**No-touch harvesting in off-pump coronary artery bypass grafting with sequential saphenous vein graft: a single-centre prospective randomized controlled trial**

**Abstract**

**Introduction:** Nowadays, coronary artery bypass grafting(CABG) mainly consists of the left internal mammary artery and saphenous vein, and the patency rate of vein grafts has always been considered to be not ideal. An increasing number of studies support that the No-touch(NT) procedure can improve the patency rate of vein grafts. We report a protocol of a randomized controlled trial exploring the safety and efficacy of the no-touch technique in off-pump coronary artery bypass surgery.

**Methods and Analysis：**This is a prospective single-centre randomized controlled clinical trial. A total of 200 patients undergoing off-pump coronary artery bypass grafting will be randomly assigned to two groups: the NT group and the control group. The NT group vein graft will be harvested with a pedicle of surrounding tissue and not be distended, while the control group the perivascular tissue will be stripped off, and the vein will be distended. 3 and 12months follow-up will be carried out. The primary outcome will be the occlusion rate of venous grafts at one year after operation assessed by cardiac computed tomography angiography (CCTA). The secondary outcomes include major adverse cardiac and cerebrovascular events(MACCEs) rate at three months and one year after surgery.

**Discussion:** This trial will help to further whether the NT technology in off-pump CABG is safe and effective.

**Ethics and Dissemination:** The study has been approved by the Ethics Committee of Beijing Anzhen Hospital and Capital Medical University (Approval Numbers:2018036X). Each patient signed informed consent before entering the group.

**Keywords:** Coronary artery bypass grafting(CABG), No-touch technique, off-pump CABG, Saphenous vein graft

**Trial Registration**：ClinicalTrials.gov NCT03729531

**Background**

At present, coronary artery disease remains one of the major diseases that seriously threaten human health. Coronary artery bypass surgery is an effective way for the treatment of multi-vessel disease, complex lesions, and severe left main coronary heart disease [1-3]. The graft material is mainly the combination of the left internal mammary artery and saphenous vein(SV)[4]. Early graft failure after CABG is presented in up to 12% of grafts[5]. The low patency rate of the saphenous vein is a big challenge in the field of surgery[6]. One month after the operation, the main factor affecting the venous patency rate is the formation of acute thrombus. 1-12 months after the surgery, it was mainly the hyperplasia of venous intima. The long-term patency rate after the operation is closely related to venous atherosclerosis[7]. The existence of these reasons seriously affects the early and late patency rate of the saphenous vein and further affects the life safety and quality of life of the patients[8]. In 1996, the Swedish expert Souza team initiated the NT technology, which retained part of the tissue around the vein and did not dilate artificially after harvesting the vein. On the one hand, it reduces the damage to the intimal tissue of the vein; on the other hand, the preserved tissue may have an excellent protective effect on the vein. Their clinical trials yielded encouraging results: the technique is safe and feasible, and after 16 years of follow up, the patency rate of venous grafts in the NT group is comparable to that of the left internal mammary artery[9-11]. At present, NT technology is recommended as class IIa in the 2018ESC/EACTS guide[12]. However, the previous study has its shortcomings, the sample size is small, and patients mainly received coronary artery bypass surgery under cardiopulmonary bypass. So the real effect of NT technology needs to be further verified by more clinical trials. We are intended to test the reliability of the NT technology in off-pump CABG.

**Method**

**Study design**

This is a single-centre, randomized controlled study to compare the difference patency of saphenous vein between NT and traditional vein harvested way. Two hundred patients with at least three branches of coronary artery diseases and needed the left internal mammary artery and a sequential vein graft will be recruited from the Beijing Anzhen hospital in China. Participants will be randomly assigned (on a 1:1 ratio) to the NT group and the control group by the randomized block method. The enrollment of participants in the group will be determined by selecting random envelopes. The flowchart and study design schedule is presented in Figure 1.

