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Original Article

Stable Hemodynamics within "No-Touch" Saphenous Vein Graft

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Purpose: To investigate the hemodynamics characteristics of the "no-touch" saphenous vein graft (SVG) conduits by nicardipine intraluminal administration in vivo experiment.
Methods: A total of 59 consecutive patients were enrolled and underwent a sequential SVG to three non-left anterior descending (LAD) targets with the average runoff ≤2 mm, 30 with "no-touch" harvest technique (group A) and 29 with conventional preparation (group B). The patients were subject to nicardipine intraluminal injection during off-pump coronary artery bypass grafting (CABG) procedure. The intraoperative flow was measured with the ultrasonic transit time flow meter (TTFM), and the graft patency testified by multi-detector computed tomography (MDCT) angiography, respectively.
Results: The baseline blood flow was higher in group A than that in group B ($p < 0.05$). However, the increases in blood flow of SVG conduits in group A were lower than those in group B with 19.7 ± 5.9 vs. 35.4 ± 9.2 mL/min, 14.8 ± 5.6 vs. 23.1 ± 6.8 mL/min, 6.6 ± 2.1 vs. 11.2 ± 4.3 mL/min before the first, second, and third anastomose after nicardipine intraluminal administration, respectively (all $p < 0.01$).
Conclusions: No-touch SVGs were associated with higher baseline blood flow and less rises after nicardipine intraluminal administration during off-pump CABG procedure compared with conventional preparation. The no-touch SVGs seemed to be less spastic and well-tolerated on flow dilatation.

Keywords: nicardipine, saphenous vein, off-pump coronary artery bypass, no-touch technique

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Introduction

The long-term efficacy of coronary artery bypass grafting (CABG) is mostly limited by vein graft failure.[1,2] The saphenous vein graft (SVG) using conventional harvest technique is damaged due to considerable surgical and mechanical trauma, a situation that affects graft patency.[3] The "no-touch" harvest technique improves graft patency comparable to that of the left internal mammary artery (LIMA) for up to 16 years of angiographic follow-up.[4] In saphenous vein composite grafts based on the left internal thoracic artery, no-touch technique further improved the early and 1-year patency of SVG.[5] Suggestions had been made that adipocyte-derived relaxing factor, nitric oxide, leptin, adiponectin, prostanoids, hydrogen sulfide, and neurotransmitters, as

well as mechanical protection contributed to the superior patency of "no-touch" compared to conventional SVGs, but the mechanism is still undefined.[6] Previous study showed "no-touch" harvest vein grafts presented with tone regulation on the vascular wall in vitro.[7] However, little is known about its altered vasomotor performance in vivo experiment and consequences of different vein harvest techniques for vasomotor development after intraluminal administration of anti-spastic medication have not been previously evaluated. We proposed that higher baseline blood flow and less dynamic fluctuations were associated with the superior anti-spastic and distension-tolerant function of "no-touch" vein grafts in CABG surgery. In this study, we administered intraluminal injection of nicardipine, with the best pharmacokinetic qualities for the prevention of no-reflow during coronary intervention,[8] and compared the in vivo vasomotor performance of two distinct SVGs using different harvest techniques by ultrasonic transit-time flow meter (TTFM).

Materials and Methods

This clinical trial (NCT03126409) was performed in accordance with the ethical standards of Ethics Committee of Fuwai Hospital and the written informed consent was acquired from the patients' relatives preoperatively. The patients with coronary artery disease in one surgical ward from October 2017 through December 2017 were prospectively recruited and randomly assigned by computerized block randomization to receive "no-touch" (group A) or conventional (group B) SVGs harvest technique.[9] The emergency coronary bypass surgery, concomitant valve or aortic surgery, severe poor-quality SVGs, and ventricular aneurysm were excluded from the enrollment. All the included patients in this study had triple vessel disease and underwent the same procedure protocol that LIMA anastomosed to left anterior descending (LAD) artery and a sequential SVG onto the other three coronary arteries at the left side of heart with target runoff ≤2 mm. Saphenous vein harvest was performed by an experienced cardiac surgeon and completed after half-dosage systemic heparinization therapy. A blunt-tipped cannula was inserted into the distal end. The vein graft was gently infused with heparin–papaverine–saline mixture for the sake of preventing thrombosis and then with blood for detecting any potential leakage. The bleeding site was closed with silver clip or a slipping suture if any. The leg wounds were closed in two layers: a continuous 2-0 subcuticular and intradermic absorbable suture. The method for wound hemostasis with tension bandage was conventionally adopted on postoperative day 1.

