



# No-touch versus conventional vein in coronary artery bypass grafting: three year follow-up of multicentre randomised PATENCY trial

Meice Tian,<sup>1</sup> Xianqiang Wang,<sup>1</sup> Wei Feng,<sup>1</sup> Huaibin Wang,<sup>2</sup> Su Liu,<sup>3</sup> Zhigang Liu,<sup>4</sup> Yu Chen,<sup>5</sup> Qi Miao,<sup>6</sup> Pixiong Su,<sup>7</sup> Xi Li,<sup>8</sup> Yang Wang,<sup>9</sup> Bin Lu,<sup>10</sup> Kai Chen,<sup>1</sup> Changwei Zhang,<sup>1</sup> Shengshou Hu<sup>1</sup>

For numbered affiliations see end of the article

Correspondence to: S Hu  
huss@fuwaihospital.org;  
(ORCID 0000-0001-8136-0224)

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## ABSTRACT

### OBJECTIVE

To assess the three year outcomes of the no-touch vein harvesting technique in coronary artery bypass grafting surgery compared with the conventional approach.

### DESIGN

Three year extended follow-up of the randomised PATENCY (graft patency between the no-touch vein harvesting technique and conventional approach in coronary artery bypass graft surgery) trial.

### SETTING

Seven cardiac surgery centres in China; enrolment between April 2017 and June 2019.

### PARTICIPANTS

2655 participants aged 18 and older undergoing isolated coronary artery bypass grafting surgery.

### INTERVENTIONS

Patients were randomly assigned 1:1 to the no-touch vein harvesting technique group or the conventional approach group during surgery and followed up.

### MAIN OUTCOME MEASURES

Vein graft occlusion (based on computed tomography angiography) at three years.

### RESULTS

Mean age of participants was 61 years (standard deviation  $\pm 8$  years) and 22% were women. 99.4% (2621) attended the three year follow-up visit, while 86.5% (2281) received computed tomography angiography. At three years, the no-touch group showed a significantly lower vein graft occlusion rate (5.7% v 9.0%,  $P < 0.001$ ) than the conventional group

(odds ratio 0.62, 95% confidence interval 0.48 to 0.80), with absolute risk difference of  $-3.2\%$  (95% confidence interval  $-5.0\%$  to  $-1.4\%$ ). The intention-to-treat analysis, including all 2655 randomised patients with multiple imputations for missing data, showed consistent findings, with occlusion rates of 6.1% in the no-touch group versus 9.3% in the conventional group (odds ratio 0.63, 95% confidence interval 0.51 to 0.81; absolute risk difference  $-3.1\%$ , 95% confidence interval  $-4.9\%$  to  $-1.4\%$ ;  $P < 0.001$ ). These results confirm the robustness of the no-touch technique in reducing vein graft occlusion.

### CONCLUSIONS

The no-touch technique consistently and robustly reduced the risk of vein graft occlusion and several cardiac events by one third to one half within three years after coronary artery bypass grafting surgery.

### TRIAL REGISTRATION

ClinicalTrials.gov NCT03126409.

### Introduction

Coronary artery bypass grafting (CABG) surgery remains the standard surgical treatment for patients with multivessel coronary artery disease, particularly those with complex lesions not amenable to percutaneous coronary intervention.<sup>1</sup> Although arterial grafts, such as the left internal mammary artery, are the gold standard owing to superior long term patency, saphenous vein grafts remain indispensable in CABG given the need for several conduits in most patients, constituting approximately 80% of all grafts used.<sup>2</sup> However, compared with arterial grafts, vein graft occlusion rates are comparatively high. Vein graft occlusion was observed at a rate of 10-15% after one year, 13.7% at three years, and an increase of 2-4% annually after surgery.<sup>2-14</sup> Vein graft failure is associated with adverse outcomes, including recurrent angina, myocardial infarction, repeat revascularisation, and even death.<sup>3 15-21</sup> The underlying mechanisms of saphenous vein graft occlusion vary with time: technical and haemodynamic factors dominate early failures, while intimal hyperplasia and progressive atherosclerosis drive failures beyond one year.<sup>22</sup>

Traditional vein harvesting methods, which involve extensive mechanical handling and adventitial stripping, exacerbate endothelial damage and inflammation, disrupting the graft's structural and functional integrity. These factors predispose grafts to thrombosis and late intimal hyperplasia, leading to early and late occlusions.<sup>23</sup> In recent

## WHAT IS ALREADY KNOWN ON THIS TOPIC

The no-touch vein harvesting technique has been shown to reduce saphenous vein graft occlusion rates at three and 12 months after coronary artery bypass grafting surgery

Robust evidence about durability and clinical benefits of this technique remains limited

## WHAT THIS STUDY ADDS

This extended follow-up of a randomised trial involving 2655 patients found significantly reduced vein graft occlusion (5.7% v 9.0%), non-fatal myocardial infarction, and repeat revascularisation in the no-touch group at three years after coronary artery bypass grafting surgery

The no-touch vein harvesting technique ensures sustained graft patency over an extended period and shows a tendency to improve patient outcomes by reducing the incidence of myocardial infarction and repeated revascularisation

years, alternative approaches to vein harvesting and grafting have emerged, offering unique benefits and limitations. Endoscopic vein harvesting, a minimally invasive technique, has gained popularity owing to its ability to reduce wound complications and enhance recovery. However, concerns persist about its impact on long term graft patency because endoscopic vein harvesting might lead to endothelial damage during the harvesting process.<sup>24</sup> Similarly, arterial grafts such as the radial artery are increasingly favoured for their enhanced durability compared with saphenous vein grafts.<sup>25</sup> Despite these advantages, radial artery grafts present specific challenges, including competitive flow, a higher risk of vessel spasm, and technical complexity during harvesting and anastomosis.<sup>26 27</sup> The no-touch vein harvesting technique was developed to mitigate these issues. Unlike conventional methods, the no-touch technique preserves the vein's adventitia and surrounding perivascular tissue, maintaining the integrity of the vasa vasorum and endothelial function. This approach minimises endothelial injury and reduces the inflammatory response, thereby enhancing graft patency.<sup>28-30</sup>

Previous small trials, mostly with sample sizes less than 300 patients and angiographic follow-up rates lower than 80%, have implied reduced occlusion of saphenous vein grafts harvested using the no-touch approach.<sup>20 31 32</sup> The 2018 European Revascularization Guidelines recommend using the no-touch technique when performing open harvesting of vein grafts (class of recommendation IIa, level of evidence B).<sup>33</sup> Larger trials