**Recruiting isolated off-pump CABG patients**

**Screening for eligibility**

**Randomization**

**Conventional group(n=100)**

**No-touch group(n=100)**

**3months and 12months follow up**

**Occlusion of grafts and MACCEs**

Figure 1 Trial flow chart ：CABG: coronary artery bypass grafting; MACCEs: major cardiac, or cerebrovascular events.

**Participants**

The trial plans to recruit 200 patients with coronary heart disease who will be performed off-pump coronary artery bypass surgery.

 Inclusion criteria are (a) aged 18–80 years; (b) three-vessel coronary artery disease; (c) voluntarily joins the study and signs the informed consent.

 Exclusion criteria are: (a) simultaneous other operations (such as heart valve or lung or abdominal surgery); (b) emergent surgery; (c) ejection fraction ≤ 35%; (d) complicated with the interventricular septal perforation and ventricular aneurysm; (e) redo CABG; (f) internal diameter of great saphenous vein ≤ 0.2mm, or varicose great saphenous vein, or venous tortuosity; (g) complicated with the severe malignant tumour or other serious systemic diseases; (h) severe renal insufficiency(creatinine >200μmol/L); (i) dual antiplatelet taboo (j) severe peripheral vascular disease; (k) allergic to the radiocontrast agent; (l) participating in other clinical trials at the same time.

**Patient and public participation**

After the preoperative examination, the patients are evaluated whether they meet the inclusion criteria. If the patients comply with the requirements, explain the relevant contents of the study with the patient and their families. Ensure the patient and their families participating in the study by voluntarily, and let their families sign the informed consent. Then keep the phone number of the patient or family member, add we-chat. Ask the patient regularly whether there are cardiac cerebrovascular events and whether the wound is well healed. Before the follow-up date, we will contact the family members or patients through we-chat, informing them to recheck on time. Explain the current situation of the condition to the patients in detail according to the recheck results, and carry out health education for the patients.

**Randomization**

The study is individually randomized, with a random permuted block length of 4 patients per block, to ensure that trial groups at each block are balanced. Randomization is based on the computer-generated random digits table. Put all the random numbers in a sealed opaque envelope, then seal them with a stapler and lock them in the file cabinet. When patients who satisfy all inclusion criteria and do not meet any of the exclusion criteria, it will open the cabinet to take out the envelope and draw lots. The special scientific research secretary keeps random envelopes, and others do not participate in the drawing of lots. In our study, patients are blinded.

**Interventions**

**Surgical procedure**

**NT group**

The leg incision is cut longitudinally along the ultrasound mapping line made before the operation, and the trunk of the vein is exposed. The visible branches are separated and ligated with a ligation line, and then clamped with a silver clip near the trunk, and the distal end of the branch clipped with the same silver clip, and finally, the branch cut off. When the trunk of the vein is dissociated, the surrounding tissue about 2mm is retained on both the left and right sides. After harvesting the vein, not dilate the vein. Mark it with a signal pen to make preparations for distinguishing the course and direction of the vein when venous anastomosed. After removal, the vein is stored in a solution containing heparinized saline and papaverine hydrochloride. The vein is anastomosed proximally with the ascending aorta with 6-0 polypropylene. After the anastomosis is completed, the distal end of the vein is clamped. The vein will be fully pre-dilated by aortic pressure and then examine the leakage of the vein. If there is a leaking branch, clamp it with a silver clip. After the internal mammary artery is anastomosed to the anterior descending branch, the no-touch grfat is placed into the target vessel, and the graft length is evaluated. The sequential vein graft anastomoses are constructed end-to-side in the diagonal branch, circumflex branch, and right crown system with 7-0 or 8-0 polypropylene. It is necessary to entirely peel off the tissue around the venous incision at the site of the anastomosis, to prevent the existence of venous sinus, thus affecting the effect of the operation. When all the anastomoses are completed, check the venous tissue again for bleeding and close the bleeding site with a silver clip. The part of the vein graft with a long distance between the two anastomoses is sutured to the surface of the heart to prevent the vein from being twisted and kinked. Before closing the chest, recheck the venous tissue for bleeding spots. If the trunk of the vein is exposed very slender, or varicose or tortuous, it will be converted to the traditional technique, and the patient will be excluded from this study.

