The No-Touch Saphenous Vein as the Preferred Second Conduit for Coronary Artery Bypass Grafting

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Background. Injury incurred while saphenous veins are being obtained results in poor graft patency and impairs the results of coronary artery bypass grafting. A novel method of obtaining veins, the no-touch technique, has shown improved long-term saphenous vein graft patency.

Methods. This randomized trial included 108 patients undergoing coronary artery bypass grafting and compared the patency of no-touch saphenous vein with that of radial artery grafts. Each patient was assigned to receive one no-touch saphenous vein and one radial artery graft to either the left or the right coronary territory to complement the left internal thoracic artery.

Results. Angiography was performed in 99 patients (92%) at a mean of 36 months postoperatively. Graft and grafted coronary artery patency was evaluated. The patency of grafts for no-touch saphenous vein and radial artery was 94% versus 82% ($p = 0.01$), respectively. The patency of coronary arteries grafted with no-touch saphenous vein and radial artery grafts was 95% versus 84% ($p = 0.005$), respectively. Eighty-nine of 96 (93%) left internal thoracic artery grafts were patent.

Conclusions. No-touch saphenous vein grafts showed a significantly higher patency rate than the radial artery grafts and the patency was comparable to the patency for left internal thoracic artery grafts. This highlights the improvement in saphenous vein graft quality with the no-touch technique and increases the number of situations in which saphenous veins may be preferable to radial artery grafts as conduits in coronary artery bypass grafting.

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Worldwide, approximately one million patients undergo coronary artery bypass grafting (CABG) annually. The limitations of current strategies for improving saphenous vein (SV) graft patency has led to widespread acceptance of the radial artery (RA) as the second conduit for CABG [1] after the left internal thoracic artery (LITA).

In the late 1980s when the RA graft was revived, it was recognized that modification of the technique for obtaining RA was mandatory for the success of this conduit [2]. Currently, the RA is obtained preferentially as a pedicle graft, whereas the SV is still obtained by the conventional technique wherein the SV is stripped of surrounding tissue and distended to overcome spasm. These manipulations, however, cause severe endothelial [3], medial [4], and adventitial [5] damage.

Our institution has been using the no-touch technique (NT) [6, 7] for SV graft preparation since the beginning of the 1990s. The NT is more than simply the avoidance of direct surgical trauma. The technique also preserves the vein's cushion of perivascular fat and vasa vasorum [8], and it avoids spasm and the need for distention. Randomized trials comparing NT with the conventional technique of obtaining SV graft have demonstrated a considerably better short-term [9] and long-term [10] patency rate for NT SV grafts. This randomized trial compared the midterm angiographic patency of NT SV with RA grafts.

Patients and Methods

This single-center randomized trial studied consecutive patients undergoing elective, first-time, and only CABG at the Department of Cardiovascular Surgery, University Hospital, Örebro, Sweden. The study was approved by the local ethics committee, and written informed consent was obtained from each participant. One hundred eight

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patients were included in the study between January 2004 and August 2009.

Study Design

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

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

One hundred fifty milligrams acetylsalicylic acid (Pfizer Inc, New York) 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 randomly allocated 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. The angiography assessors were independent and were blinded to the outcome of randomization.

Surgical Aspects

The RA grafts were prepared with similar technique as the NT SV grafts [6] (Fig 1). In summary, the grafts were obtained with a pedicle of surrounding fat tissue and left in situ until after heparinization. After removal, the grafts were stored in heparinized blood and were neither flushed nor distended.

Classic principles to achieve complete revascularization were followed by the use of single and sequential grafts to bypass coronary arteries with stenosis greater than 50%. The distal anastomoses for both RA and NT SV grafts were performed first with 7-0 Prolene continuous sutures. Calibrated probes were used to measure the diameter of grafted coronary arteries. Graft flow data were collected after the patients were weaned from extracorporeal circulation once stable hemodynamic conditions were achieved, by use of a Ultrasonic transit-time flowmeter (VeriQ system, Medi-Stim Inc).