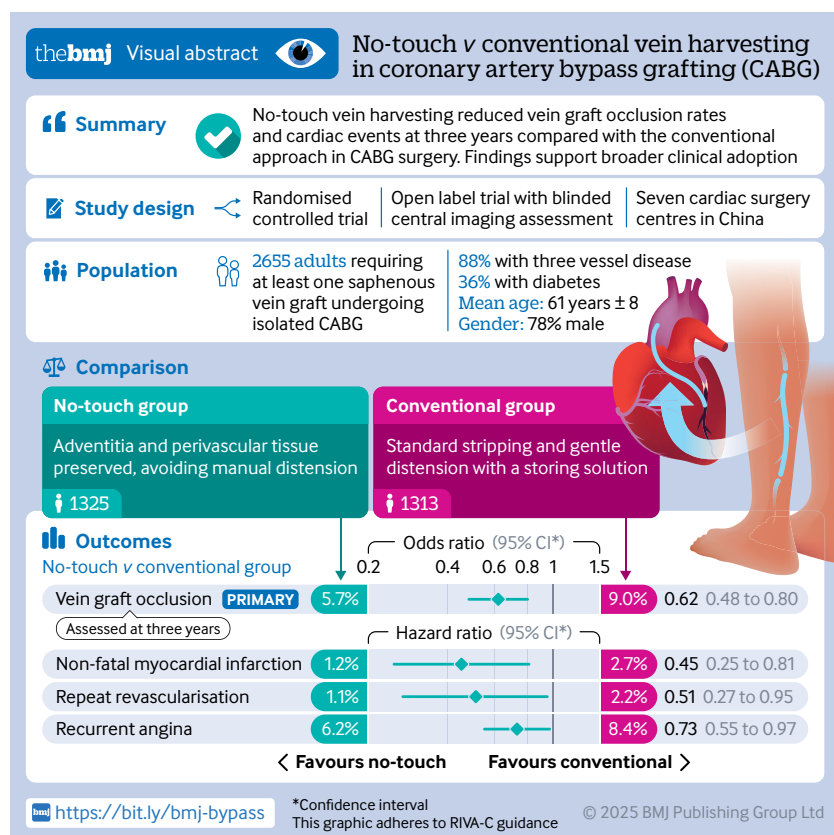
have also been conducted, such as no-touch saphenous vein grafts in coronary artery surgery (SWEDEGRAFT), which involved 900 patients.<sup>34</sup> Despite its promise, the no-touch technique is underused in clinical practice because of concerns about higher rates of leg wound complications.<sup>35</sup> However, the extended efficacy of the no-touch technique remains uncertain, and more importantly, evidence about its clinical benefit is still lacking. The PATENCY (graft patency between the no-touch vein harvesting technique and conventional approach in coronary artery bypass graft surgery) trial was a multicentre randomised study comparing the effects of the no-touch vein harvesting technique with the conventional approach in CABG surgery.<sup>36</sup> Earlier findings from the PATENCY trial showed that the no-touch technique significantly reduced the risk of vein graft occlusion at three months (2.8% v 4.8%;  $P<0.001$ ) and 12 months (3.7% v 6.5%;  $P<0.001$ ) after surgery, with fewer patients with recurrent angina at 12 months (2.3% v 4.1%;  $P=0.007$ ).<sup>37</sup> This study aims to address the critical gap in evidence regarding the extended efficacy of the no-touch vein harvesting technique in CABG surgery. Specifically, we sought to evaluate whether the no-touch technique provides sustained improvements in saphenous vein graft patency and clinical outcomes compared with the conventional harvesting approach over a three year period. By using the findings from this large randomised controlled trial, we aim to establish robust evidence to inform clinical practice and guideline recommendations.

## Methods

### Study design

The PATENCY trial was conducted at seven hospitals in China. The study was registered at ClinicalTrials.gov (identifier NCT03126409). The design of this trial, including detailed inclusion and exclusion criteria, has been published previously.<sup>36</sup> The PATENCY trial was designed to assess the long term efficacy of the no-touch vein harvesting technique, with plans for follow-up extending up to 10 years documented in the original study protocol. Although extended follow-up was not explicitly stated on ClinicalTrials.gov at registration, it was decided at the study's inception, and the registry was later updated to align with ongoing efforts to ensure transparency. This study was conducted in accordance with the Declaration of Helsinki and Guidelines for Good Clinical Practice.

Patients scheduled to undergo isolated CABG with median sternotomy and requiring at least one saphenous vein graft were identified and assessed for eligibility. Patients younger than 18 years, requiring concomitant cardiac procedures, redo or emergent CABG, and those with malignant diseases or other severe organ dysfunction were excluded (eMethod 1 in appendix 2). This decision was made to minimise confounding factors that could impact the study outcomes. Malignant diseases and severe organ dysfunction are associated with a reduced life expectancy and might lead to competing risks, such as non-cardiac mortality, which are unrelated



to the intervention. Additionally, these conditions could impair the feasibility of completing long term follow-up.

Eligible participants were randomly assigned 1:1 (randomisation details are described elsewhere<sup>36 37</sup>) to receive the no-touch vein harvesting technique or the conventional approach the day before surgery. A web based central randomisation system incorporated in the registration system was used for allocation (<https://ccsr.cvs-china.com/>). The randomisation code with fixed block size was generated by SAS. Randomisation was stratified by investigation centre. When an eligible patient gave informed consent, the investigator logged onto the randomisation webpage and obtained a random number along with the treatment group (no-touch or conventional group) automatically distributed by the system after the basic patient information was confirmed. The CABG procedures were performed by experienced surgeons who had treated at least 100 patients. Whether the operation was performed on pump or off pump was at the discretion of the surgeons. As described previously, vein harvesting for each participant was conducted by qualified senior residents.

Vein grafts were harvested from both lower legs through open incisions in all participants. In the no-touch technical group, venous adventitia and perivascular tissue were meticulously preserved, and manual distension of the veins was strictly avoided. In the conventional group, the adventitia of the vein was dissected and removed, while the vein was gently dilated with the storing solution using a syringe. The lower limb incisions of both groups of patients were sutured with two layers of continuous sutures. eMethod 2 in appendix 2 gives detailed information on surgical procedures.

Dual antiplatelet treatment was prescribed to all patients from the first day after CABG surgery until at least 3 months after the procedure. Concomitant drugs and follow-up drugs, including  $\beta$  blockers, nitrates, and statins, were prescribed by local physicians following the American College of Cardiology Foundation/American Heart Association Task Force guideline recommendations.<sup>4 38</sup>

### Outcomes

The primary outcome for the initial trial was three month vein graft occlusion, as diagnosed by computed tomography (CT) angiography or earlier clinically driven coronary angiography. Secondary outcomes were 12 month vein graft occlusion and clinical events at three and 12 months, including major adverse cardiac and cerebrovascular events (ie, death, non-fatal myocardial infarction, stroke, and repeat revascularisation), recurrence of angina, and readmission to hospital for cardiac reasons. Safety outcomes were also included as secondary outcomes and included assessment of leg wound complications at three and 12 months after surgery (eMethod 3 in appendix 2).

After the 12 month follow-up, all participants were further invited to three year follow-up visits at the study sites. Data on graft occlusion were obtained through CT angiography, either scheduled or clinically indicated. As prespecified,<sup>39</sup> graft occlusion was suspected if a conduit did not fill with contrast or if a string sign was observed in any segment. The outcomes of CT angiography were examined by two radiologists dedicated to this study (BL and Zhihui Hou) in an independent capacity at the central Core Laboratory, as in the previous study. CT angiography results and clinical outcomes were centrally adjudicated by research personnel who were unaware of the treatment assignments. eMethod 4 in appendix 2 presents criteria for clinical events adjudication.

Recurrence of angina was defined as a patient reported episode of angina symptoms confirmed by a healthcare provider, with the start date determined as the first documented visit to a local hospital because of these symptoms. All patients in the two randomised cohorts (no-touch and conventional groups) were followed according to a predefined, identical follow-up schedule, ensuring that all assessments were conducted uniformly and in a blinded manner. This standardised protocol minimised potential biases related to differences in follow-up timing or reporting between the two groups.