**Control group**

The leg skin is also cut longitudinally along the preoperative ultrasound marking line to expose the trunk of the vein and separate the visible branches. The branch is ligated with the ligation line, close to the trunk clamped with a silver clip, the distal end of the branch also clamped with the same silver clip, and then the branch cut off. When dissociating the trunk of the vein, the surrounding tissue is not retained. The ankle vein is fixed with a small adaptor that connected to a 10ml syringe. The distal residual severed vein was ligated with a ligation line. Dilate the vein with a syringe filled with normal saline and then check for leakage. If any leakage is discovered, clamp it with a silver clip. Then put the vein in a solution with heparinized saline and papaverine hydrochloride. The vein is anastomosed to the aorta with 6-0 polypropylene. Then anastomose the internal mammary artery to the anterior descending branch. Finally, the diagonal branch, the circumflex branch, and the right crown system are anastomosed sequentially with 7-0 or 8-0 polypropylene. When all the anastomoses are completed, recheck the venous tissue for bleeding. Before closing the chest, check the venous tissue again for bleeding spots.

 All patients are examined by bilateral great saphenous vein ultrasonography and marked before the operation. To reduce the possibility of mismatching the size of the internal coronary artery, we will choose the SV from the lower leg rather than the SV from the thigh in both two groups. When the veins of the two groups are anastomosed proximally, the corresponding instrument is selected to block the ascending aorta according to the conditions of the ascending aorta. When the aorta is severely calcified, and the tissue is hard, choose to use Heartstring. If the texture of the aorta is soft, choose to use lateral wall forceps. If hemodynamic instability or ventricular fibrillation occurs during off-pump bypass surgery, and the drug can't maintain, it is necessary to establish cardiopulmonary bypass and to perform surgery on-pump. Then the patient will be excluded. The leg wound is sutured in three consecutive layers, and the leg wound is pressurized with an elastic bandage. Remove the bandage on the second day after the operation and wear elastic socks for three months.

 All patients receive off-pump coronary artery bypass surgery. Each chief surgeon with at least three years of surgery experience, who performs at least 300 bypass surgeries per year, controls the annual mortality rate of about 0.5%. Our research centre had sent a doctor to Sweden to learn the technology of NT technology. Senior residents harvest the saphenous vein. All senior residents are trained in NT technology, which is assessed by professional doctors after the training. Passing the examination later, they must harvest at least 30 cases of NT veins independently before they can participate in this experiment.

**Medicine**

All patients are given anticoagulant therapy with low molecular weight heparin after admission, and oral anticoagulants are discontinued. Patients with other underlying diseases (such as hypertension, diabetes, hyperlipidemia) continue to take medicines until the day before the operation. The first day after the surgery, aspirin plus anticoagulant therapy is resumed.

**Outcome measures**

The main clinical end event is the occlusion rate of venous grafts one year after the operation, which is detected by cardiac computed tomography angiography (CCTA). Evaluation of graft failure: the number of failures is calculated by distal anastomosis, and the graft and anastomotic failure are evaluated according to the FitzGibbon classification system. FitzGibbon-A refers to a wide range of unobstructed grafts or less than 50% narrow grafts; FitzGibbon-B is a limited flow graft with a narrowing higher than 50%. FitzGibbon-O refers to an occlusive graft without blood flow. In this study, FitzGibbon-A/B is used as patency and FitzGibbon-O as graft failure[13]. If the lesion is located at the proximal /distal anastomosis site or the graft trunk, the diseased graft is also regarded as a lesion.

