The no-touch saphenous vein is an excellent alternative conduit to the radial artery 8 years after coronary artery bypass grafting: A randomized trial

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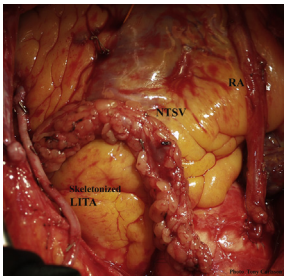
ABSTRACT

Background: In 2004, a prospective randomized trial demonstrated that after 3 years, saphenous veins (SVs) harvested with a no touch (NT) technique had a greater patency than radial grafts for coronary bypass surgery. Here we report the 8-year follow-up data of this trial.

Methods: The trial included 108 patients undergoing coronary artery bypass grafting (CABG). Each patient was assigned to receive 1 NT SV and 1 radial artery (RA) graft to either the left or right coronary territory to complement the left internal thoracic artery (LITA). Sequential grafting was common, so overall graft patency as well as the patency of each anastomosis were assessed.

Results: Angiography was performed in 84 patients (78%) at mean of 97 months postoperatively. Graft patency were high and similar for both NT and RA: 86% for NT versus 79% for RA ($P = .22$). The patency of coronary anastomoses was significantly higher with the NT SV grafts (91% vs 81%; $P = .046$). The NT grafts also had excellent patency in coronary arteries with <90% stenosis (93% patency) and in coronary arteries of small diameter (87% patency) or with mild calcification (88% patency). Patency for the LITA was 92%.

Conclusions: NT SV grafts have excellent patency similar to that of RA grafts after 8 years. In addition, NT SV grafts can be used in situations that are not ideal for RA grafts. (J Thorac Cardiovasc Surg 2021;161:624-30)



Complete revascularization using the left internal thoracic artery, radial artery, and no touch saphenous vein.

CENTRAL MESSAGE

The "no touch" saphenous vein graft is an excellent complementary conduit to the arterial grafts.

PERSPECTIVE

This study highlights the improvement in saphenous vein graft quality with the "no touch" technique and increases the number of situations in which the saphenous vein may be preferable to radial artery grafts as a conduit in CABG surgery, even in the long-term.

See Commentaries on pages 631 and 634.

The use of arterial grafts as the second conduit of choice in coronary artery bypass surgery (CABG) holds the promise of increased patency and better clinical outcomes.[1,2] The evidence to support a second internal thoracic artery (ITA) or radial artery (RA) graft is evolving and, although persuasive to some, is not yet sufficient to convince the majority of coronary surgeons. Technical challenges and uncertain requirements are primary obstacles to the

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Abbreviations and Acronyms

CABG = coronary artery bypass grafting
CT = computed tomography
ITA = internal thoracic artery
LAD = left anterior descending artery
LITA = left internal thoracic artery
NT = no touch
NT SV = no touch saphenous vein
RA = radial artery
SV = saphenous vein

widespread use of multiarterial grafting. Furthermore, it is unclear how soon these issues can be resolved. This lack of progress in alternatives to SV grafting is a strong incentive to provide a vein that is a more durable conduit.

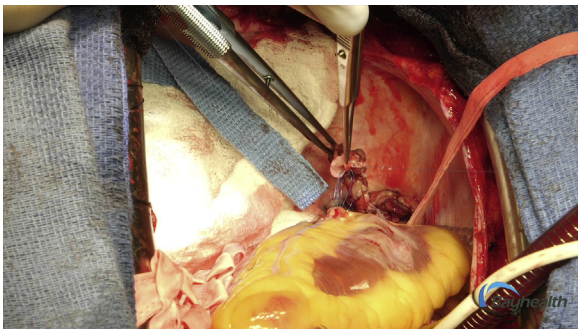
For some years now, our group has assessed ways of improving the results of vein grafts. In the mid-1990s, a novel vein graft harvesting technique was introduced, the NT technique, in which the SV is harvested with its pedicle of perivascular adipose tissue intact (Video 1).[3] The NT avoids conduit distension and resultant endothelial damage.[4,5] Preservation of the perivascular adipose tissue of the NT also maintains blood supply to the media of the SV,[6] contributing to a vasodilating effect in the graft,[7] and helps avoid kinking of the graft during and after surgery.[8]