### Statistical analysis

The current study reports the three year outcomes of the PATENCY trial, with the primary outcome being three year vein graft occlusion (per graft). We calculated the original sample size for the study based on an assumed effect size of a 43% relative risk reduction for the primary endpoint (from 8.4% to 4.8%). Using a two sided significance level of 0.05 and aiming for 90% power, the initial calculation indicated that 2000 patients would be required to achieve sufficient statistical power. We performed this initial calculation under the assumption of independent samples at the patient and vessel level. However, recognising that several veins are harvested from each patient, an intraclass correlation coefficient of 0.99 was applied to account for clustering within individuals. Given that we expected an average of two vein grafts per patient, the sample size was subsequently adjusted to target a total of 4000 grafts (ie, 2000 patients  $\times$  2 grafts per patient) to ensure adequate power for the vessel level analysis. During the course of the trial, the Data and Safety Monitoring Board recommended a recalculation of the sample size based on the observed average of 1.5 veins per patient, which was lower than initially assumed. As a result, we recalculated the final sample size target to 2600 patients (4000 grafts  $\div$  1.5 veins per patient). This adjustment ensured that the original goal of 4000 grafts was maintained, while the number of patients exceeded the original plan of 2000. This adjustment was made in a blinded manner and did not impact the type I error of the study. Moreover, this amendment did not reduce the theoretical power of the study because

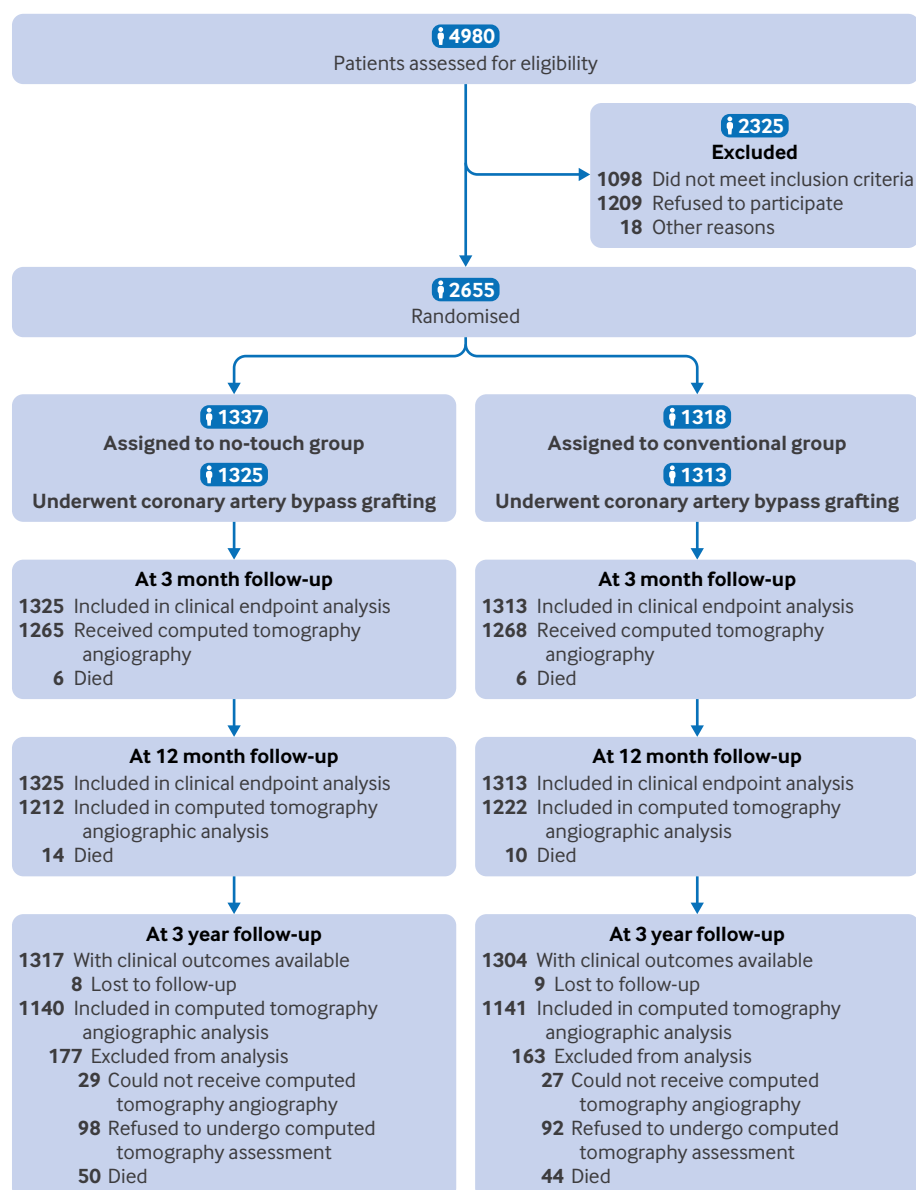


Fig 1 | Flow diagram of the study. Patient distribution of extended PATENCY trial at three year follow-up

the adjustment maintained the total number of grafts and preserved the original statistical assumptions.

All analyses were conducted on an intention-to-treat (ITT) and a modified intention-to-treat (mITT) basis. The ITT analysis included all randomised patients, including those who withdrew consent or had their surgeries cancelled before the operation. For patients with missing outcomes, we performed multiple imputation to estimate their primary outcome (three year vein graft occlusion). The imputation process assumed that missingness was at random and was conducted using chained equations, including baseline patient characteristics and available follow-up data as predictors. The mITT analysis evaluated the treatment effect among patients who received the intended surgical intervention. Therefore, patients who did not undergo surgery for reasons unrelated to

the study intervention were excluded from the mITT analysis.

Normally distributed data are presented as mean ( $\pm$ SD) and non-normally distributed data as median (range) or frequencies. Comparisons across the groups were performed using a two tailed unpaired t test for normally distributed continuous variables and Mann-Whitney for non-normally distributed variables. Pearson's  $\chi^2$  test was performed for categorical variables.

We used a generalised linear model with the generalised estimating equation to estimate the effect of the vein graft harvesting technique on graft occlusion. This model was chosen because it is well suited for accounting for correlated data, which is the clustering of graft outcomes within individual patients and provides robust population averaged estimates.

**Table 1 | Baseline characteristics of participants**

Characteristic	No-touch (n=1337)	Conventional (n=1318)
Men	1052 (78.7)	1030 (78.1)
Age (years), mean (SD)	61.0 (8.5)	60.9 (8.1)
Body mass index, mean (SD)	25.7 (3.1)	25.5 (3.1)
Clinical history		
Smoking	719 (53.8)	732 (55.5)
Diabetes	486 (36.4)	464 (35.2)
Hypertension	864 (64.6)	813 (61.7)
Hyperlipidemia	898 (68.1)	907 (69.3)
Chronic obstructive pulmonary disease	8 (0.6)	11 (0.8)
Peripheral arterial disease	103 (7.7)	87 (6.6)
Previous stroke	47 (3.5)	36 (2.7)
Previous myocardial infarction	281 (21.0)	270 (20.5)
Previous PCI	194 (14.5)	201 (15.3)
LVEF (%), mean (SD)	60.8 (6.1)	60.3 (6.5)
LVEDD (mm), mean (SD)	48.9 (5.0)	49.0 (5.3)
CCS class		
I	159 (12.0)	137 (10.4)
II	590 (44.5)	606 (46.2)
III	526 (39.7)	503 (38.3)
IV	51 (3.8)	66 (5.0)
NYHA class		
I	122 (9.2)	117 (9.0)
II	664 (50.3)	660 (50.5)
III	518 (39.2)	513 (39.3)
IV	17 (1.3)	17 (1.3)
Diseased vessels		
two	149 (11.1)	159 (12.1)
three	1188 (88.9)	1159 (87.9)
Left main disease	430 (32.2)	412 (31.3)
Syntax SCORE (%)		
0-22	249 (19.0)	239 (18.5)
23-32	488 (37.2)	486 (37.7)
≥33	574 (43.8)	565 (43.8)
EuroSCORE* (%)		
0-2	1065 (79.7)	1027 (77.9)
3-5	242 (18.1)	257 (19.5)
≥6	29 (2.2)	34 (2.6)

Data are numbers (%) unless stated otherwise. Baseline characteristics are presented for all randomised patients (n=2655). Of these, 17 patients did not undergo surgery and were excluded from the modified intention-to-treat (mITT) analysis. Baseline characteristics for mITT population (n=2638) are shown in eTable 1 in appendix 2.