Angiographic Assessment

Angiographies were performed with manual injections of iodixanol 320 mg/mL (Visipaque, GE Health Systems, Little Chalfont, Buckinghamshire, UK). All angiograms were evaluated by visual assessment by two interventional cardiologists.

Grafts and grafted coronary arteries were categorized as either patent or failed. Failed grafts were defined as having a stenosis more than 70% of the diameter of any part of the graft or presence of string sign (diffuse narrowing of the graft to less than 1 mm in diameter with persistent flow). Grafted coronary arteries not visualized during angiographic assessment were defined as failed.

Statistical Methods

The study was designed as a test of noninferiority. A sample size of 108 subjects achieves 83% power at a 5% significance level by use of a one-sided equivalence test of correlated proportions when the base proportion (RA) is 0.80 and the maximum allowable difference between proportions (RA – NT SV) is 0.08. We initially calculated a one-sided 95% confidence interval (CI) and the corresponding one-sided p value for noninferiority for our primary endpoint, patency. This was done by the method proposed by Sidik [11]. To allow conventional interpretation of results, we calculated regular two-sided 95% CI and two-sided p values for superiority.

Before the analyses, the database was restructured into three datasets allowing for analysis on the patient level (99 patients), graft level (198 grafts for 99 patients), and grafted coronary artery level (303 target vessels for 198 grafts for 99 patients). Each analysis was performed with consideration of the intrapatient and intragraft correlations. Patency outcome was analyzed with a logistic regression model, and outcome flow with a mixed linear model. The main explanatory factor was type of graft, NT SV or RA, and the primary analysis was therefore restricted to this factor. Secondary subgroup analyses

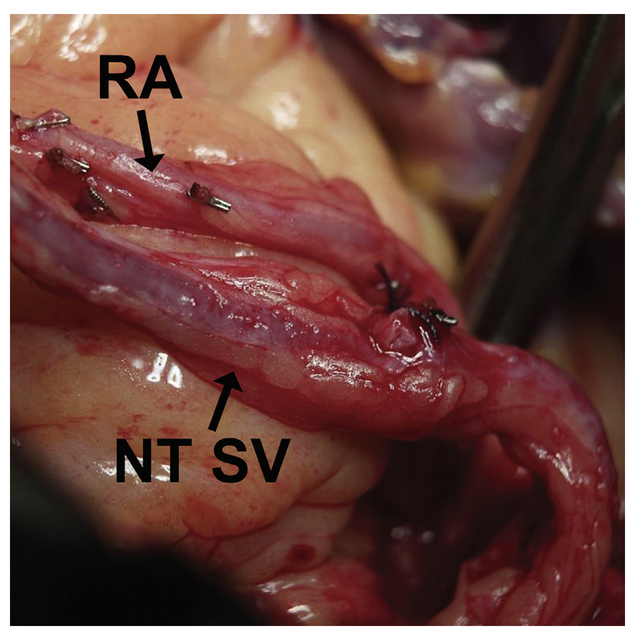

Fig 1. No-touch saphenous vein (NT SV) graft. Both grafts obtained with the same technique and after implantation. (RA = radial artery graft.)

were performed to investigate whether the effect of graft type was homogenous over different important clinical variables; however, these analyses should be considered as indicative and exploratory because of the smaller sample sizes. The results are reported with the outcome parameter as odds ratio (OR) with 95% CI, or in the case of flow as means and differences in means. Bootstrap analyses supplemented the analytic methods. Computations were performed mainly with the STATA package (version 12).

Results

The patients were followed up between March 2009 and November 2010 at a mean time of 36 (range, 12–69 months) after operation. The patients' flow chart is shown in Figure 2. Two eligible male patients, aged 61 and 64 years, declined participation in the study. The baseline characteristics of the final study cohort of 99 (92%) patients are presented in Table 1.

No perioperative or postoperative myocardial infarction or deaths occurred, nor was there any need for additional revascularization. The majority of patients (92, 93%) used 75 mg acetylsalicylic acid daily, and 23 (23%) were taking calcium channel blockers.