 Graft flow values and pulsatile index are routinely measured by an ultrasonic transit-time flow measurement (Medi- stim Butterfly flowmeter, Medi-stim AS, Oslo, Norway). The graft flow values and pulsatile index need to meet the following conditions when they are measured. Keep the heart at the normal position, and the anesthesiologist cooperates with the drugs adjustment. Control the blood pressure of the radial artery at about 110-120mmHg, and the heart rate at 60-100 beats/minute. If the mean flow value is less than 10 ml/min, or pulsatile index greater than 5.0, the anastomosis will require revision.

Secondary Outcome Measure:

1.Major adverse cardiac and cerebrovascular events(MACCEs，including cardiovascular death, myocardial infarction, stroke, repeat revascularization)at 3 and 12months after surgery.

2. The healing of the lower leg incision：the healing of the incision will be divided into three types.

(1) Primary healing, fewer tissue defects, neat wound edges, no infection, adhesion, or suture to create a tightly wound.

(2) Delayed healing, which means the wound does not close within one month.

(3) Infection, the wound does not close after three months, or necrotic tissues are seen in the incision.

3．Incidence of recurrent angina pectoris and readmission at three months and one year after the operation.

**Data Collection**

Each patient in the group is prepared to fill in a case report form to record the details of perioperative and postoperative follow-up. 1.Preoperative information: patient's age, sex, height, weight, etc.; and complicated diseases (such as hypertension, diabetes, hyperlipidemia, etc.), drugs taken before operation; angiographic CD showing coronary artery disease, blood pressure, heart rate; biochemical, blood routine, electrocardiogram, cardiac ultrasound, and other tests results. 2. Intraoperative information: record the chief surgeon and obtain the saphenous vein physician, operation time, graft flow values, pulsatile index, arrhythmia, rescue, IABP (intra-aortic balloon pump) implantation, and so on. 3. Postoperative information: tracheal intubation time, ICU (Intensive care unit) stay time, second thoracotomy exploration, rescue, perioperative myocardial infarction, atrial fibrillation, renal insufficiency, pulmonary infection, cerebral infarction, death, healing of leg and chest wound. All the information in the case report form should be entered into the computer within one week after the patient is discharged from the hospital.

We will retain all discharged patients’ home addresses and contact numbers, adding patient We-chat to facilitate communication with discharged patients, reminding and notifying patients of follow-up dates, and arranging follow-up time in advance. Two professional Radiologists will detect the patency rate of grafts independently. A third radiologist will determine the difference in occlusive events based on clinical consensus. The occurrence of MACCEs and the healing of leg and chest wounds is included in the case report form. Input the information into the computer in time according to the follow-up information.

**Statistical methods**

**Sample size calculation**

Using the difference test of the comparison of the two groups of rates, *α*=0.05, the degree of control is 90%. The results of meta-analytic evidence indicate that the one-year patency rate of vein grafts with the traditional method is 85%, and that of the no-touch way is expected to 95%. According to the formula, the sample size of each group is 188 cases, and then increased by 15% in case of loss of follow-up, and the sample size of each group is 217 cases. Every patient has a sequential venous graft, with at least two anastomoses. According to the anastomotic ratio of 1 to 2, and one anastomotic occlusion is an occurrence of the event, so the number of cases is about 200.

 SPSS 22.0 for Mac (IBM SPSS Statistics) was used for statistical analyses. Continuous variables were reported as the mean +/− standard deviation or median (interquartile range) (IQR). Categorical variables were reported as the absolute frequency and as a percentage. A Student *t*-test was applied for continuous data with equal or unequal variances. The Mann-Whitney U test was applied for continuous data that were not normally distributed. Pearson’s $χ$*2* and Fisher’s exact tests were used for categorical data. Statistical significance was accepted at *p*＜0.05.