\*Euroscore II was used to assess preoperative risk in all participants.

CCS class=Canadian Cardiovascular Society angina class; LVEF=left ventricular ejection fraction; LVEDD=left ventricular end-diastolic diameter; NYHA class=New York Heart Association heart failure class; PCI=percutaneous coronary intervention; SD=standard deviation.

Unlike mixed effects models, which focus on subject specific effects, the generalised estimating equation model aligns with our study objective of estimating the overall impact of the no-touch technique on graft occlusion at the population level.<sup>40</sup> For the models, an exchangeable covariance structure was used to model the correlation of responses from the same patients. Owing to the stratification of randomisation by investigational site, the model incorporated the site variable to account for the potential centre effect. Risk estimates of graft occlusion were presented as odds ratios with the corresponding 95% confidence intervals. In addition, absolute risk differences (ARDs) between the two groups were calculated for graft occlusion outcomes. ARDs were derived by comparing the probabilities of the outcome between the groups, and 95% confidence intervals were computed using the delta method. We also performed multiple imputations as sensitivity analysis to the ITT analysis on the primary outcome. The ITT analysis results are

presented as odds ratios with corresponding 95% confidence intervals. ARDs with 95% confidence intervals were also calculated.

We obtained hazard ratios from Cox proportional hazards regression to analyse the clinical events. Survival curve analysis was determined using Kaplan-Meier analysis. To complement hazard ratios, ARDs for clinical outcomes were estimated at three years, representing the difference in event probabilities between the no-touch and conventional groups at the end of follow-up. These probabilities were derived from Kaplan-Meier survival estimates. The corresponding 95% confidence intervals for ARDs were calculated using bootstrap resampling with 5000 iterations to account for variability in the survival curves. For secondary outcomes, we conducted mITT analyses because imputing data for all outcomes might introduce additional uncertainty. As an additional sensitivity analysis, the secondary outcomes were assessed using a competing risk regression (Fine



Table 2 | Computed tomography follow-up results of vein grafts from three months to three years

Outcome	No-touch	Conventional	Odds ratio (95% CI)	Absolute risk difference, % (95% CI)	P value§
<b>Primary outcomes (per graft)*</b>					
Three month vein graft occlusion†	62/2207 (2.8)	105/2180 (4.8)	0.57 (0.41 to 0.80)	-2.01 (-3.16 to -0.73)	<0.001
12 month vein graft occlusion	78/2117 (3.7)	136/2107 (6.5)	0.56 (0.41 to 0.77)	-2.77 (-4.14 to -1.50)	<0.001
Three year vein graft occlusion	114/1988 (5.7)	175/1953 (9.0)	0.62 (0.48 to 0.80)	-3.15 (-4.96 to -1.41)	<0.001
<b>Vein graft failure (per graft)</b>					
Three month	136/2207 (6.2)	226/2180 (10.4)	0.57 (0.41 to 0.80)	-4.21 (-5.69 to -2.32)	<0.001
12 month	160/2117 (7.6)	234/2107 (11.1)	0.66 (0.53 to 0.83)	-3.55 (-5.37 to -1.62)	<0.001
Three year	176/1988 (8.9)	245/1953 (12.5)	0.67 (0.54 to 0.84)	-3.59 (-5.72 to -1.68)	<0.001
<b>Vein graft occlusion (per patient)‡</b>					
Three month	60/1265 (4.7)	97/1268 (7.7)	0.60 (0.43 to 0.84)	-2.91 (-4.78 to -1.03)	0.002
12 month	71/1212 (5.9)	119/1222 (9.7)	0.58 (0.43 to 0.78)	-3.88 (-6.00 to -1.76)	<0.001
Three year	105/1140 (9.2)	152/1141 (13.3)	0.66 (0.51 to 0.86)	-4.11 (-6.70 to -1.52)	0.002
<b>Vein graft failure (per patient)</b>					
Three month	126/1265 (10.0)	199/1268 (15.7)	0.59 (0.47 to 0.75)	-5.73 (-8.33 to -3.14)	<0.001
12 month	143/1212 (11.8)	202/1222 (16.5)	0.68 (0.54 to 0.85)	-4.73 (-7.49 to -1.97)	<0.001
Three year	158/1140 (13.9)	210/1141 (18.4)	0.72 (0.57 to 0.90)	-4.54 (-7.56 to -1.53)	0.003

Data are number/total number (%) unless stated otherwise. CI=confidence interval.

\*The per graft data represent outcomes at the graft level. Each patient could have several grafts, and the denominators reflect total number of grafts rather than number of patients.

†According to the FitzGibbon criteria, graft occlusion was considered when a conduit did not fill with contrast at all or with string sign found in any segment. Graft failure was defined by graft occlusion or graft stenosis >50% but not occluded.

‡The per patient data represent outcomes at patient level, and denominators reflect total number of patients with computed tomography follow-up results in each group.

§P values were based on odds ratios.

and Gray model), considering non-cardiac death as a competing risk.

We conducted exploratory subgroup analyses with the generalised estimating equation models. These analyses included treatment group, subgroup, and technique by subgroup interaction to explore the consistency of estimate effects among key subgroups (eg, age, sex, smoking history, hypertension, hyperlipidemia, diabetes mellitus, the territory of the target vessel, sequential anastomosis, degree of proximal stenosis, the use of cardiopulmonary bypass, and participating centres).

All analyses were performed using SAS 9.4 (SAS Institute, Cary, North Carolina, USA) and R (version 4.0.1, R Foundation for Statistical Computing, Vienna, Austria). Two sided P values <0.05 were considered statistically significant.

#### Patient and public involvement

Patients or members of the public were not directly involved in the design, conduct, reporting, or analysis of this trial. This trial was initiated before patient and public involvement became widely recognised as a standard element in clinical research. Furthermore, the technical and surgical nature of the trial, combined with its focus on graft patency and clinical outcomes, posed practical challenges in involving patients and the public directly in the research process. Nonetheless, the study protocol and treatment strategies underwent thorough consultation with leading cardiac surgeons and clinical cardiologists, then approved by an independent ethics board.

#### Results

Figure 1 presents a flowchart of the current study. Between April 2017 and June 2019, 2655 patients were enrolled at seven hospitals in China and were randomised 1:1 to the no-touch group (n=1337) or the

conventional group (n=1318). In brief, the mean age of patients was 61±8 years; 22% were female, 36% of the patients had diabetes, 88.4% had three vessel disease, and 31.7% had left main disease. The participants' characteristics were well balanced between the two groups (table 1).