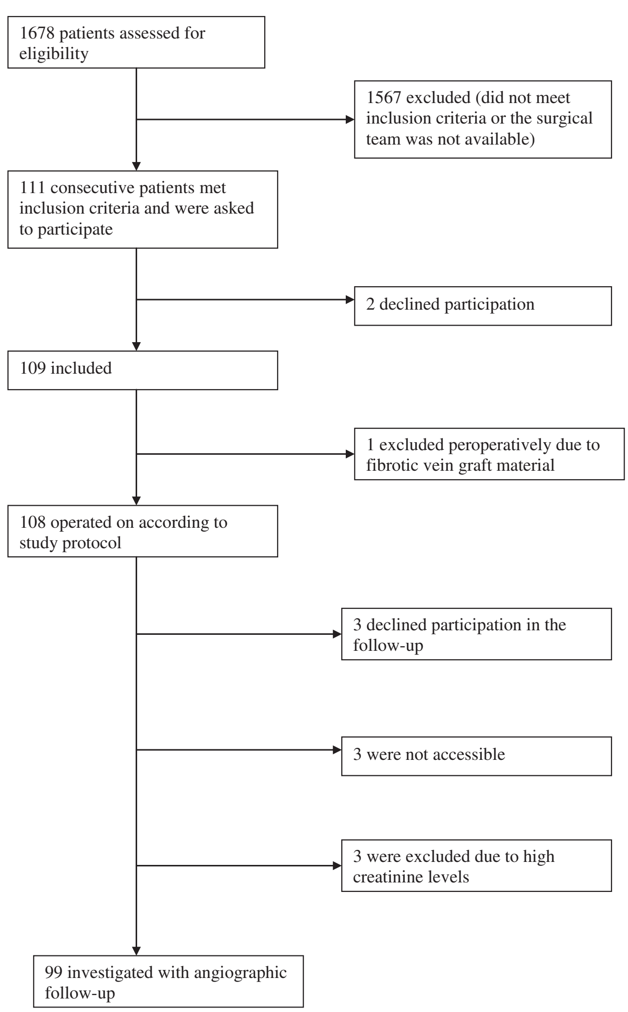

Fig 2. Flow chart of patients in study.

Table 1. Clinical Characteristics of 99 Patients Preoperatively

Characteristic	Preoperative Values NT SV Left RA Right (n = 47)	Preoperative Values NT SV Right RA Left (n = 52)
Age, years: mean (SD; min–max)	58.2 (6.4; 38–67)	59.7 (5.5; 40–69)
Myocardial infarction, n (%)	14 (31)	20 (39)
Female sex, n (%)	6 (12)	6 (12)
NYHA classification, n (%)		
I	2 (4)	2 (4)
II	17 (36)	23 (44)
III	22 (47)	20 (38)
IV	6 (14)	7 (16)
Diabetes, n (%)	8 (17)	10 (19)
Hypertension, n (%)	27 (57)	23 (44)
Dyslipidaemia, n (%)	42 (89)	47 (90)
Smoking history, n (%)		
Never smoked	16 (36)	22 (43)
Ex-smoker	18 (40)	19 (37)
Current smoker (1 year)	14 (31)	10 (20)

NT SV = no-touch technique saphenous vein graft; NYHA = New York Heart Association; RA = radial artery graft; SD = standard deviation.

Surgical Aspects

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

The mean graft flow was significantly higher for the NT SV grafts (63.6 mL/min) than for the RA grafts (42.6 ml/min) (difference 21.1, 95% CI 11.4–30,7, $p < 0.0001$). There was also a highly significant increase of mean flow associated with the number of grafted coronary arteries ($p < 0.0001$), and this increase was significantly higher for NT SV than for RA ($p = 0.006$). This is illustrated in Figure 3, where the positive, but nonparallel, slopes for mean flow versus number of grafted coronaries for the two graft types are shown, with the highest gradient associated with NT SV.