A randomized controlled trial comparing patency rates for NT and conventionally harvested SV grafts published in 2006 showed a significantly higher patency rate for NT SV grafts (90% vs 76%; $P = .01$) and comparable patency for left ITA (LITA) grafts (90%) at 8.5 years after surgery.[8] A follow-up study of the same patient cohort showed that the NT SV grafts maintained a remarkable patency rate (83% vs 64%; $P = .03$) even at 16 years after surgery.[9]

A trial comparing NT SV and RA grafts would be a more rigorous test of any improvement in vein graft quality. Such a trial was started in 2004 and had some similarities to the RAPS trial,[10] in that SV and RA conduits were randomized in each individual patient after the LITA to the left anterior descending artery (LAD). Angiographic follow-up at a mean of 36 months after the operation showed a higher patency rate for NT SV grafts compared with RA grafts, along with a higher rate of patent coronary anastomoses.[11] Here we report the angiographic results at a mean of 8 years after surgery.

MATERIALS AND METHODS

This single-center randomized trial studied consecutive patients undergoing elective, first-time and only CABG surgery at the Department of Cardiothoracic and Vascular Surgery, University Hospital, Örebro, Sweden. The study was approved by the local Ethics Committee (approval Dnr 2014/052; April 29, 2014), and written informed consent was obtained from each participant. The study has been registered at ClinicalTrials.gov (identifier NCT02158455). A total of 108 patients were included in the study between January 2004 and August 2009.



VIDEO 1. The no-touch saphenous vein harvesting technique presented by Professor John Mannion. Video available at: https://www.jtcvs.org/article/S0022-5223(19)32357-8/fulltext.

Study Design

Patients who had at least 3-vessel coronary artery disease were eligible for inclusion. Exclusion criteria included age >65 years, left ventricular ejection fraction <40%, serum creatinine >120 μmol/L, use of anticoagulants, coagulopathy, allergy to contrast media, positive Allen's test or abnormal Doppler study of the arms, history of vasculitis or Raynaud's syndrome, bilateral varicose veins, or previous vein stripping.

Each patient received the LITA, 1 RA, and 1 NT SV graft as conduit material. The LITA was used to bypass the LAD coronary artery, whereas the RA and NT SV grafts were randomized to bypass either the left or right coronary territory.

Acetylsalicylic acid 150 mg (Pfizer, New York, NY) was administered within 6 hours postoperatively; thereafter, 75 mg was prescribed daily. Calcium channel blockers were used only for treatment of hypertension.

Randomization and Masking

To compensate for differences according to territory, such as number of coronary arteries to be grafted and peripheral runoff, the study grafts were allocated at random en bloc to the left or right coronary territory according to a computer-generated list.

The surgeon enrolled and assigned participants to intervention. After making the decision as to which coronary arteries should be grafted, the randomization was revealed in the operating room by opening enumerated, sealed envelopes provided by the statistician. Angiography assessors were independent and blinded to the outcome of randomization.

Surgical Aspects

The NT SV grafts were prepared with a similar technique as used for the RA grafts[3] (Figure 1, *A* and *B*). In brief, both grafts were harvested with a pedicle of surrounding fat tissue intact and left in situ until after heparinization. After removal, the grafts were stored in heparinized blood and were neither flushed nor distended.

Classical principles to achieve complete revascularization were followed, using single and sequential grafts to bypass coronary arteries with >50% stenosis. The distal anastomoses for both RA and NT SV grafts were performed first, using 7-0 Prolene continuous sutures. Calibrated probes were used to measure the diameter of grafted coronary arteries. Graft flow data were collected after weaning from extracorporeal circulation once stable haemodynamic conditions were achieved using an ultrasonic transit-time flowmeter (VeriQ System; Medistim, Oslo, Norway).