CABGs were performed by 32 surgeons across a total of 13 departments. Surgery was cancelled for 17 patients, including two who died before the operation. eTable 1 in appendix 2 presents baseline characteristics for the mITT population. Eleven participants crossed over—nine patients (0.7%) in the no-touch group received the conventional approach, while two patients (0.2%) in the conventional group had their veins harvested by the no-touch technique. A total of 557 (42.0%) patients in the no-touch group versus 573 (43.6%) in the conventional group received on-pump CABG (P=0.41). Other surgical details and events in hospital are shown in eTable 2 in appendix 2. Three years after surgery, 2621 participants (99.4%) completed clinical follow-up, and 2281 patients (86.5%) received scheduled CT angiography. There was no significant difference in the rate of clinical follow-up (98.9% v 99.2%, P=0.41) or CT follow-up (86.9% v 86.0%, P=0.56) between the two groups.

#### Primary outcome

Table 2 presents the follow-up vein graft outcomes. The three month and 12 month results have been reported previously.<sup>37</sup> In the no-touch group, vein graft occlusion was significantly reduced at three months (odds ratio 0.57, 95% confidence interval 0.41 to 0.80; ARD -2.0%, 95% confidence interval -3.2% to -0.7%) and 12 months (0.56, 0.41 to 0.77; -2.8%, -4.1% to -1.5%) after CABG. At three years after CABG, 2281 (86.5%) patients received CT angiography. At the graft level, the occlusion rate of vein graft was 5.7% (114/1988) in the no-touch group

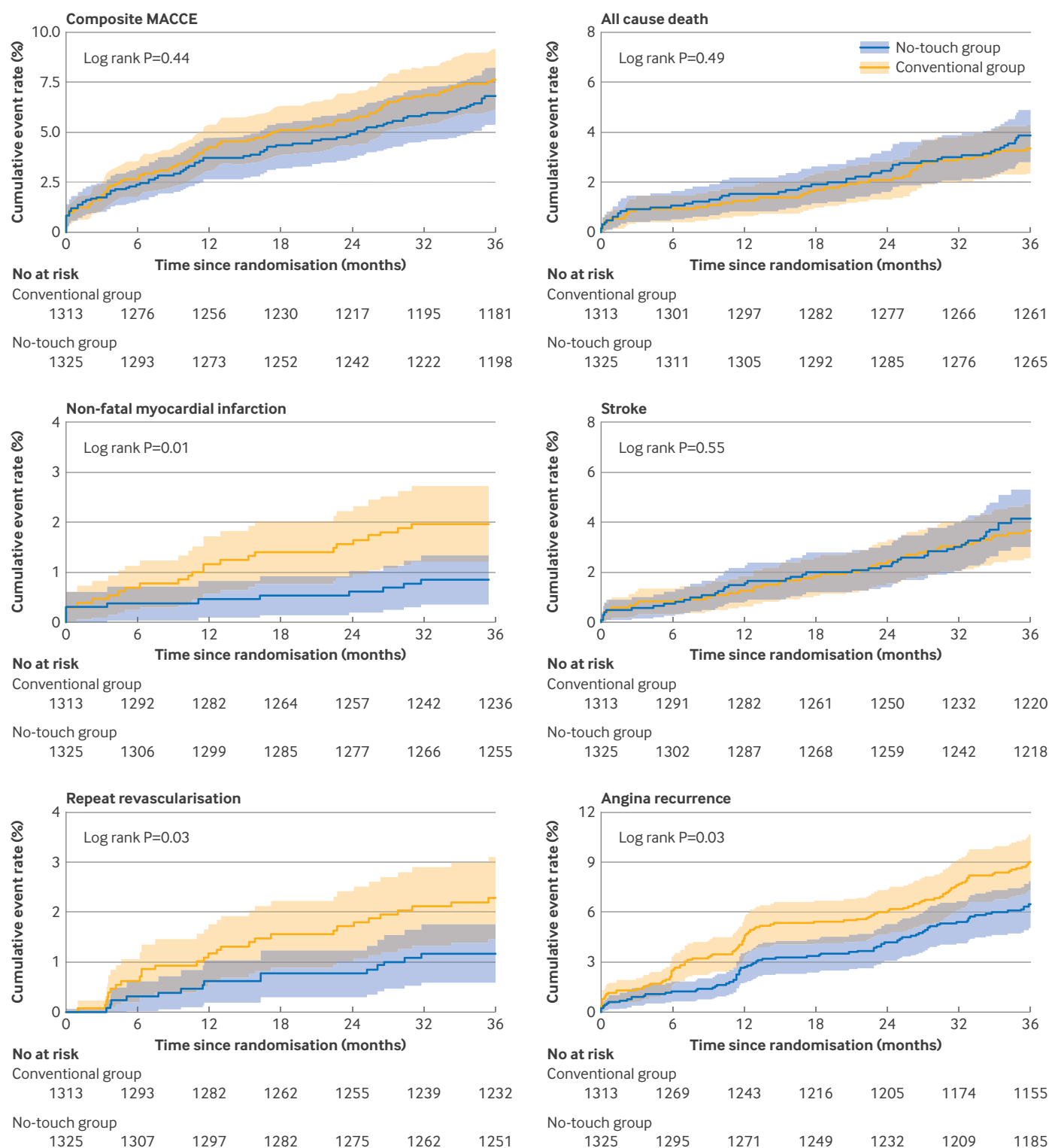


Fig 2 | Kaplan-Meier cumulative event rates at three year follow-up. MACCE=major adverse cardiac and cerebrovascular events

and 9.0% (175/1953) in the conventional group. The no-touch technique continued to show a statistically significantly lower incidence of vein graft occlusion than the conventional approach (0.62, 0.48 to 0.80; -3.2%, -5.0% to -1.4%;  $P<0.001$ ).

The ITT analysis, including all 2655 randomised patients with missing data imputed, confirmed these results. The three year vein graft occlusion rate was significantly lower in the no-touch group compared with the conventional group (6.1% v 9.3%; odds ratio

**Table 3 | Clinical outcomes at three year follow-up**

Clinical outcomes	No-touch (n=1325)	Conventional (n=1313)	Hazard ratio (95% CI)	Absolute risk difference, % (95% CI)	P value*
<b>Composite MACCE</b>	86 (6.5)	95 (7.2)	0.89 (0.67 to 1.19)	-0.74 (-2.71 to 1.25)	0.44
<b>Individual events</b>					
All cause death	50 (3.8)	44 (3.4)	1.15 (0.77 to 1.74)	0.51 (-0.90 to 1.92)	0.49
Cardiac death	34 (2.6)	32 (2.4)	1.06 (0.65 to 1.71)	0.15 (-1.03 to 1.34)	0.83
Myocardial infarction (any)	16 (1.2)	35 (2.7)	0.45 (0.25 to 0.81)	-1.48 (-2.55 to -0.42)	0.01
Stroke (any)	49 (3.7)	43 (3.3)	1.13 (0.75 to 1.71)	0.44 (-0.98 to 1.83)	0.55
Repeat revascularisation (any)	15 (1.1)	29 (2.2)	0.51 (0.27 to 0.95)	-1.10 (-2.10 to -0.14)	0.03
Three year recurrence of angina	82 (6.2)	110 (8.4)	0.73 (0.55 to 0.97)	-2.25 (-4.25 to -0.26)	0.03
Three year hospital readmission for cardiac reasons	94 (7.1)	134 (10.2)	0.68 (0.52 to 0.89)	-3.17 (-5.36 to -0.97)	0.004

Data are numbers (%). Total number of patients in follow-up cohort (n=2638) includes only those who underwent coronary artery bypass grafting surgery. Seventeen patients randomised but who did not undergo surgery owing to cancellations or withdrawals before surgery are excluded from this analysis.

