Rationale and design of a multicenter randomized trial to compare the graft patency between no-touch vein harvesting technique and conventional approach in coronary artery bypass graft surgery

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Background Vein graft failure is a crucial challenge in coronary artery bypass graft (CABG) surgery. Previous studies have suggested a patency benefit of the No-Touch vein harvesting technique, but only with small sample sizes.

Materials and methods This study is a prospective, multicenter randomized clinical trial with a large sample size, aiming to investigate the efficacy of the No-Touch technique compared with the conventional approach. All patients requiring isolated CABG with left internal mammary artery plus at least one saphenous vein graft will be considered for entry into the study. Two thousand cases (1000 in each arm) will be enrolled over 1 to 2 years in 7 hospitals in China. Participants will be randomized in equal proportions between two surgical strategies: the No-Touch or conventional technique. The primary endpoint is graft vessel occlusion at 3 months after CABG surgery by CT coronary angiography. Secondary outcomes are major adverse cardiac or cerebrovascular events at 3 and 12 months post-operation and graft vessel occlusion at 1 year.

Discussion This study will define the role of the No-Touch vein harvesting technique in CABG surgery and provide strong evidence to answer whether this technique could reduce vein graft occlusion. (Am Heart J 2019;210:75-80.)

Vein graft occlusion is one of the most crucial challenges in coronary artery bypass graft (CABG) surgery; it substantially increases recurrence of angina and may require repeat revascularization.[1-7] Since CABG was introduced in 1968,[8] surgical technique and perioperative management have evolved, therefore hospital morbidity and mortality have been reduced despite the increasing age and comorbidities of patients.[9] Saphenous vein grafts are used in almost 80% of CABG cases to complete revascularization.[10] At 1 year after CABG, about 10% of SVG are occluded,[6,11] with the occlusion rate increasing 1% to 2% annually in the next 1 to 6 years, and increasing 4% annually during 6 to 10 years postoperatively. Ten years after surgery, up to approximately 50% of vein grafts are occluded.[6,12,13] Although dual antiplatelet therapy can reduce the risk of vein graft occlusion, the risk of occlusion is still high. A randomized clinical trial shows that 14.3% of vein grafts became occluded 3-month after CABG in patients receiving only aspirin as antiplatelet therapy, and 8.4% in those taking aspirin plus clopidogrel.[14]

Damage to the vein during harvesting is a potential reason for occlusion. Adventitia of saphenous veins are stripped off and forced distention by syringe is usually performed, which are believed to be the major causes of damage.[15] The No-Touch technique was introduced by Dr. Souza in 1996, which features saphenous vein adventitia preservation and avoidance of manual distension after removal from the leg.[16] Theoretically, vessel wall integrity of the vein graft can be well protected and spasm may be avoided. After 16-year follow-up, 17% of saphenous vein grafts harvested by No-Touch technique were occlusive, comparing to 36% by conventional approach. However, this study is limited by its small

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RCT# NCT03126409.
Clinical Trial Registration: https://www.clinicaltrials.gov (NCT03126409).
Submitted March 28, 2018; accepted November 27, 2018.
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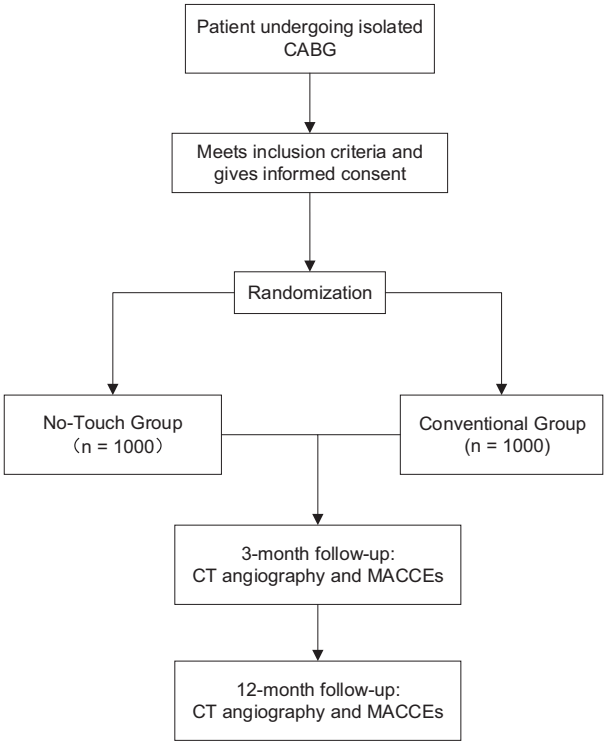
0002-8703

https://doi.org/10.1016/j.ahj.2018.11.011

Figure 1



Flowchart of the study. CABG, coronary artery bypass graft; CT, computed tomography; MACCE, major cardiac or cerebrovascular event.