ADULT

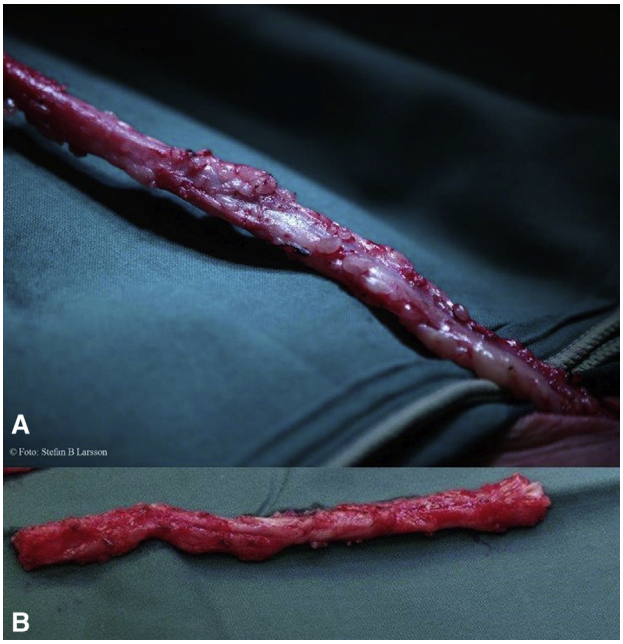


FIGURE 1. A, No touch saphenous vein graft. B, Radial artery graft.

Angiographic Assessment

The first follow-up at a mean of 36 months was performed with conventional angiography in 99 patients (92%).[11] The second and current follow-up was performed at 97 months using computed tomography (CT) angiography with a Somatom Flash dual-source CT scanner (Siemens, Erlangen, Germany). All subjects received 0.25 mg of nitroglycerin sublingually. Those with a heart rate >70 bpm and no contraindications were also given up to 10 mg of metoprolol intravenously before the examination. Contrast media (60-70 mL of Iomeron 400 mg/mL; Bracco, Milan, Italy) was administered with a pressure injector at a flow rate of 6 mL/s, followed by a 60-mL saline bolus.

Scanning started at the left subclavian artery and ended at the base of the heart. The images were reviewed on a Siemens SyngoVia workstation. All images were independently reviewed by 2 thoracic radiologists who were blinded to group assignment. Disagreements were resolved by consensus. Where possible, the studies were compared with reports and images from previous coronary angiographies. A graft was judged as occluded when the graft was not opacified by contrast media. Graft stenosis was deemed significant when the narrowing of the lumen diameter was >50% relative to the adjacent parts of the vessel.

Statistical Methods

The study was designed as a test of noninferiority. A sample size of 108 subjects achieved 83% power at a 5% significance level using a 1-sided equivalence test of correlated proportions when the base proportion (RA) was 0.80 and the maximum allowable difference between proportions (RA – NT SV) was 0.08. We initially calculated a 1-sided 95% confidence interval (CI) and the corresponding 1-sided P value for noninferiority for our primary endpoint, patency. To allow conventional interpretation of results we calculated regular 2-sided 95% CIs and 2-sided P values for superiority.

Before our analyses, the database was restructured into a dataset allowing for analysis of grafted coronary territory level (261 target vessels for 168 grafts for 84 patients). The adjusted analysis was performed with consideration of the intrapatient and intragraft correlations using the method of generalized estimation equations. Patency outcome was analyzed with a logistic regression model. The main explanatory variable was type of graft, NT SV or RA, and thus the primary analysis was restricted to this variable. Secondary subgroup analyses were performed to investigate whether the effect of graft type was homogenous over different important clinical variables; however, these analyses should be considered indicative and exploratory because of smaller sample sizes. Results are reported as odds ratio (OR) with 95% CI and P value. The main statistical analyses were performed with PROC GENMOD in SAS version 9 (SAS Institute, Cary, NC).

RESULTS

Follow-up was performed between October 2014 and May 2015, at a mean of 97 months (range, 66-128 months) after surgery. All patients in this second follow-up except 1 also participated in the first follow-up, at 36 months after surgery. The study flow chart is illustrated in Figure 2. Two eligible male patients, age 61 and 64 years, declined to participate in the study. The clinical baseline characteristics of the final study cohorts of 84 patients (78%) are presented in Table 1. Only 1 patient, with an occluded LITA, experienced a new MI within 97 months. Two patients (both female) had undergone percutaneous coronary intervention, both directed against LAD. None of the patients had redo CABG surgery. Most patients (90%) were in New York Heart Association class I. The majority (87%) used 75 mg acetylsalicylic acid daily. None of the patients was receiving dual antiplatelet inhibition treatment. At 97 months, 20 patients (24%) were receiving a calcium channel blocker for hypertension.