\*P values were based on hazard ratios.

MACCE=major cardiac and cerebrovascular events.

0.63, 95% confidence interval 0.51 to 0.81; ARD -3.1%, 95% confidence interval -4.9% to -1.4%;  $P<0.001$ ). The mITT analysis, which included 2638 patients who underwent the assigned surgical intervention, showed a similar reduction in graft occlusion rates (6.1% v 9.3%; 0.63, 0.50 to 0.80; -3.2%, -5.0% to -1.6%;  $P<0.001$ ; eTable 3 in appendix 2). These consistent findings across both analyses provide robust evidence of the efficacy of the no-touch technique.

Per patient vein graft occlusion was 9.2% (105/1140) in the no-touch group and 13.3% (152/1141) in the conventional group (odds ratio 0.66, 95% confidence interval 0.51 to 0.86; ARD -4.1%, 95% confidence interval -6.7% to -1.5%;  $P=0.002$ ). Other three year graft outcomes, including the vein graft occlusion by different coronary territories and outcomes of the arterial grafts, are shown in eTables 4 and 5 in appendix 2. Although the occlusion rates for the circumflex territory grafts were similar between the no-touch and conventional groups (5.4% v 5.1%;  $P=0.80$ ), statistically significant differences were observed in the diagonal branch (3.6% v 7.7%;  $P=0.005$ ) and right coronary artery (5.5% v 9.8%;  $P<0.001$ ) territories. The underlying reasons for these variations are unclear, and a definitive biological explanation could not be determined.

The occlusion rates of the left internal mammary artery were consistently low across groups (4.2% v 4.2%;  $P=0.97$ ), reflecting the high surgical expertise of the participating centres. The sample sizes for the right internal mammary artery and radial artery were relatively small. Although the observed outcomes align with expectations from previous studies, these results should be interpreted with caution.

### Secondary outcomes

Table 3 presents our clinical outcomes. At three years, the incidence of non-fatal myocardial infarction was significantly lower in the no-touch group than the conventional group (1.2% v 2.7%; hazard ratio 0.45, 95% confidence interval 0.25 to 0.81; ARD -1.5%, 95% confidence interval -2.6% to -0.4%;  $P=0.01$ ). Similarly, the need for repeat revascularisation was lower in the no-touch group than the conventional

group (1.1% v 2.2%; 0.51, 0.27 to 0.95; -1.1%, -2.1% to -0.1%;  $P=0.03$ ). The three year follow-up also showed a lower incidence of recurrent angina in patients who underwent the no-touch technique than those who underwent conventional vein harvesting (6.2% v 8.4%; 0.73, 0.55 to 0.97; -2.3%, -4.3% to -0.3%;  $P=0.03$ ). The rates of readmission to hospital for cardiac reasons were also significantly lower in the no-touch group (7.1% v 10.2%; 0.68, 0.52 to 0.89; -3.2%, -5.4% to -1.0%;  $P=0.004$ ; eFigure 1 in appendix 2). There was no significant difference in all cause death (3.8% v 3.4%; 1.15, 0.77 to 1.74; 0.5%, -0.9% to 1.9%;  $P=0.49$ ), stroke (3.7% v 3.3%; 1.13, 0.75 to 1.71; 0.4%, -1.0% to 1.8%;  $P=0.55$ ), and composite major adverse cardiac and cerebrovascular events (6.5% v 7.2%; 0.89, 0.67 to 1.19; -0.7%, -2.7% to 1.3%;  $P=0.44$ ; fig 2). At the three year follow-up, the use of secondary prevention drugs was of no significant difference between the two groups (eTable 6 in appendix 2).

A competing risk analysis was performed for the secondary outcomes of non-fatal myocardial infarction, stroke, and repeat revascularisation, considering non-cardiac death as a competing risk (eTable 7 in appendix 2). The analysis showed that the reduced incidence of non-fatal myocardial infarction in the no-touch group compared with the conventional group remained statistically significant (hazard ratio 0.45, 95% confidence interval 0.25 to 0.81;  $P=0.01$ ). Similarly, the risk of repeat revascularisation was significantly lower in the no-touch group (0.51, 0.27 to 0.95;  $P=0.03$ ). These results were consistent with the primary analysis.

### Safety outcomes

eTable 8 in appendix 2 presents our results of leg wound complications. The incidence of before discharge leg wound symptoms was significantly higher in the no-touch group than the conventional group (skin numbness 23.2% v 17.8%,  $P<0.001$ ; exudation 4.3% v 1.9%,  $P<0.001$ ; oedema 19.0% v 12.9%,  $P<0.001$ ). No patients developed severe complications such as necrosis or compartment syndrome.