The course of the vein was obtained from the less dense perivascular tissue when viewed anteriorly or bilaterally. Veins were harvested mostly from the left leg, with a skin incision directly over the marked location, and then extending from the ankle to the knee. The approach of sequential grafting technique was conventionally adopted by a single surgeon. The harvested length of vein graft was mainly prepared according to the diameter line of heart three-dimensional room. Therefore, it was usually as equal to one and a half of surgical scissors.

In group A, in which the "no-touch" technique was used, an effort was made to keep a pedicle of 3–5 mm surrounding tissues. All dissection was implemented with scissors. The branches from the vein were tied with fourth silk thread.[10] In group B, in which the conventional method was used, the adventitia of the veins and perivascular fat was almost totally stripped off.

All of the CABG procedures were performed with off-pump via median sternotomy. All the SVGs were anastomosed in the way of a sequential bypass onto three non-LAD artery at the left side of heart. Conventionally, the anastomosis was started from posterior descending branch or posterior branch of left ventricle, and then, obtuse marginal branch to diagonal branch was successively preformed. The whole grafts were left slightly longer than the anatomical distance between the revascularized artery points to avoid anastomosis tension. Side-to-side anastomoses in a diamond shape were done with continuous double armed Prolene 6-0 suture for the proximal bypasses and with Prolene 7-0 for the terminal connections.[11] Oral medicine statin and aspirin were routinely prescribed to all of the patients within postoperative first day if no serious complications, and continuing indefinitely. Ticagrelor or clopidogrel was given if the distal target vessels were seriously diseased.

The hemodynamics of all the grafts was examined after the anastomosis with the heart restoration to original position. The blood flow was detected using TTFM methodology (VeriQ; Medi-Stim, Inc., Oslo, Norway) before and after intraluminal injection of 0.2–0.3 mL isovolumic dilution solution of saline and nicardipine (Astellas Pharma Inc., Tokyo, Japan) into vein graft proximal to aorto-SVG anastomosis. The TTFM values in the sequential bypass grafts were consecutively acquired before the anastomosis of terminal of three arteries, whereas in the LIMA-LAD bypass graft, it was

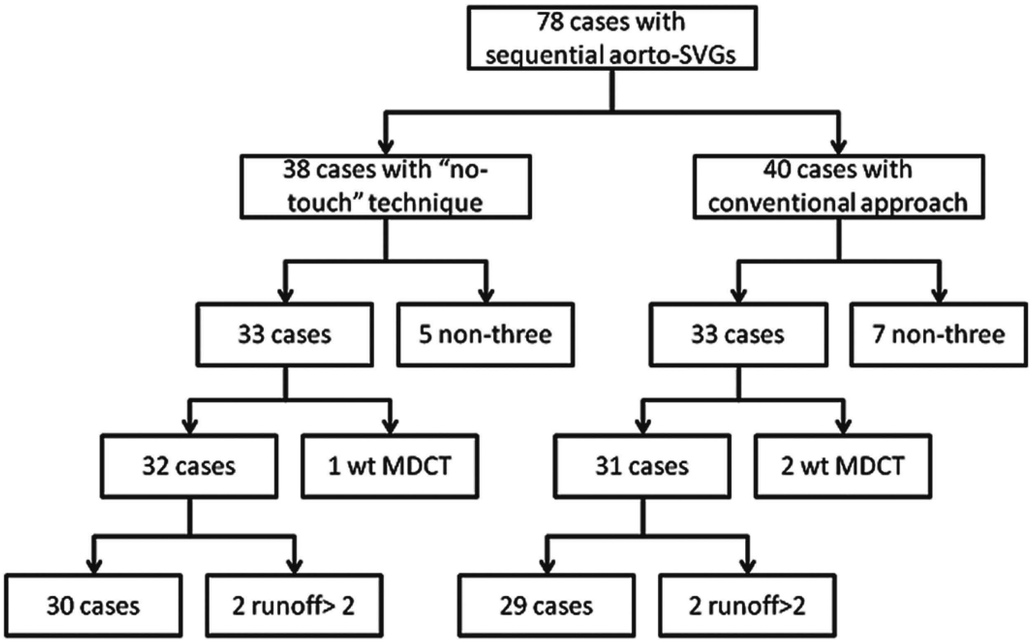

Fig. 1 Study protocol. Group A indicated no-touch vein harvest and Group B indicated conventional vein harvest. LAD: left anterior descending; MDCT: multi-detector computed tomography; SVGs: saphenous vein grafts

measured from near the distal end of anastomosis. All the values were measured under the stable conditions with mean arterial pressure of 60–80 mm Hg and the heart rate ranging from 60 to 80.