Surgical Aspects

All patients were operated on-pump by the same surgical team. The NT SV grafts were harvested from the calf, and the RA grafts were harvested from the nondominant arm. According to the study protocol, NT SV and RA grafts were to be used as aorta-coronary bypass conduits. Two RA grafts were too short to reach the ascending aorta; thus, 1 graft was proximally connected to the LITA, and the other was connected to a NT SV graft. Both of these composite grafts were included in this study.

Angiographic Assessment

The characteristics of 261 grafted coronary territories and 168 grafts are presented in Table 2. The patency rate was 86% for the NT SV grafts versus 79% for the RA grafts ($P = .22$). The patency rate for grafted coronary territories was 91% (125 of 137) for NT SV grafts versus 81% (101 of 124) for RA grafts (OR, 2.29; 95% CI, 1.01-5.16; $P = .046$). The patency for grafts to the left side was 96% (82 of 85) for NT SV and 83% (65 of 78) for RA (OR, 5.51; 95% CI, 1.40-21.68; $P = .015$). The patency of NT SV and RA grafts varied according to the degree of coronary artery stenosis: 90% versus 72%, respectively ($P = .059$) for stenosis <70% and 95% versus 74%

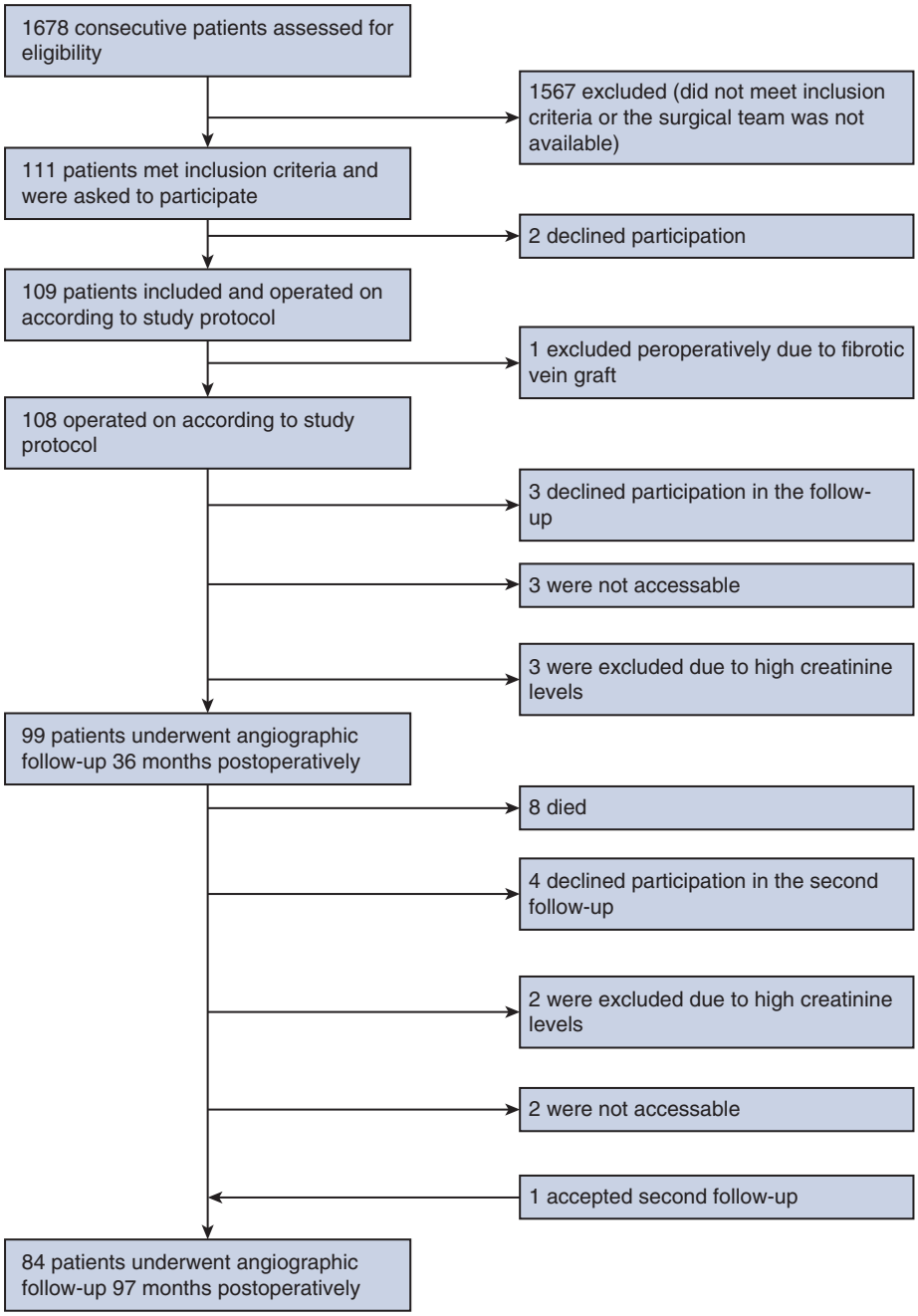


FIGURE 2. Patient selection flowchart.

($P = .017$) for stenosis 70% to 89%. As in our previous study, it was found that the vast majority of RA grafts (41 of 43; 95%) that were anastomosed to target vessels with a stenosis of ≥90% were still open. The patency of NT SV grafts was greater than that of RA grafts regardless of whether they were used as single, double-, or triple-sequential grafts (Table 2). Compared with the 36-month angiographic follow-up, new occlusions had occurred in 11 grafts, including 3 single NT SV and 3 single RA grafts, 2 double-sequential NT SV and 2 double-sequential RA grafts, and 1 triple-sequential NT SV graft. The majority of those grafts were connected to the right coronary territory (5 of 6 NT SV grafts and 3 of 5 RA grafts). ITA patency was 92% (77 of 84).