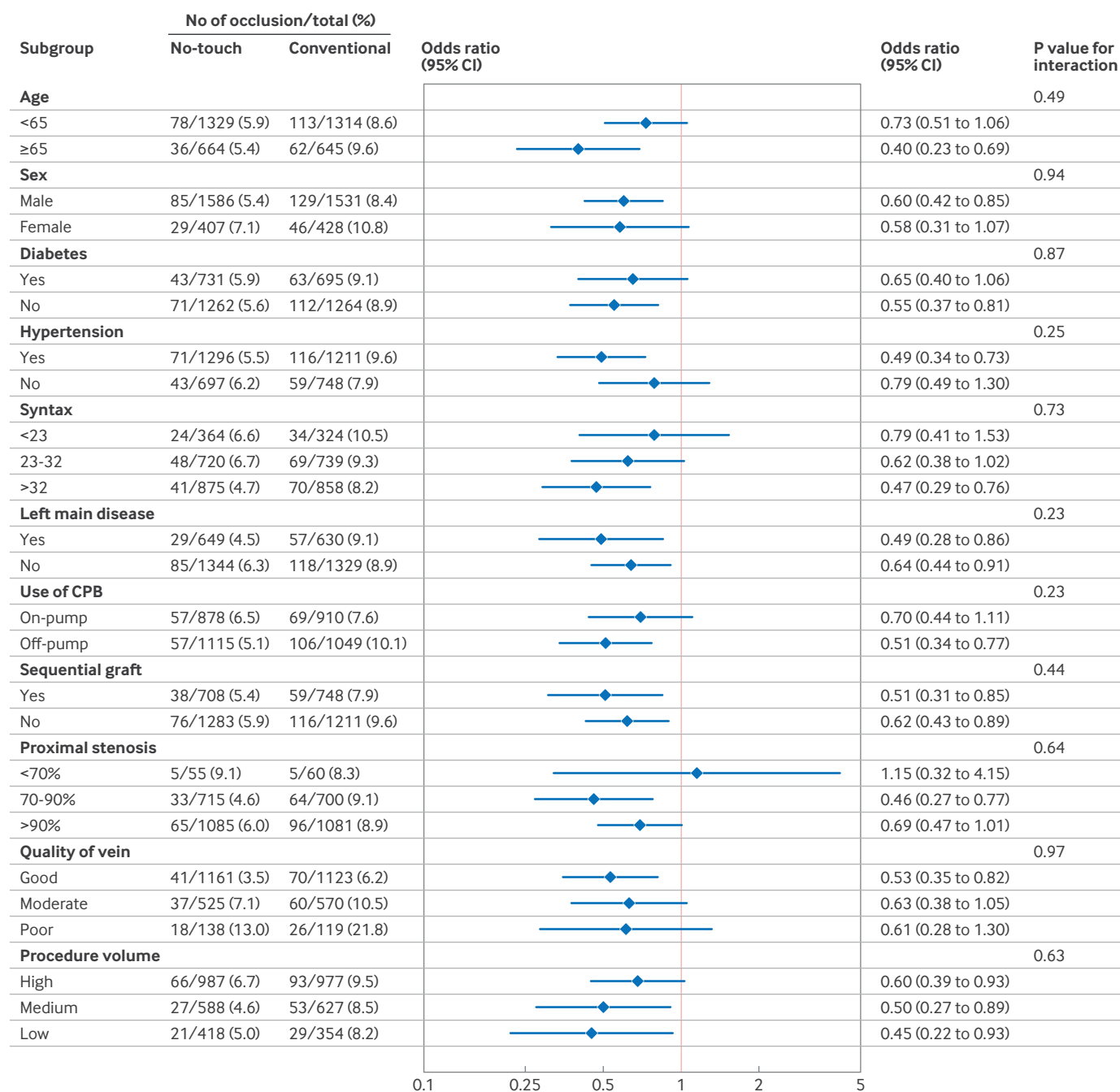


Fig 3 | Subgroup analysis of the primary endpoint. CPB=cardiopulmonary bypass

At three months, significantly more participants in the no-touch group required subsequent surgical intervention for leg wound unhealing (10.3% v 4.3%,  $P<0.001$ ). At 12 month visits, the rates of additional surgical treatment were comparable between groups. According to our observation, there was a continuous decline in leg wound complication rates across the study enrolment phases (eFigure 2 in appendix 2). Moreover, there was no significant difference in leg complications between centres with different procedure volumes (eTable 9 in appendix 2).

### Subgroup analysis

Figure 3 reports the three year subgroup treatment effect interactions. No treatment by subgroup interaction was found among different patient populations.

### Discussion

#### Principal findings

The findings from this extended follow-up study of the PATENCY trial underscore the substantial influence of the no-touch vein harvesting technique on sustained graft patency and clinical outcomes in the medium

to long term after CABG surgery. This study provides robust evidence supporting the use of the no-touch technique to reduce the risk of vein graft occlusion, a critical factor in the long term success of CABG surgery. The decreased rates of vein graft occlusion observed in the no-touch group translate into meaningful clinical benefits, as demonstrated by the lower incidences of non-fatal myocardial infarction and repeat revascularisation.

### Strengths of this study

Our study stands out as a large, recent randomised trial focusing on vein graft occlusion and patient prognosis. The no-touch technique significantly reduces vein graft occlusion rates, with an odds ratio of 0.62 and ARD of -3.1% up to three years after surgery compared with the conventional approach. The results of the ITT and mITT analyses, including multiple imputations for missing data of the primary outcome, were consistent across analyses, reinforcing the robustness of our findings.

Our analysis revealed differences in occlusion and failure rates by target vessel territory, particularly in the diagonal branch and right coronary artery territories. However, no clear biological mechanism could be identified to explain these variations. Although factors such as haemodynamic flow, vessel anatomy, or local conditions might contribute, these remain speculative.<sup>41</sup> It is also possible that these findings reflect random variation rather than a true biological effect. These findings emphasise the importance of further research in understanding territory specific outcomes in CABG.

We also acknowledge the consistently low occlusion rates of the left internal mammary artery, which underscore the high surgical expertise at the participating centres. Although the results for the right internal mammary artery and radial artery were in line with earlier research,<sup>35 42</sup> the validity of conclusions is limited by the comparatively small sample sizes for these conduits. As part of our ongoing efforts to explore the benefits of the no-touch technique among various conduits, we are conducting a randomised controlled trial comparing the one year occlusion rates of no-touch veins and radial artery grafts in CABG surgery.<sup>43</sup> This trial aims to provide further insights into the comparative patency and clinical implications of these two conduits, thereby contributing to a more nuanced understanding of graft selection in CABG procedures.

The subgroup analyses revealed no significant treatment by subgroup interactions across various patient populations, including stratifications by age, sex, and comorbidities. This consistency suggests that the no-touch technique offers uniform benefits irrespective of patient specific factors. However, it cannot be completely ruled out that the subgroup analysis was underpowered owing to the sample size established for the main analysis.

### Comparison with other studies

Although previous studies reported longer term no-touch saphenous vein graft outcomes (failure rates

of 9% at 8.5 years and 17% at 16 years),<sup>20 32</sup> our trial provides more comprehensive evidence, particularly for intermediate term outcomes. Our findings align with smaller studies, such as that of Tsuneyoshi and colleagues, which reported a no-touch saphenous vein graft failure rate of 4.2% at a mean follow-up of 43 months.<sup>44</sup> These results further validate the durability of the no-touch technique in maintaining graft patency, consistent across different studies with varying follow-up durations and designs.

Previous research on vein graft failure has primarily relied on older observational data, which are prone to confounders and biases. For instance, Gaudino and colleagues conducted a pooled individual patient data analysis of clinical trials, reporting a vein graft failure rate of 19.7% at a median follow-up of 1.02 years.<sup>21</sup> However, the included studies were launched between 2002 and 2015, making the findings relatively outdated. Additionally, follow-up rates ranged between 78% and 93% at one year, which is lower compared with the follow-up achieved in our study.

Our study's randomised controlled design is a critical strength that mitigates such limitations. With 2655 patients, this large study provides sufficient statistical power to detect significant differences in clinical outcomes. Further evidence will also be available from the ongoing SWEDEGRAFT trial, which is another moderately large, binational, multicentre study investigating the two year patency of the no-touch and conventional vein graft harvesting techniques.<sup>34</sup>

Furthermore, the vein graft occlusion rate of 9% in the conventional group is lower than rates reported in previous studies (15-35% within five years of CABG).<sup>3 45 46</sup> This result reflects the expertise of participating surgeons and adherence to postoperative drug regimens.

### Policy implications

The findings of this study have important implications for clinical practice and guideline development. Current guidelines, such as the 2018 European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines on Myocardial Revascularisation, assign a class IIa recommendation to the no-touch technique for open vein harvesting.<sup>33</sup> The robust findings from the PATENCY trial, supported by its large sample size and rigorous design, could raise this recommendation in future updates.

The findings from the current study and our previous report of 12 month results (3.7% v 6.5%; odds ratio 0.56)<sup>37</sup> show a proportional change of difference from one to three years after CABG, indicating that the no-touch technique ensures sustained graft patency and reduces the likelihood of late vein graft occlusion. However, it remains unknown whether grafts that are patent at three years will continue to show superior durability or if there could be a delayed progression of intimal hyperplasia or atherosclerosis leading to a catch-up in occlusion rates between the two groups. Sustained patency over three years strongly predicts favourable patient outcomes, but further extended

follow-up is required to confirm whether these benefits persist beyond the intermediate term and translate into long term improvements in clinical outcomes.

Our study also shows that the no-touch technique improves graft patency and tends to improve patient outcomes by reducing the incidence of myocardial infarction and repeat revascularisation. These benefits extend beyond graft patency to broader clinical outcomes, suggesting that the no-touch technique could play a pivotal part in enhancing long term patient health and reducing the burden of recurrent cardiac events. However, owing to limited access to local hospital records, it remains unclear whether these events are directly related to graft occlusion or to the progression of native coronary disease.