Angiographic Assessment

The characteristics of 198 grafts and 303 grafted coronary arteries are presented in Table 2. The primary results showed that the patent graft rates were 93/99 (94%) for NT SV versus 81/99 (82%) for RA. The difference (RA–NT SV) is thus contrary to the à priori hypothesis negative, −0.12,

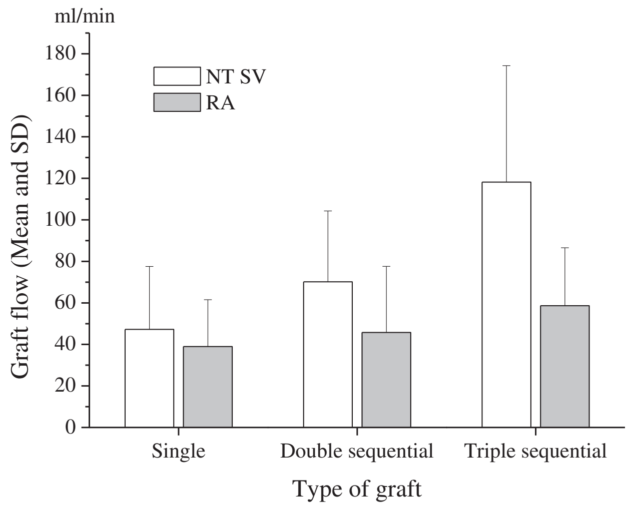

Fig 3. Mean values and standard deviation (SD) for graft flow stratified for type of graft. (NT SV = no-touch saphenous vein graft; RA = radial artery graft.)

with a 95% upper confidence limit of -0.04, $p = 0.0001$ for a comparison with our maximum allowable difference of $+0.08$. Continued testing and confidence intervals are then presented for two-sided superiority as stated in the methods section. The odds ratio for patency comparing NT SV with RA is in favor of NT SV (OR 3.4, 95% CI 1.3–9.1, $p =$ 0.013). The patency rates for both NT SV and RA grafts did not differ whether they were used in the left or the right coronary territory. The patency rates for grafted coronary arteries were 149/157 (95%) versus 123/146 (84%) (OR 3.5, 95% CI 1.5–8.4, $p = 0.005$) for NT SV and RA grafts, respectively. Concerning the LITA grafts, 89/96 (93%) were patent.

For NT SV grafts, there were 49/52 (94%) patent single, 33/36 (92%) patent double-sequential, and 11/11 (100%) patent triple-sequential grafts. Even triple-sequential grafts to small coronary arteries were all patent (Fig 4). Six NT SV grafts were considered failed; two were completely occluded (both single grafts), and one single graft had a localized stenosis more than 70%. All three failed single NT SV grafts were used to bypass the right coronary territory. Three double-sequential grafts were distally occluded.

For RA grafts, there were 51/58 (88%) patent single, 27/35 (77%) patent double-sequential, and 3/6 (50%) patent triple-sequential grafts. Eighteen were considered failed; eight were completely occluded (five single, two double-sequential, and one triple-sequential). Four double-sequential and two triple-sequential grafts were occluded distally. Six of seven failed single grafts were connected to the right coronary territory. All 11 failed sequential RA grafts were anastomosed to at least one coronary artery with a stenosis less than 90%. Both RA composite grafts were open.

Two single and two double-sequential RA grafts showed string sign. The single grafts were used to bypass coronary arteries that had stenosis between 70% and 89%. The double sequential grafts had at least one of their grafted coronary arteries with a stenosis less than 90%. Among the patent grafts, two NT SV grafts showed a stenosis less than 30%, two RA had a stenosis of 30% to 49%, and one RA had a stenosis of 50% to 70%. All other grafts in both groups were completely open and smooth.

The patency rates for grafted coronary arteries according to their territories, degree of stenosis, sizes, and quality are given in Table 2. Coronary arteries of the left territory had a significantly higher patency rate (OR 5.7, 95% CI 1.5–21.2, $p = 0.01$) when grafted with NT SV. Regardless of size and degree of stenosis, the patency rate for NT SV grafted coronary arteries was above 90%. All 46 RA grafted coronary arteries with a stenosis more than 90% were patent (Fig 5), but patency rates were lower with stenosis $<90\%$. For patients with diabetes mellitus, 19/20 (95%) NT SV versus 14/20 (70%) RA grafts were patent. The number of patent RA grafts in patients treated versus those not treated with calcium channel blockers was 19/23 (83%) and 61/76 (80%), respectively.