sample size from a single center.[1] Therefore, it is still uncertain whether No-Touch harvesting technique can reduce rates of vein graft occlusion.

Objectives

Accordingly, we are conducting a multicenter randomized controlled trial to assess whether the No-Touch vein harvesting technique during CABG can reduce vein graft occlusion compared to the conventional vein harvesting technique.

Study design

This is a prospective, multicenter, open-label, randomized controlled trial. We aim to randomize 2000 patients undergoing isolated CABG who had at least one vein graft from 7 hospitals in China. We consecutively screen patients during the study enrollment period and seek informed consent from all eligible patients. Patients who give informed consent are randomly assigned to undergo No-Touch vein harvesting or conventional vein harvesting by a central randomization system. We will follow-up participants via face-to-face interview until at least 1 year after the operation. Each participating hospital records all patients who are screened, their screening status, and reasons for non-enrollment. Flowchart of enrollment and follow-up is shown in Figure 1. To reduce the variation among participating hospitals, we only include hospitals in which annual in-hospital mortality of CABG are lower than 5% from year 2012 to 2016. The annual mortalities from 2012 to 2015 of each participating hospital are shown in Appendix 1 of Supplement Material. To reduce the variation among surgeons, we require that both CABG and vein graft harvesting are performed by qualified surgeons. The ethics committees at all 7 participating hospitals approved this Study. The study was registered at http://www.clinicaltrials.gov (NCT03126409).

Patient population

This study includes patients aged 18 or older who undergo primary isolated open-chest CABG with at least one graft from saphenous vein, with or without cardiopulmonary bypass. Patients who fulfill any of the following criteria are ineligible.

- Concomitant cardiac or vascular surgeries (i.e. valve repair or replacement, Maze surgery)
- Redo CABG
- Emergent CABG
- Use of vascular stapler for anastomosis
- Endarterectomy of coronary artery during surgery
- Left ventricular repair due to ventricular aneurysm
- Malignant tumor or other severe systemic diseases
- Severe renal insufficiency (i.e. creatinine >200 μmol/L).
- Contraindications for dual antiplatelet therapy, such as active gastroduodenal ulcer.
- Participant of other ongoing clinical trials.

Randomization

A web-based central randomization system incorporated in the registration system is used for allocation (http://ccsr.cvs-china.com/). The randomization code with fixed block size is generated by SAS. Randomization is stratified by investigation center. When an eligible patient gives informed consent, the investigator logs in to the randomization webpage and obtain the random number along with treatment group (No-Touch or Conventional group) automatically distributed by the system after the basic patient information be confirmed. The statistician responsible for the randomization code and the staff who develops the Interactive Web-based Response (IWR) system are independent of each other.

Intervention

Surgical procedure. Anesthetic technique and method of myocardial protection are left to individual hospitals to decide. All patients undergo either off-pump or on-pump CABG at the surgeon's discretion on the basis of anatomic and clinical findings.