The recurrence of angina was also less common in the no-touch group at three years (6.2% *v* 8.2%), highlighting the symptomatic benefits of improved graft patency. The no-touch technique offers potential economic benefits by reducing readmissions to hospital and repeat procedures. These findings warrant consideration in future guideline updates, emphasising the technique's potential to lower healthcare costs while improving patient outcomes. We acknowledge that the economic implications in this study are speculative because this trial did not directly measure cost effectiveness. Although the no-touch technique might incur higher short term costs owing to the risk of wound infections, its potential long term benefits—such as reduced rates of readmissions to hospital and repeat procedures—could make it cost effective over time. Nevertheless, evidence from previous studies supports the economic advantages of reduced revascularisation and readmission to hospital after CABG.<sup>47 48</sup>

Although we showed significant reductions in certain individual adverse events, such as non-fatal myocardial infarction, repeat revascularisation, recurrent angina, and readmission to hospital, no significant differences were observed in all cause or cardiac specific mortality, or in the overall major adverse cardiac and cerebrovascular events. These findings could be attributed to several factors. Firstly, mortality in patients undergoing CABG is influenced by a complex interplay of factors, including patient comorbidities, progression of native coronary disease, and non-cardiac conditions, which might not be directly mitigated by improvements in vein graft patency. Secondly, the follow-up duration of three years might not be long enough to observe significant differences in mortality because these outcomes often manifest over a longer timeframe. Lastly, the relatively low overall mortality rates observed in our cohort could reflect the high quality surgical techniques and postoperative care, which could limit the power to detect differences in this endpoint. Additionally, the composite major adverse cardiac and cerebrovascular events measure includes overlapping events in some patients (eg, myocardial infarction and repeat revascularisation), which might have further complicated the analysis. These findings highlight

the complexity of interpreting composite measures and underscore the need to evaluate individual event rates to gain a more comprehensive understanding of clinical outcomes. Continued follow-up is necessary to better understand the long term impact of the no-touch technique on mortality and other patient centred outcomes.

### Encouraging broader adoption

Although concerns about leg wound complications have hindered the technique's broader adoption, our previous reports showed that these complications are generally mild and can be mitigated through dedicated harvesting skill training.<sup>31 37 49</sup> In our study, leg complications were managed with standard clinical interventions, including regular wound care, appropriate use of antibiotics for infection control, and in rare cases, surgical debridement. Importantly, the observed decrease in wound complication rates over time (shown in eFigure2) suggests a learning curve effect, with improved outcomes associated with increased surgeon experience. Further studies are needed to optimise the technique and evaluate strategies to further reduce the risk of wound complications without compromising the benefits of the no-touch approach.

While open harvesting is still widely used in many jurisdictions, endoscopic vein harvesting has increasingly become the standard of care in regions such as the United States owing to its potential benefits in reducing wound complications and improving patient recovery.<sup>24 35 50</sup> However, evidence on the use of the no-touch technique in combination with endoscopic vein harvesting remains limited. Future research exploring the adaptation of the no-touch technique to endoscopic methods is necessary to assess its feasibility and efficacy in clinical practice. These efforts would help determine the broader applicability of the no-touch technique.

### Limitations

Despite the strengths of this study, several limitations should be acknowledged. Firstly, while the extended follow-up at three years was part of the study's original design, specific sample size calculations for this phase were not performed. The sample size was determined based on the vein graft occlusion at three months, and the extended follow-up relied on this original calculation. Although the large sample size and high follow-up rate provided sufficient statistical power to detect differences in graft and clinical outcomes at three years, future studies might benefit from explicit sample size calculations tailored to long term outcomes. Secondly, the follow-up rate of CT angiography, although high, was not complete. The imputation process, while rigorous, can introduce uncertainty, and the actual effect might vary if all data were observed.

Thirdly, the study was conducted within the geographical and healthcare context of China, where open surgical techniques for vein harvesting remain

common practice. However, patient populations could differ in demographic and clinical characteristics compared with those in other regions. Additionally, surgical practices, including endoscopic vein harvesting and arterial grafting, are more widely adopted in certain areas, such as North America and Europe, which might yield different results compared with the open harvesting techniques used in this study.

## Conclusions

In conclusion, this three year follow-up study of the PATENCY trial provides evidence that the no-touch vein harvesting technique significantly reduces vein graft occlusion and improves patient outcomes in CABG surgery. Moreover, the persistent advantage in reducing vein graft occlusion at longer term follow-up and the tendency to improve patient outcomes highlight the broader clinical benefits of this innovative technique.

## AUTHOR AFFILIATIONS

<sup>1</sup>Department of Surgery, National Center for Cardiovascular Disease, China & Fuwai Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

<sup>2</sup>Beijing Hospital, Beijing, China

<sup>3</sup>The Second Hospital of Hebei Medical University, Shijiazhuang, Hebei Province, China

<sup>4</sup>TEDA International Cardiovascular Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Tianjin, China

<sup>5</sup>The Second People's Hospital of Anhui Province, Hefei, Anhui Province, China

<sup>6</sup>Peking Union Medical College Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

<sup>7</sup>Beijing Chaoyang Hospital, Capital Medical University, Beijing, China

<sup>8</sup>National Clinical Research Center for Cardiovascular Diseases, National Center for Cardiovascular Disease, China & Fuwai Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

<sup>9</sup>Medical Research & Biometrics Center, National Center for Cardiovascular Disease, China & Fuwai Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

<sup>10</sup>Department of Radiology, National Center for Cardiovascular Disease, China & Fuwai Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

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**Contributors:** MT contributed to the trial design, monitored data collection for the whole trial, drafted and revised the paper. XW and WF contributed to the trial design, monitored data collection for the trial, and provided technical support to trial participants. HW, SL, ZL, YC, QM, and PS were site trial coordinators and monitored data collection in their respective sites. XL contributed to the trial design and revised the paper. YW was the trial statistician, wrote the statistical analysis plan, conducted all statistical analyses and drafted and revised the paper. BL provided technical support to trial participants. KC and CZ contributed to the trial design and data collection. SH was the chief investigator, initiated the collaborative project, designed the trial, provided management oversight of the whole trial, chaired the trial management group, drafted and revised the paper, and is guarantor. MT, XW, and WF contributed equally to this manuscript. All authors had full access to all of the study data and take responsibility for the integrity of the data and the accuracy of the data. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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**Ethical approval:** The protocol for PATENCY was reviewed and approved by the independent institutional review board of Fuwai Hospital, Chinese Academy of Medical Science (2016-827). All participants provided written informed consent to participate in the trial. The full trial protocol is provided in appendix 1.

**Data sharing:** Deidentified data and codes are shared at DRYAD (identifier: <https://doi.org/10.5061/dryad.dz08kps7j>). These data might not be used for commercial purposes. A formal application and research proposal are required to obtain approval for data use for research purposes. Please contact the corresponding author ([huss@fuwaihospital.org](mailto:huss@fuwaihospital.org))

**Transparency:** The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and if relevant registered) have been explained.

**Dissemination to participants and related patient and public communities:** The results of this study were presented at the 2023 International Coronary Congress, and will be disseminated through scientific publications in peer reviewed journals and presentations at national meetings in China. The results will also be shared with the clinicians at participating sites via an investigator meeting. To ensure effective dissemination of the results, we plan to engage the clinical and patient community after publication by presenting the findings at major cardiology and cardiac surgery conferences in China and internationally. Furthermore, we aim to communicate the results to patients and the public through accessible channels, including press releases and professional society meetings, to promote the adoption of the no-touch technique in clinical practice. This dissemination will help bridge the gap between research and patient care, encouraging wider implementation and ultimately improving patient outcomes.

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**Web appendix 1:** Appendix 1—Study protocol

**Web appendix 2:** Appendix 2—Online methods, tables, figures