
Male (%)	363 (75.6)
Risk factors	
Hypertension	334 (69.6)
Hyperlipidaemia	429 (89.4)
Diabetes	185 (38.5)
Cerebrovascular disease	102 (21.3)
COPD	7 (1.5)
Chronic renal disease	14 (2.9)
Smoker	226 (47.1)
Body mass index, kg/m^2	25.6 (23.7–27.5)
Ccr <60 mL/min/1.73 m^2	7 (1.5)
Cardiovascular characteristics	
Previous MI	49 (10.2)
Previous heart failure	10 (2.1)
Peripheral vascular disease	46 (9.6)
Ejection fraction, %	63.0 (59.0–65.0)
Ejection fraction ≤40%	23 (4.8)
CAD symptoms	
Silent ischaemia (after medical therapy)	90 (18.8)
Non-ischaemia symptom	20 (4.2)
Stable angina	370 (77.1)
CCS I–II	325 (87.8)
CCS III–IV	45 (12.2)
Number of anti-anginal medications	
0	118 (24.6)
1	154 (32.1)
2	149 (31.0)
3	59 (12.3)
Extent of coronary disease	
3-vessel disease	451 (94.0)
Left main disease	129 (26.9)
Risk classification	
SYNTAX score	22.5 (16.5–29.5)
SYNTAX score tertiles	
Low risk (0–22)	237 (49.4)
Intermediate risk (23–32)	157 (32.7)
High risk (≥33)	86 (17.9)
SYNTAX score II recommendation	
PCI	11 (2.3)
CABG	153 (31.9)

Continued

Table 3 Continued

Characteristics	Patients for discussion (n=480)
Equipoise	316 (65.8)
SYNTAX score II 2020 10-year mortality (%)	
CABG	14.8 (9.1–24.7)
PCI	19.4 (11.6–32.2)
Euroscore II mortality (%)	0.80 (0.58–1.06)
SinoSCORE II mortality (%)	0.82 (0.47–1.18)
STS score (incidence of postoperative events)	
Mortality (%)	0.49 (0.36–0.70)
Mortality or major complications (%)	5.30 (4.43–6.56)
Reoperation (%)	1.72 (1.46–2.07)
Renal failure (%)	0.43 (0.32–0.61)
Stroke (%)	0.96 (0.73–1.36)
Prolonged ventilation (%)	3.20 (2.62–3.98)
DSWI (%)	0.10 (0.08–0.14)
Prolonged hospitalisation (%)	1.79 (1.33–2.53)
Treatment strategy in real world	
PCI	287 (59.8)
CABG	116 (24.2)
Medical therapy	77 (16.0)

Data presented as median (IQR) and n (%).
CABG, coronary artery bypass graft; CAD, coronary artery disease; Ccr, creatinine clearance rate; CCS, Canadian Cardiovascular Society; COPD, chronic obstructive pulmonary disease; DSWI, deep sternal wound infection; MI, myocardial infarction; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons; SYNTAX, Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.

assigned to different arms by stratification randomisation. Then we establish heart teams with randomised membership to reduce social factors that may have negative implications on individual decision-making.[36] Cases are also randomised into 6 sets of 80 cases each to ensure relatively equal heart team exposure to case complexity. Third, all heart team training and meetings are held via video conference using an online decision-making support system, which makes it possible to involve specialists from multiple hospitals, reduce the negative influence of a few influential individuals on face-to-face decision-making and eliminate the risk of viral spreading in COVID-19.[37] Fourth, we provide the most up-to-date risk scores (such as SYNTAX II 2020 score,[23] SinoSCORE II[27] and QFR,[20] a novel angiography-derived physiological assessment approach, in structured information for the specialists to adjudicate the optimal treatment strategy.

The study has several limitations. First, cases discussed are retrospectively selected rather than prospectively enrolled. All cases have already been treated from August 2016 to August 2017 in the original hospitalisation, thus

it is unable to reveal the causal link between heart team meetings and real-world decision-making and outcomes in routine clinical practice. Prospective design is needed for the next step. Second, the intervention in the standardised protocol group is an integrated approach and the potential differential outcomes associated with its use cannot be attributed to a single point of the process. Additional quantitative and qualitative analysis is needed to find out which steps work on the decision-making stability. Third, heart team decisions will be made independently of patient preferences, while in real-world clinical practice, patient preference is an important factor for the final treatment decision. Patient involvement in shared decision-making should be considered in future trials.

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