For the No-Touch vein harvesting technique in our institutions, a longitudinal incision is made on bilateral shanks (unilateral shank, thigh or small saphenous vein will be chosen if great saphenous vein quality is judged before the operation or after the skin incision to be too poor for CABG). As previous reported,[16,17] the adventitia and perivascular tissue are carefully kept intact to avoid damage. Then a margin of about 5 mm from both sides of the vein is created to include the fat pedicle using electrocautery, and all visible side branches are ligated with 4–0 silk or by metal clipping (branches are divided at the pedicle margin rather than the vein trunk). The saphenous vein is then separated from its bed using scissors and electrocautery, together with surrounding tissue. The vein is left in situ and covered with a saline-moistened gauze until systemic heparin is administered and graft anastomosis is ready. After removal, a small adaptor is inserted into the open distal end and secured with a ligature. The pedicled vein is stored in saline solution to which heparin (2500 U) and papaverine (30 mg) have been added. We use the same storage solution for patients of the No-Touch group and the conventional technique group. Storing the vein grafts in heparinized saline results in similar vein graft occlusion rates compared with storage in heparinized blood.[18] Since heparinized blood cannot be easily obtained during off-pump CABG, we used heparinized saline with papaverine rather than heparinized blood to store vein grafts for patients undergoing either off-pump CABG or on-pump CABG. Forced distension or flushing using a syringe is strictly prohibited. Before each anastomosis, side braches of the vein are checked by the operator and re-clipped. After proximal anastomosis is completed, each graft is re-checked for leakage due to undiscovered branches or invalid clipping and re-clipped if necessary.

For the conventional vein harvesting technique, the incision is the same as in the No-Touch technique. After exposure, the vein is stripped off its adventitia by blunt dissection with scissors. All visible side branches are ligated or clipped. After reaching the needed length, the vein is removed from the distal length, and then a small adaptor is inserted into the open distal end and secured with a ligature. The vein is gently distended by syringe with the storing solution. Remaining unsecured branches are ligated or clipped, and 7–0 polypropylene sutures are made to secure the avulsed branches if necessary.

Leg incisions are closed with continuous suture for both two groups. Remaining coronary bypassing techniques are same in both groups according to clinical practice of the hospital and preference of the operator. Before chest closure, mean flow values and pulsatile index are obtained with transit-time flow measurement (Medistim Butterfly flowmeter, Medi-stim AS, Oslo, Norway). If mean flow value is less than 10 ml/min, or pulsatile index greater than 5.0, or any possible graft kinking or compression detected, the anastomosis is redone.

An intraoperative paper questionnaire is answered by the operator after completion of surgery to evaluate the quality of each vein graft. Vein quality is classified as good, moderate, or poor, according to whether there is varicose or aneurysmal dilatation, inflammatory wall thickness, focally thinned wall, or too-small diameter. Although discouraged, exclusion of patients for any other reason is also recorded.

All surgical procedures will be completed by qualified surgeons who have performed at least 100 CABGs. Vein harvesting is performed by qualified senior residents. We identify senior residents who have performed at least 100 cases of vein harvesting in CABG and gave them standard training of No-Touch vein harvesting. When they perform at least 50 cases of No-Touch vein harvesting, they are evaluated by two independent training surgeons to be qualified for vein harvesting. Although ultrasonic mapping is reported to be helpful in preventing unnecessary incision and large skin flaps,[1,19] it is not widely used in clinical practice in China. According to our experience, well-trained surgeons with sufficient qualifications can harvest the veins with No-Touch technique without ultrasonic mapping. Ultrasonic mapping is not adopted in this study.

Medication. All participants are prescribed dual antiplatelet therapy with aspirin 100 mg plus clopidogrel 75 mg daily from the first day post-CABG until 3 months post-operation. Prescription of other concomitant medications such as β-blockers, nitrates, statins, and antihypertensive agents is determined by local surgeons according to ACC/AHA guidelines.[9]

Outcome measurement

Primary endpoint. Graft vessel occlusion at 3 months after CABG.

Graft occlusion is detected by multislice computed tomography angiography (MSCTA). Graft assessment is conducted according to the FitzGibbon criteria.[20] Each graft is graded as A (excellent), B (fair), or O (occluded). Contrast filling of the grafts, anastomoses, and coronary arteries beyond the graft are considered in each assessment. Grade A indicates that the graft is patent with ≤50% stenosis. Grade B indicates that graft stenosis is >50% but not occluded. When a conduit does not fill with contrast at all, it is considered Grade O and included with string sign found in any segment (including proximal anastomotic site, distal anastomotic site, and main trunk). Both of these latter findings are considered together and referred to as occlusion in the analysis.

Secondary endpoint.
1. Graft vessel occlusion at 1 year after the CABG (determined by MSCTA).
2. Major adverse cardiac or cerebrovascular events (MACCE, including cardiovascular death, non-fatal myocardial infarction, stroke and target vessel revascularization) at 3 months and 1 year after the CABG.