Coronary computed tomography angiograms were completed routinely before discharge of hospital to testify the graft patency, otherwise the case was excluded. The 64-slice dual-flush computed tomography (multi-detector computed tomography (MDCT), Somatom Definition Flash, Siemens Medical Solutions, Forchheim, Germany) angiography was resorted to determine the graft patency from morphologic characteristics.

All statistical analyses were performed with SPSS software (version 17.0; SPSS Inc., Chicago, IL, USA). The enumerated data were presented as frequencies and percentages, and compared using the chi-square test or Fisher's exact test. The measurement data were expressed as means ± SD, and were compared using the unpaired t-test. Statistical significance was accepted when p value <0.05.

Results

Of 78 patients who were recruited into the trial, 12 patients were excluded from this study due to change of different anastomoses number or kind. A total of 66 patients who received a sequential aorto-SV bypass graft to three non-LAD targets were included. Patients without MDCT coronary angiogram evaluation before discharge of hospital were also excluded (renal insufficiency, n = 1; tachycardia, n = 2). Another four patients were also excluded out because the average runoff was above 2 mm, resulting in a final number of 59 patients meeting our established standards. The included patients were randomized and allocated into group A (no-touch vein harvest, n = 30) or group B (conventional vein harvest, n = 29) depending on the SVGs harvest technique (**Fig. 1**).

The two groups showed no significant differences with respect to demographic features and comorbidities. We did not also observe the significant difference on SYNTAX score which was used to evaluate coronary artery stenosis severity. There were no significant differences on left ventricular end-diastolic diameter and preoperative medication profile (P >0.05) (**Table 1**). The measurements on LIMA-LAD flow were not significantly different between the two groups, but the baseline values of the SVGs segments in group A were remarkably higher than those in group B, with 57.0 ± 11.1 vs. 47.7 ± 12.0 mL/min, 35.7 ± 8.8 vs. 29.1 ± 6.3 mL/min, 17.4 ± 5.4 vs. 14.4 ± 5.0 mL/min before the first, second, and third anastomose, respectively. Nonetheless, lower

Table 1 Preoperative data

Variable	Group A	Group B	P value
Male (cases)	21	20	0.931
Age (years)	64.5 ± 8.8	64.2 ± 6.9	0.900
Active smokers (cases)	5	5	0.953
Hypertension (cases)	16	13	0.514
Diabetes mellitus (cases)	8	9	0.711
Hyperlipidemia (cases)	14	11	0.497
History of cerebrovascular event (cases)	3	7	0.148
Left stem stenosis (>50%)	8	6	0.590
Atrial fibrillation (cases)	2	3	0.612
Left ventricular end-diastolic diameter (mm)	55.4 ± 5.1	55.0 ± 4.9	0.759
Left ventricular ejection fraction (%)	59.5 ± 6.8	60.0 ± 7.7	0.765
SYNTAX score	28.3 ± 2.3	28.4 ± 2.2	0.805
Preoperational medication (cases)			
β-blockers	29	28	0.981
Ca-inhibitor	13	11	0.673
Nitrates	26	27	0.413
Statins	30	29	1.0
Aspirin	5	3	0.478
Lactate (preoperatively)	0.86 ± 0.25	0.90 ± 0.21	0.569

Notes: Group A indicated no-touch vein harvest; Group B for conventional vein harvest.

Table 2 Transit time flow meter measurements of saphenous vein grafts

SVGs flow (mL/min)	Group A(n = 30)			Group B(n = 29)		
	Pre-N	Post-N	Value	Pre-N	Post-N	Value
LIMA-LAD	23.9 ± 4.7	36.3 ± 5.9	12.4 ± 5.1	25.1 ± 6.7	35.9 ± 7.3	10.8 ± 5.3
SVG-A1	57.0 ± 11.1	76.3 ± 12.8	19.7 ± 5.9	47.7 ± 12.0**	83.2 ± 9.5*	35.4 ± 9.2**
SVG-A2	35.7 ± 8.8	50.5 ± 9.9	14.8 ± 5.6	29.1 ± 6.3**	52.2 ± 7.4	23.1 ± 6.8**
SVG-A3	17.4 ± 5.4	24.0 ± 5.4	6.6 ± 2.1	14.4 ± 5.0*	25.7 ± 6.0	11.2 ± 4.3**

*P <0.05, **P <0.01 (between two groups)

Pre-N: prior to nicardipine administration; Post-N: post-nicardipine administration; LIMA-LAD: left internal mammary artery (LIMA) anastomosed to left anterior descending artery; A1, A2, A3: anastomose 1-3; SVGs: saphenous vein grafts. Group A indicated no-touch vein harvest; Group B for conventional vein harvest.

increases in blood flow after intraluminal nicardipine administration were in group A compared with those in group B with 19.7 ± 5.9 vs. 35.4 ± 9.2 mL/min, 14.8 ± 5.6 vs. 23.1 ± 6.8 mL/min, 6.6 ± 2.1 vs. 11.2 ± 4.3 mL/min before the first, second, and third anastomoses, respectively (**Table 2**).