Agreement between the two angiography assessors was high. Regarding patent grafts, the κ value was 0.84, and for native coronary artery stenosis preoperatively the weighted κ value was 0.64.

Comment

This is the first randomized trial designed to compare the patency rate of RA and SV grafts prepared with optimal NT. Contrary to our anticipations of noninferiority, our results show a significantly better midterm patency rate for NT SV than for RA grafts (OR 3.4, 95% CI 1.3–9.1, $p = 0.013$).

The patency rate for NT SV was maintained above 90%, irrespective of its use as a single or sequential graft, independent of the size, degree of stenosis, and territory of the grafted coronary arteries. The significant difference in patency between the NT SV and RA grafts shown here appears to be related to an improvement in the SV grafts, not an unexpected drop in RA graft patency. Two recent studies [12, 13] have noted a similar midterm RA graft patency.

Several factors may explain the improved performance of NT SV grafts [14]. The NT provides for an intact endothelium, and the preservation of vasa vasorum could conceivably prevent medial ischemia. In addition, the pedicle of surrounding tissue protects the grafts against kinking.

Radial artery conduits are noted for their ease of use and consequently are often considered as the second conduit for CABG. However, there are numerous situations in which may be best to avoid using RA grafts. The territory of target vessels grafted [15], the absence of severe stenosis [16], and the presence of diabetes [13] have all been raised as conditions that might lower RA graft patency. Our findings are in agreement with some, but not all, of these relative contraindications, but the point remains that in routine coronary operations there are a significant number of patients or coronary arteries wherein RA conduits are either not favored or contraindicated. This point underlines a larger potential drawback of extensive arterial grafting; even with

Table 2. Surgical characteristics of 198 grafts and 303 grafted coronary arteries

Variable	NT SV Assessed[a]	NT SV Patent[b]	RA Assessed[a]	RA Patent[b]	Odds ratio (95% CI), *p* Value for Main Hypotheses
Grafts, n (%)	99 (100)	93 (94)	99 (100)	81 (82)	3.4 (1.3–9.1), $p = 0.013$
Graft type, n (%)					
Single	52 (53)	49 (94)	58 (59)	51 (88)	2.2 (0.5–9.2)
Double sequential	36 (36)	33 (92)	35 (35)	27 (77)	5.4 (1.4–20.9)
Triple sequential[c]	11 (11)	11 (100)	6 (6)	3 (50)	
Graft flow, average, n (%)[d]					
<20 mL/min	7 (7)	4 (57)	17 (18)	11 (65)	0.7 (0.1–4.2)
20–39 mL/min	24 (24)	23 (96)	36 (37)	29 (81)	5.6 (0.6–49.1)
40–59 mL/min	26 (26)	24 (92)	22 (23)	18 (82)	4.2 (0.8–22.5)
60 mL/min[e]	41 (42)	41 (100)	22 (23)	21 (95)	
Coronary arteries, n (%)	157 (100)	149 (95)	146 (100)	123 (84)	3.5 (1.5–8.4), $p = 0.005$
Coronary arteries side, n (%)					
Left coronary territory	93 (59)	90 (97)	96 (66)	81 (84)	5.6 (1.5–20.8)
Right coronary territory	64 (41)	59 (92)	50 (34)	42 (84)	2.2 (0.7–7.7)
Coronary arteries stenosis, n (%)					
<70%	61 (39)	58 (95)	45 (31)	32 (71)	7.9 (2.2–27.9)
70–89%	40 (25)	39 (97)	55 (38)	45 (82)	2.0 (0.6–6.4)
90–100%[f]	56 (36)	52 (93)	46 (32)	46 (100)	
Coronary arteries diameter size, n (%)					
1.0–1.5 mm	64 (41)	58 (91)	48 (33)	39 (81)	2.2 (0.7–7.3)
1.5–2.0 mm	83 (53)	81 (98)	71 (49)	61 (86)	7.6 (1.6–36.4)
>2 · 0 mm[g]	10 (6)	10 (100)	27 (18)	23 (85)	
Coronary arteries quality, n (%)					
Good	112 (71)	106 (95)	116 (79)	96 (83)	3.7 (1.4–9.6)
Mild calcification	45 (29)	43 (96)	30 (21)	27 (90)	2.4 (0.4–16.0)