3. Individual MACCE, including cardiovascular death, non-fatal myocardial infarction, stroke and target vessel revascularization at 3 months and 1 year after surgery.
4. Recurrence of angina

All clinical events including myocardial infarction, stroke, target lesion revascularization, and death will undergo central adjudication by an independent clinical events committee (CEC) according to pre-specified criteria (see Appendix 2 of Supplement Material).

Data collection

A web-based and paperless data submission system (http://ccsr.cvs-china.com) for the No-Touch study has been established. A total of 7 hospitals are participating in the study and each has been granted access to the data submission system. For web-data transmission, a high level secure socket layer is adopted. For in-hospital data collection, 12 modules have been set (preoperative saphenous vein screening, patient basic information, preoperative risk factors, cardiovascular presentation, tests and examinations, general information of operation, record of CABG, post-operative complications, preoperative medications, medication prescriptions at discharge, 3-month follow-up results and 12-month follow-up results) with over 300 items. We collect relevant anatomical characteristics, e.g., sites of proximal and distal anastomosis, graft type and quality, proximal lesion stenosis rate, graft flow and pulsation index, application of sequential anastomosis. As to sequential anastomosis, one failure of distal anastomosis will be considered occlusion of the sequential graft. Particularly, as we routinely harvest saphenous veins from bilateral shanks, there is a concern that risk of surgical-site infection will increase due to larger skin flaps caused by this technique.[21] Therefore, another postoperative questionnaire regarding leg wound condition is filled before patient discharge and during follow-up visit. Visual Analogue Scale[22] is employed for evaluation of leg pain, and any wound healing disturbances including both non-infectious leg wound complications and infection are recorded.[23] Coordinators and investigators are required to submit complete in-hospital data within 14 days of discharge. The No-Touch study adheres to a rigorous standard for medical record transmission and data abstraction, similar to the previously published China Patient-Centered Evaluative Assessment of Cardiac Events (China PEACE)-Retrospective Acute Myocardial Infarction Study and the Percutaneous Coronary Intervention Study.[24,25]

Clinic visits are required. Study coordinators will telephone participants to remind them of the scheduled date of return to the hospital. The 2000 randomized patients will undergo predefined clinical follow-up at 3 months and 12 months post-procedure. MSCTA are to be performed, and image discs from all participating hospitals are collected and assessed by a central Core Laboratory. The results of MSCTA are independently reviewed by 2 radiologists blinded to patients' randomized allocation. Discrepancies in occlusion judgment are reviewed by a third radiologist and resolved by consensus. According to our procedural preference, the saphenous veins will be harvested from both shanks if more than one SVG is required. As randomization is per patient, harvesting technique must be consistent for all SVGs of the same patient. Outcomes will be determined both at patient-level and per-graft level. At each follow-up visit, all current medications and events since the last visit are recorded and compared between the two groups. We collect the information of both surgeons of CABG and vein harvesting residents. Surgeon-specific and site-specific outcomes will be considered in exploratory analyses. In order to assess the long-term efficacy of the No-Touch technique, we will continue to follow-up these patients at 5 years and 10 years postoperatively.

Sample size and statistical analysis plan

According to our published work, the vein graft occlusion rate is 8.4% in the conventional harvesting group.[14] A previous trial showed that No-Touch would reduce vein graft occlusion rate by 58.6%.[1] We assume a more conservative effect of 43% relative risk reduction. A trial of 2000 participants would have 90% power at $2P < 0.05$ to detect a 43% relative risk reduction with 1% drop-out rate. The allocation rate is 1:1. The study originally planned to enroll 1500 on-pump CABG patients from 7 hospitals. During the recruitment, considering that both on-pump and off-pump CABG are widely used in clinical practice, we decided to include patients undergoing both off-pump and on-pump procedures to achieve better generalizability of the results. And we decided to increase sample size to 2000 so that the study is sufficiently powered to detect a more conservative effect of reducing occlusion.