The operation time of the two groups was not significantly different. There was no significant difference in coronary artery endarterectomy procedure between the two groups. The operator took down certain anastomose and revised the grafting procedure two patients in group A and three patients in group B due to unsatisfactory anastomosis. The cerebrovascular accidents only consisted of the transient delirium and confusion. The lactate level at 12 hours postoperatively was lower in group A than that in group B (P <0.05). Coronary MDCT images were obtained before discharge of hospital at a mean of 6.4 ± 2.5 and 6.2 ± 1.8 days postoperatively in group A and group B, respectively (P >0.05). The graft patency from MDCT images was 100% in both groups (**Table 3**).

Discussion

This study investigated the intraluminal flow characteristics of SVGs by nicardipine intraluminal administration with Laser-Doppler flowmetry in patients who underwent either “no-touch” harvesting technique or conventional preparation. Although the SVGs patency of two kinds of harvesting techniques was comparable before discharge of hospital, the veins harvested by “no-touch” technique had higher primary

Table 3 Operational results and postoperational events

Variable	Group A (n = 30)	Group B (n = 29)	P value
Run-off (mm)	1.53 ± 0.27	1.50 ± 0.33	0.754
Operation time (minutes)	204 ± 24	200 ± 22	0.480
Coronary artery endarterectomy	4	3	0.723
Resumption SVGs anastomosis	2	3	0.612
New-onset atrial fibrillation	3	5	0.417
Cerebrovascular complication	3	2	0.669
Re-open for bleeding on branch	0	0	
Re-open for bleeding	0	1	
Wound infection of the sternum	0	0	
SVGs harvesting site infection	0	0	
MDCT of days postoperationally	6.4 ± 2.6	6.1 ± 1.8	0.479
MDCT graft patency	30	29	1.0

AF: atrial fibrillation; MDCT: multi-detector computed tomography; SVGs: saphenous vein grafts. Group A indicated no-touch vein harvest; Group B for conventional vein harvest.

blood flow and less rises after nicardipine injection compared with conventional management. Therefore, it indicated that "no-touch" SVGs had the anti-spastic and distention-tolerant quality in vivo experiment.

There were some experimental studies with medicines such as phentolamine which had been demonstrated in intro vasodilatory effects of cardiovascular agents on the CABG grafts.[12] Nicardipine was regarded as the best choice in preventing coronary no-reflow during intervention manipulation with regard to its minimal systemic side effects and modest negative inotropic and chronotropic effects.[8] From this study that a sequential aorto-SV bypass grafted onto three non-LAD targets, we observed that the blood flow of SVGs was significantly enhanced after nicadipine intraluminal administration. That could be explained by the evidence that spasm happened on SVGs during off-pump CABG surgery and the nicardipine administration was effective at inducing vasodilatation of the implanted SVGs.

The "no-touch" harvesting technique, in which the SVG is harvested with its surrounding tissue, with protection of the entire vein wall during dissection, which avoids mechanical injury during adventitia stripping and prevents against spasm and manual distention.[13] "No-touch" technique, cholesterol-lowering and anti-platelet medication have been currently available treatment measures in enhancing graft patency rate[14] on the account that the use of cardiopulmonary bypass during surgical revascularization has a controversial impact.[15] The preservation of the adventitial vasa vasorum and signs of normal cellular integrity demonstrated that the "no-touch" technique did not cause mechanical or pressure damage to the vessel wall.[16] LIMA graft is commonly harvested with a pedicle of surrounding tissue and is also avoided from dilation. The high patency rate of this arterial graft can partly be ascribed to the "no-touch" harvesting technique, especially for the beginner.[17]

The total vasa vasorum area was about a third lower than that in "no-touch" technique compared with that in conventional preparations, indicating diminished blood supply from the graft in conventional vein grafts.[18] The cushion of surrounding tissue prevents the vein from contact damage and drying before the bypass procedure. The vein is never directly touched with instruments even during the process of suturing the anastomoses, since the assistant surgeon only holds the vein's surrounding tissue with forceps. The SVGs using "no-touch" harvesting technique presents with an molecular and morphologic pattern consistent with less vascular smooth muscle cell activation than conventional harvesting couterparts.[19] Furthermore, the piece of vascular pedicle avoids from remarkable SVGs rotation and mechanical twisting and kinking at the placement of graft implantation. Therefore, it seemed that SVGs using "no-touch" procedure do not require pharmacological relaxation or mechanical distention.