DISCUSSION

In this trial, we compared the 8-year patency of NT SV and RA grafts, and because sequential grafting was used

TABLE 1. Baseline patient characteristics

Variable	Total (N = 84)	NT SV left RA right (N = 43)	NT SV right RA left (N = 41)	*P* value
Age, y, mean (SD)/median (range)	59.0 (5.9)/60.5 (39.9-67.5)	58.3 (6.1)/60.4 (41.0-66.0)	59.6 (5.6)/60.8 (39.9-67.5)	.32
Myocardial infarction, n (%)	28 (34.6)	13 (31.7)	15 (37.5)	.75
Female sex, n (%)	10 (11.9)	4 (9.3)	6 (14.6)	.68
NYHA classification, n (%)				
I	3 (3.6)	1 (2.3)	2 (4.9)	
II	29 (34.5)	11 (25.6)	18 (43.9)	
III	44 (52.4)	26 (60.5)	18 (43.9)	
IV	8 (9.5)	5 (11.6)	3 (7.3)	.084
Diabetes	16 (19.0)	8 (18.6)	8 (19.5)	1.00
Hypertension	46 (54.8)	26 (60.5)	20 (48.8)	.39
Dyslipidemia	56 (66.7)	28 (65.1)	28 (68.3)	.94
Smoking history				
Never smoked	35 (41.7)	16 (37.2)	19 (46.3)	
Ex-smoker	37 (44.0)	19 (44.2)	18 (43.9)	
Current smoker (1 y)	12 (14.3)	8 (18.6)	4 (9.8)	.28

For comparison between groups, Fisher's exact test was used for dichotomous variables, the Mantel-Haenszel χ^2 test was used for ordered categorical variables, and the Mann-Whitney *U* test was used for continuous variables. *NT SV*, No touch saphenous vein; *RA*, radial artery; *SD*, standard deviation; *NYHA*, New York Heart Association.

frequently, we also assessed the patency of the coronary anastomoses created from these grafts. The results demonstrate a similar high patency for both the NT SV and RA grafts at 8 years (86% vs 79%; $P = .22$). The number of anastomoses that remained patent was statistically superior for the NT SV compared with the RA conduits (91% vs 81%; $P = .046$). Our data also demonstrate that the NT SV can be recommended in situations where an RA graft is not ideal, such as small vessel size, moderate coronary stenosis, imperfect coronary quality, or the right coronary