The trial data will be analyzed on an intention-to-treat basis with patients included in the groups assigned at randomization, irrespective of future management and events. Subgroup analysis will also be performed according to the actual harvesting technique a patient receives, (e.g., crossover from No-Touch to conventional approach). Demographic and clinical variables will be summarized as means (SDs) for continuous and counts (percentages) for categorical variables. Comparisons across the groups will be performed using a 2-tailed unpaired t test for continuous variables and the Pearson's χ^2 test for categorical variables. Cochran Mantel–Haenszel χ^2 test will be used for the primary endpoint. A generalized linear model with the general estimate equation will be used to estimate treatment effects for the graft level analysis in order to account for the cluster effect of grafts from same patient. Patient-level analysis

will also be performed to compare in-hospital death, postoperative complications, follow-up death and MACCE. A P value of less than 0.05 will be considered as statistically significant for all analyses.

According to our practice experience and previous literature, we estimate the cross-over rate to range from 1% to 5%, mainly from the No-Touch group to the conventional group. Thus, we consider the effect of cross-over to be minor. Given variations in the quality of vein grafts, an intraoperative questionnaire for evaluation of the graft quality is required to be answered by the operator immediately after completion of the surgery. Graft quality is stratified as good, moderate, or poor, according to the presence of side branch tears, inflammatory wall thickness, or signs of varicosity.[26] Subgroup analysis will be performed regarding different graft qualities and target vessel runoffs. Use of extracorporeal circulation will also be analyzed as subgroups, using tests for interactions. A variation in graft occlusion differences between the on/off pump subgroups is not expected. Postoperative and follow-up leg wound healing disturbance will also be compared between the two harvesting approaches according to records collected by the questionnaire mentioned above.

Data monitoring and interim analysis. An independent data safety monitoring board (DSMB) is established before the start of recruitment. Only one interim analysis will be carried out (when 50% of subject finish their scheduled follow-up) according to the DSMB charter. The DSMB review will focus on safety issues. There is no pre-specified stopping rule regarding the primary efficacy endpoint, so there is no need to adjust the type I error rate. The DSMB members will suggest whether the study should be stopped due to unexpected risk for patients. If the safety signal is acceptable, the study will continue to the planned recruitment number and data analysis will be based on the entire population.

Clinical events committee. All clinical events including myocardial infarction, stroke, target lesion revascularization, and death will undergo central adjudication by an independent clinical events committee (CEC) according to pre-specified criteria (see Appendix 2 of Supplement Material).

Conclusion

This is by far the largest multi-center RCT comparing the No-Touch vein harvesting technique and the conventional approach. This study will define whether the No-Touch technique could reduce vein graft occlusion. Inherently, this surgical-based multicenter clinical trial is faced with a number of challenges that investigators must consider when designing the trial protocol. Although the follow-up of 1-year is not very long, we may consider follow-up studies with extended follow-ups of up to 10 years.

Differing from Dr. Souza's study, CT angiography will be used in our trial for occlusion assessment instead of coronary angiography. The decision of using of CTA during follow-up was made in light of patient compliance, as coronary angiography is much more traumatic and costly, and too many cases of refusal or loss of contact from the patients will greatly bias the result.

Aside from graft occlusion, MACCEs are also included in the endpoints for evaluation of follow-up mortality and morbidity to enable investigations of whether CABG with No-Touch vein grafts is associated with better patient outcomes.

One limitation of this study is that ultrasound mapping is not adopted, which is reported to be helpful in preventing unnecessary incision and large skin flaps.[1,19] However, it is not widely used in clinical practice in China and according to our experience, well-trained surgeons with sufficient qualification can harvest veins with the No-Touch technique without this instrument.

Current status of the trial

The first patient was randomized into the trial in April 27th, 2017, and as of the revision of this manuscript, 1980 patients have been enrolled. Completion of recruitment is expected by late November, 2018 with results of the 3-month follow-up becoming available in May, 2019.

Acknowledgements

This study is supported by the Evaluation of Key Technologies of Cardiovascular Surgery and Quality Improvement Project funded by the Beijing Municipal Science & Technology Commission in China. The sponsors did not participate in the design and will not participate in the implementation of the study, including the collection, management, analysis, interpretation of the data and the preparation of the manuscript. We thank Tianna Zhou for editing the manuscript.

Conflicts of interest

None.

Appendix. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ahj.2018.11.011.

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