Contrary to in vitro experiment, we observed that the blood flow of SVGs harvested by "no-touch" technique was significantly higher than that prepared with conventional method, but less rises after nicardipine intraluminal injection compared with conventional approach, which implied that no-touch SVGs could limit build-up of blood and counteract lumen dilation. It was assumed that the higher flow in the "no-touch" sequential SVGs helps to keep conduits with similar lumen and coronary arteries with parallel runoff more open under the conditions of

equivalent systemic pressure and conduit length. It could be explained by that spasm observably happened on SVGs harvested by conventional surgical technique. The "no-touch" harvest SVGs presented with better anti-spastic function. Meanwhile, the less rises of blood flow by "no-touch" harvest SVGs was attributable to its better distention-tolerant function so that the blood flow did not increase to the extent as that by conventional approach after nicardipine administration.

The conditions of storage solution also played a major effect on graft function and patency.[20] Numerous studies had sought to determine the best solution to preserve optimal endothelial function of the harvested vein and, therefore, maintain high graft patency rates. However, no clear consensus exists on which storage medium is better. We thought the internal environment would be the optimal medium for the conduits so that the SVGs were usually dissected just before CABG surgery as late as possible.

The operator routinely performed the same protocol that LIMA-LAD anastomose and a sequential SVG onto the other coronary arteries at the left side of heart. The ascending aorta was the only proximal inflow for a sequential SVG, no left internal thoracic artery-SV composite graft was constructed in any patient. In this study, we only recruited the patients who underwent sequential SVGs onto three targets for the sake of resistance homogeneity. Thus, we just recruited the triple-vessel disease patients performed by the single surgeon who commonly preferred the protocol. A sequential graft of three anastomose possesses only third of vascular resistance of a single graft if the resistance on each connection is assumed to be similar. Measurements from the proximal site of the sequential bypass graft represented the combined cumulative run-off of the distal anastomosis. The increase in flow velocity into a sequential graft is directly associated with the reduction in vascular resistance. Previous studies showed that the patency of sequential vein grafts was superior to that of single vein grafts,[21] it also hold true for radial artery graft.[22]

It had been demonstrated that the graft patency of "no-touch" SVGs management is superior to that of conventional preparation. Different from previous clinical follow-up study, the research focused on the intraoperative hemodynamic characteristics instead of the "no-touch" SVGs graft patency. Thus, we did not initiate a long-term follow-up to compare the patency rate of "no-touch" SVGs graft and conventional counterparts, and just completed coronary artery computed tomography angiography (CTA) examination before discharge of hospital to testify the patency of the two kinds of harvest approach. Nonetheless, "no-touch" SVGs took on superior baseline flow from the aspect of TTFM measurements and less lactate level, which expected with better long-term patency.

The functional leg recovery was similarly acceptable in both groups at discharge as previously described.[23] More often than not, a two-layer continuous 2-0 suture was used to close the leg incision. In our experience, if there was too much slack in the thread, the suture must be pulled tight to take up the slack as early as possible. We did not confront with serious incision complication[24] except for the appearance such as subcutaneous ecchymosis and swelling.

There are some limitations in this study that must be recognized. First, although a randomized self-controlled trial was conducted, this was a small sample study after a series of selection. Second, although the study used consistent procedure and anastomose protocol, we did not control the bias from intraoperative anesthetic drugs, in addition to preoperative medications, all of which could result in uncertain effect on nicardipine efficacy. Third, it was only proof study on hemodynamics characteristics of the "no-touch" SVGs, so a long-term follow-up entailed to demonstrate the difference on the graft patency of two kinds of SVG grafts harvesting technique, although there was seemed positive association between blood flow and SVGs patency.

Conclusion

This was the first clinical trial demonstrating that SVGs harvested by "no-touch" surgical technique was associated with stronger anti-spastic function and pressure-tolerant capacity than that by conventional preparation through nicardipine intraluminal administration. Our results added another piece of evidence that the "no-touch" technique was more stable flow hemodynamic in CABG procedure, and indicated that it should be both more widely studied and perhaps more widely adopted. Meanwhile, nicardipine intraluminal administration was proposed as an alternative to topical and systemic vasodilators for reducing SVGs intraoperative spasm.

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Disclosure Statement

The authors declare that they have no conflict of interest.

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