TABLE 2. Characteristics of 261 grafted coronary arteries and 164 grafts

Characteristic	NT SV		RA		Patency, NT SV vs RA (RA reference), OR (95% CI)	*P* value*
	Assessed, n	Patent, n (%)	Assessed, n	Patent, n (%)		
Coronary arteries	137	125 (91)	124	101 (81)	2.29 (1.01-5.16)	.046
Coronary artery subgroups						
Left	85	82 (96)	78	65 (83)	5.51 (1.40-21.68)	.015
Right	52	43 (83)	46	36 (78)	1.33 (0.47-3.79)	.59
Stenosis <70%	42	38 (90)	36	26 (72)	3.56 (0.95-13.31)	.059
Stenosis 70%-89%	43	41 (95)	43	32 (74)	6.44 (1.40-29.67)	.017
Stenosis 90%-100%	52	46 (88)	43	41 (95)	0.37 (0.10-1.36)	.13
Diameter 1.0-1.5 mm	55	48 (87)	41	31 (76)	1.75 (0.65-4.74)	.27
Diameter >1.5 mm	82	77 (94)	82	69 (84)	2.94 (0.89-9.66)	.08
Quality: Good	94	87 (93)	91	76 (84)	2.44 (0.81-7.32)	.11
Quality: Mild calcification	43	38 (88)	33	25 (76)	2.41 (0.81-7.16)	.11
Grafts	84	72 (86)	84	66 (79)	1.64 (0.74-3.60)	.22
Graft subgroups						
Single	41	36 (88)	49	41 (84)	1.38 (0.40-4.75)	.61
Double sequential	33	27 (82)	30	22 (73)	1.19 (0.33-4.36)	.79
Triple sequential	10	9 (90)	5	3 (60)	6.00 (0.39-92.28)	.20
Flow average <20 mL/min	5	3 (60)	14	6 (43)	2.04 (0.27-15.65)	.49
Flow average 20-39 mL/min	16	13 (81)	31	26 (84)	1.00 (0.19-5.23)	>.99
Flow average 40-59 mL/min	23	20 (87)	20	16 (80)	1.56 (0.45-5.45)	.49
Flow average >59 mL/min	39	35 (90)	18	17 (94)	0.55 (0.07-4.15)	.56

NT SV, No touch saphenous vein; *RA*, radial artery; *OR*, odds ratio; *CI*, confidence interval. *Adjusted for correlation within subjects; see text.

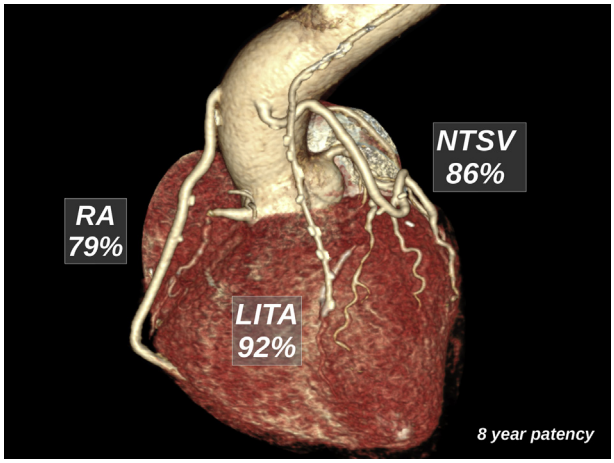


FIGURE 3. Optimal revascularization using left internal thoracic artery to left anterior descending artery, no touch saphenous vein as a sequential graft, and radial artery as a single graft. *RA*, Radial artery; *LITA*, left internal thoracic artery; *NTSV*, no touch saphenous vein.

system (Table 2). The results confirm that the NT SV is an excellent conduit, with a patency similar to the RA and comparable to the ITA after 8 years.

Concern for accelerated atherosclerosis in SV grafts is the main driver of an interest in arterial conduits. An old SV graft could represent a vulnerability, having developed clinically silent accelerated atherosclerosis, in an otherwise healthy patient. We hypothesized that the NT SVs may also offer some protection from vein graft atherosclerosis over the long term.[12] The slow attrition rate in the NT SV grafts between the third and eighth year of this longitudinal study is similar to that of the RA grafts and is not consistent with a marked degree of accelerated atherosclerosis in NT SVs.[9] These observations should help ameliorate the concern for vein conduit atherosclerosis over the long term, although more observations after 10 to 15 years are needed.