**Discussion**

The primary purpose of this study is to explore whether the NT technique in patients undergoing off-pump coronary artery bypass grafting is safe and effective. Most of the previous studies on NT technology are retrospective studies, while prospective and randomized controlled studies are mainly from the Swedish Souza team. However, their study population is all undergoing coronary artery bypass grafting under cardiopulmonary bypass, and the study population is mostly Caucasian. At present, there are more and more off-pump coronary artery bypass surgeries in China, and off-pump procedures in the hands of highly trained teams appear to be associated with a reduced risk of early morbidities, such as a stroke, and fewer transfusions[14, 15]. It is of considerable significance to study the NT technology, especially for Asian people, whether they can benefit from it.

 Although total arterialization is recommended in the selection of grafts materials for CABG, arterial grafts also have many limitations. Such as the increased incidence of mediastinitis, notably, utilize bilateral intrathoracic arteries in patients with diabetes [16]. And poor results will occur when coronary target vessels with stenosis less than 70%[17]. In addition，it is common spasms and the risk of ischemia after removal of arterial grafts, and the effect of prolonged survival with additional arterial grafts has not been confirmed in randomized trials[18]. Therefore, nowadays, the global world still mainly applies an internal mammary artery to combine the saphenous vein. This study also applies to such a combination, but there is only one vein graft in this study, and they are all sequential grafts, which per graft has at least two anastomoses. There is no difference between the sequential graft and single graft in MACCE events in some previous studies, and the sequential technique with superior long-term graft patency than individual grafts[19, 20].

 In this study, anastomose the proximal first then distal portion. The proximal first strategy has the following advantages[21]: First, the quality of the proximal anastomoses is easy to determine. Secondly, after sufficient pre-dilation, we can check whether there is leakage in the vein during the operation. Third, it is easy to adjust the grafting length. Lastly, this strategy can provide blood flow to the ischemic area of each anastomosis. This advantage is helpful for off-pump CABG, especially for patients with severe hemodynamic instability. Because NT grafts are covered with adipose tissue, it is challenging to detect graft torsion. Carefully examination of the graft for twisting and kinking is necessary. With the technique of proximal first anastomosis, it is easy to adjust the length of the graft and to check the twisting and knotting of the vein graft. In this study, the sequential vein graft is first completed with the proximal end of ascending aorta and then anastomosed with the diagonal branch, circumflex branch, and right crown system in order, so that the blood supply could be obtained after the opening of the stenotic lesions. Unlike coronary artery bypass grafting under cardiopulmonary bypass, when all lesions are anastomosed, the blood supply of each target vessel can be obtained.

 As Souza trial, ultrasound was used to locate the great saphenous vein in all patients before operation. We all know that the size of the great saphenous vein in Asian people is different from that in European people like Sweden. The saphenous vein is often thin in Asian people. The experience of preclinical trials tells us that when the ultrasound reports the vein thin, it will be challenging to succeed in harvesting vein because of the fineness of vein, even breaks the trunk of the vein. Preoperative ultrasound can also reduce unnecessary incisions and save operation time. Therefore, before the patients are recruited into the group, patients with venous diameter＜0.2mm examined by intravenous ultrasound are excluded.

 In this study, the primary endpoint event is the occlusion rate of venous graft at three months after the operation, and the secondary endpoint is occlusion at one year. The Souza team study was conducted 8.5 years after the surgery, 72 cases in each group, and 27 cases in each group 16 years after the operation. The longer follow-up time, the more significant difference between the two groups, suggests that the long-term patency rate of NT technology is more prominent. Therefore, this study will continue to follow up for one year, five years, ten years, or even longer.

 The limitation of this study is single-centre research. The patients in the group are mainly from the north of China, which may lead to a certain bias in the research results. It is expected that we can participate in a multicenter, large sample, prospective randomized controlled study in the future, which can further provide more definitive evidence for the effect of NT technology.

**Trial status**

It is expected that all enrollment will be completed in April 2020.

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**Conflicts of interest**

There is no competing interests.

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