[a] Percentages for assessed calculated in relation to number of grafts. [b] Percentages for patent calculated in relation to number of assessed. [c] Triple grafts were pooled with double grafts in analyses of odds ratios. [d] Flow missing for three grafts, one NT SV, and two RA. [e] 60 mL/min grafts were pooled with 40–59 mL/min grafts in analyses of odds ratios. [f] 90–100% grafts were pooled with 70–89% grafts in analyses of odds ratios. [g] Diameters >2.0 mm were pooled with 1.5–2.0 mm in analyses of odds ratios.

Characterized are two grafts for each patient and up to three coronary arteries per graft. Odds ratios for patency with RA as reference category, NT SV as index category.

CI = confidence interval; NT SV = no-touch technique saphenous vein graft; RA = radial artery graft.

an aggressive approach, conditions are often not ideal for arterial conduit use. Thus, an improved SV, with a greater patency and relative resistance to atherosclerosis, may be an alternative to the restricted applicability of extensive arterial grafting.

There has always been a longstanding concern that the technique of obtaining grafts may affect graft patency, and this concern is growing. The morbidity avoided with obtaining vein graft endoscopically may come with the price of trauma to the vein [17] and lower graft patency [18]. There are even recent observational publications [19] and reviews [20] suggesting that the SV graft be set aside in the arsenal of conduits for CABG. However, the only other surgical alternative, extensive arterial grafting, is still performed in only a small percentage of patients. The NT addresses the problem of trauma to the vein with its long-term consequences while retaining a conduit with the versatility of the SV graft and a promising patency rate. Advocates of the sequential graft point out the hemodynamic advantages of increased total graft flow through improved distal runoff and, by extension, increased graft patency rates [21]. Encouraging results of sequential RA grafts have been shown [22], but our results are in disagreement with those findings. In this study, the patency rate for RA grafts depended mostly on the degree of stenosis of the target vessels, independent of their use as single or sequential grafts. All 11 failed sequential RA grafts were anastomosed to at least one coronary artery with a stenosis less than 90%.

By contrast, NT SV grafts showed a higher linear increase in flow than did RA grafts as the number of anastomoses per graft increased, which may explain the better patency rate for sequential NT SV grafts. This increase occurred despite small coronary targets, making the NT particularly advantageous to surgeons who perform sequential grafting. We believe that the higher flow rates achieved in the NT SV sequential grafts help to keep small arteries with poor runoff open, in comparison with the RA grafts, and is a key feature of our program.

A few randomized trials have compared the patency rate between SV and RA grafts. Three of these studies are particularly noteworthy [12, 13, 23]. Interestingly, despite

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Fig 4. Triple-sequential no-touch saphenous vein graft used to bypass three small coronary arteries.

obtaining the SV with the conventional technique, these studies showed a similar patency rate of RA and SV grafts. In this study, by applying the NT for SV graft preparation, we have demonstrated an improved graft patency, which further strengthens the role of the SV as a conduit in CABG.

Of course, the midterm results in our study do not preclude the possibility that the patency rates will reverse and separate over time, with less atherosclerosis in the RA grafts. However, we have previously noted an encouraging resistance to lipid deposition in long-term NT SV