The enthusiasm for the RA has varied over the years. After being revived by Acar in 1992,[13] RA grafting peaked in the Society of Thoracic Surgeons database in 2002 at 12.3% and then declined steadily to 5.5% in 2009.[14] This reduction was a conscious decision. The dropoff in use occurred during a time period when surgeons were aware of the potential for improved patency of the RA over conventionally harvested SVs.[15-18] There are many reasons for the infrequent embrace of a second arterial graft in CABG. Among other factors, there is concern regarding the "confounding by indication" of propensity matching, the small number of patients in randomized trials with results for longer than 5 years, and the technical changes required when altering the standard setup and procedure for CABG. Until these issues are resolved, a surgeon reluctant to use the RA has the NT SV as an alternative to improve conduit patency.

It has been hypothesized that an ideal second conduit in CABG could improve long-term mortality and reduce cardiovascular events. The right ITA lost favor as the most likely candidate when the ARTs trial[19] showed no mortality benefit by adding a second ITA graft. Nonetheless, the goal of better patency in the second graft for CABG still has merit. A patient-level meta-analysis of the RA studies has suggested that repeat revascularization and recurrent myocardial infarction might be reduced by the improved patency of RA grafts, and this hypothesis is being tested in the ROMA trial.[20] Our results reported here suggest that there should be similar, if not better, results at 10 years for the NT vein.

However, to achieve the important goal of improved CABG outcomes, both RA and NT grafts have similar advantages and can be seen as complementary (Figure 3), not necessarily competitive. Either conduit can be used when required, thus avoiding bilateral ITA grafting, which carries a higher rate of sternal wound complications. Both conduits are readily harvested and are without length limitation. Although not permitted in a randomized trial, in clinical practice, comorbidities and technical factors may lead a surgeon to favor one conduit over another. If a target vessel is large and has a tight stenosis (>90%) and the RA is of good quality, then a RA graft might be used. Alternatively, if the RA is small or has mild to moderate atherosclerotic disease, or a target vessel has a questionable tight stenosis, an NT graft may be preferred. Within the 8-year time frame of this study, there did not appear to be any patency disadvantage in choosing an NT SV over an RA as the second conduit. The 96% patency of the NT veins for left-sided coronary territories (Table 2) is reassuring.

To decrease morbidity and the number and length of surgical incisions, the coronary surgery community has adopted vein endoharvesting; however, there is a persistent concern that this can result in poor conduit quality.[21,22] Although the technique of NT harvesting requires an open leg incision, the trade-off is an evidently improved patency.

There are some strengths, but also some limitations, of our trial design. A significant strength, similar to the RAPS study, is that the RA and NT SV conduits were both subjected to identical systemic factors that might affect patency, especially in a long-term trial. Such factors included hyperlipidemia, diabetes, and hypertension. Surgical expertise in sequential grafting was similar for both the RA and NT SV grafts. This design thus minimizes the effects of variables between patients or surgeons. The study has several limitations. First, consistent with our practice at the time, both NT SVs and RA conduits were placed to some vessels with stenosis between 50% and 70%. This might have lowered the RA patency with a minimal effect on SV graft patency, because RA grafts are more sensitive

to competitive flow.[23] Our practice has since evolved so that today, we no longer use RA conduits to bypass moderate lesions. Nonetheless, we did not observe low RA patency in this study—rather, the RA patency of 79% was almost identical to that reported by Gaudino and colleagues,[24] who did not use the RA to bypass moderate lesions. In our study, NT vein graft patency is comparable to RA patency because the NT vein is clearly superior to the conventional vein (86% patency here vs the 50% reported by Gaudino and colleagues). A second limitation for the interpretation of our study results is the frequent use of sequential grafting, which was common for both RA and NT SV conduits. Some degree of caution is warranted when comparing patency rates with series with no sequential grafting. The main limitation is that this is a single-center study, with only 108 patients enrolled. A multicenter study with a larger number of patients is needed to confirm our results and to permit a more robust subgroup analysis.

In conclusion, this study highlights the improvement in SV graft quality when using the NT technique in CABG surgery and demonstrates a number of situations in which NT SV grafts may be preferable to RA grafts, even in the long term.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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