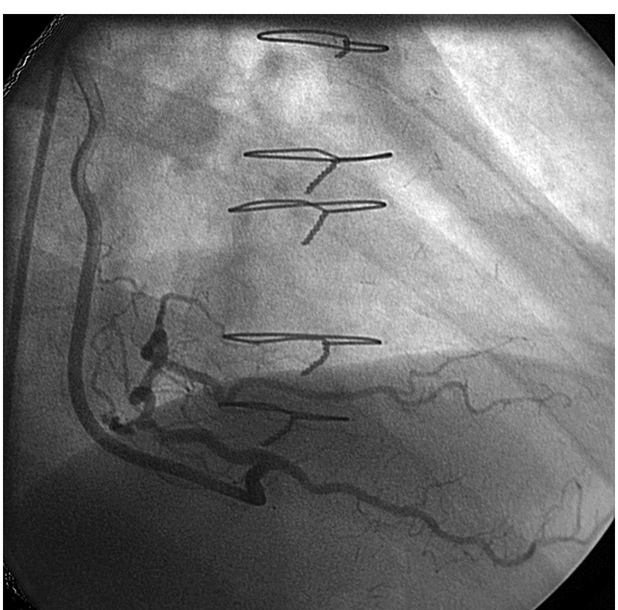

Fig 5. Patent radial artery graft implanted to a proximally occluded posterior descending artery.

grafts [24]. We believe that the improvements in conduit quality with the NT have the potential to make the SV a serious long-term competitor to arterial conduits, and we look forward to a longer-term follow-up to this study.

The midterm superior patency rate of NT SV over the RA grafts shown in this trial suggests that the NT SV, rather than the RA graft, is the second conduit for CABG.

However, as reported by others, we found that the RA is an excellent conduit when used for selected target coronary arteries but has to be used judiciously, considering several circumstances for each patient.

The main limitation of this study is that it was a single-center study, and only 108 patients were enrolled. A multicenter study with more patients is therefore required to confirm our results and to permit a more robust subgroup analysis.

In diabetic patients, there was a tendency for a higher patency for NT SV than for RA grafts, but the number of patients was too small for significance.

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INVITED COMMENTARY

More than 70% of all coronary bypass grafts in contemporary coronary surgery are saphenous vein grafts (SVGs); therefore, any techniques that could potentially improve long-term patency and patient outcomes are welcome. Dreifaldt and colleagues [1] attempt to do so, and this group's continuing efforts in this area are to be commended.

Their hypothesis is that harvesting the SVG (from the lower leg) by a no-touch (NT) technique, maintains the integrity of the vasa vasora and vessel wall architecture while avoiding SVG trauma and kinking, all of which should theoretically lead to enhanced SVG patency.

The authors have previously demonstrated patency benefits of this technique over conventional SVG harvest. More specifically this paper compares patency of the NT SVG against that of the radial artery (RA). Unfortunately, it falls short of comprehensively addressing this issue. At a general level, few patients were recruited (<2 per month), and the cohorts were unusual (mean age, 59 years; only 12% were female and only 19% diabetic). Predictably, the authors found excellent patency results with SVG at all degrees (50% to 100%) of native coronary artery stenosis (NCAS). By comparison, RA patency was lower for NCAS less than 90%, but was 100% when NCAS was greater than 90%. Unfortunately, the authors did not appear to use specific anti-spasm maneuvres for the RA, such as topical papaverine, topical and systemic nitroglycerin or calcium channel blockers perioperatively, and long-term calcium channel blockers, all of which are known important adjuncts in RA use. A more appropriate comparator graft to NT SVG, and operation, in this age group (<65 years) may have been the right internal thoracic artery and bilateral internal thoracic artery grafts.

The authors, however, have a valid argument. Because most cardiac surgeons prefer to use SVG as the second conduit of choice, and because the RA might be inappropriate for some patients (e.g., NCAS < 90%, calcified RA, connective tissue diseases, dominant RA) then perhaps the NTSVG could be an important component of our armamentarium. However, concerns regarding loss of tissue, wound healing, and potential saphenous nerve damage need to be allayed.

Because most graft patency studies beyond 5 years show superior patencies for arterial grafts (including RA when placed in vessels with >80% stenosis) compared with to SVGs [2], patency results at 36 months (as in this report), though encouraging, might be premature in predicting the long-term fate of these NT SVGs. Ten-year patency results and studies on the influence of statins on SVGs will be important endeavours for the future.

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