

Endoscopic saphenous vein harvesting for coronary artery bypass grafts: NICE guidance

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The National Institute for Health and Clinical Excellence (NICE) has produced new guidance in relation to the endoscopic harvesting of saphenous veins for coronary artery bypass graft (CABG) surgery, advising that this procedure should only be used with special arrangements for clinical governance, consent and audit or research.¹ NICE have been moved to make these recommendations in the light of recent evidence that has cast a shadow over the vein graft patency in patients who have had venous conduit dissected by the endoscopic technique.² The paper in question is the offshoot of a large north American phase III, multicentre, randomised double-blind placebo controlled trial of the ex-vivo treatment of autologous vein grafts with Edifoglide in patients undergoing initial CABG surgery (PREVENT IV). The study was not designed to test the differences between endoscopic and open vein harvested vein graft patency, and involved 107 different surgical centres, at least two different endoscopic devices, no randomisation of patients to the two techniques, no record of the experience of the surgical operator and no record of the calibre of the vein or the level of the leg from which it was dissected. NICE reports that vein grafts harvested by the keyhole procedure had a higher rate of failure (narrowing or blockage; 47%) compared with the veins harvested by the open procedure (38%) after 1 year. These statistics are misleading. The figures they give are actually the percentage of patients carrying a stenosed or occluded graft, whereas the actual vein graft failure rates were 27.2% and 22.6%, respectively, with 22.6% and 19.4% of the overall veins actually being occluded in a patient cohort of 1817. The OR of vein graft failure for patients who had the endoscopic harvest technique compared with the open technique was 1.34 (95% CI 1.14 to 1.59; $p < 0.001$) and the OR of vein graft occlusion was 1.39 (95% CI 1.17 to 1.66; $p < 0.001$). At 3 years, endoscopic vein harvesting was also associated with higher rates of death, myocardial infarction or revascularisation (20.2% vs 17.4%; adjusted HR 1.22, 95% CI 1.01 to 1.47; $p = 0.04$). In the context of the study design and weaknesses these figures give rise for concern and further investigation, but are not robust enough to cause the technique to be abandoned.

The advantages of the endoscopic procedure are that a long incision is avoided, with resulting improved mobility, earlier discharge and improved patient satisfaction. The recorded problems that can occur following the open removal of the long saphenous vein are wound dehiscence, infection, residual oedema, which can be persistent, neuropathy related to trauma to the cutaneous

nerves that straddle the saphenous nerve and occasional persistent pain. Generally, it is a slower incision to heal compared with a sternotomy incision.

Before the paper published by Lopes *et al.*,² meta-analyses have suggested that the endoscopic procedure was as safe as the open technique and had advantages as already outlined,^{3 4} and three other studies had looked specifically at angiographic evidence of graft patency. Yun *et al.*⁵ describe 166 endoscopic and 170 open vein harvest technique bypass grafts in 144 patients with occlusion rates at 6 months of 21.7% and 17.6%, respectively, and evidence of significant disease (>50% stenosis) in 10.2% and 12.4%. Endoscopic vein harvest was not found to be a risk factor for vein graft occlusion or disease (OR 1.15, 95% CI 0.65 to 2.05), but congestive heart failure (OR 2.87, 95% CI 1.34 to 6.17), graft to the diagonal artery territory (OR 1.76, 95% CI 1.06 to 2.95) and graft flow (OR 0.90, 95% CI 0.85 to 0.97) were found to be significant predictors. Perrault *et al.*⁶ examined 40 patients undergoing primary CABG surgery who were randomly assigned to have endoscopic or open vein harvest. Angiography was performed a mean of 3 months (range 1–9 months) after the operation, and they found no statistically significant difference in the patency rates of saphenous vein grafts between the groups (85.2% vs 84.4%, $p = 0.991$). Davis *et al.*⁷ describe 51 patients with endoscopic vein harvest at a mean follow-up of 0.7 ± 0.19 years with a graft patency rate of 95.4% followed up with CT angiography. In terms of the higher rates of death, myocardial infarction or repeat revascularisation reported by Lopes *et al.*,² one larger study ($n = 5825$) has subsequently reported no differences in midterm outcomes between endoscopic and open harvest techniques but found that the endoscopic saphenous vein harvest was associated with a reduced re-admission to hospital for unstable angina.⁸

The literature on vein graft patency shows that large vein calibre is associated with poorer patency,^{5 9–11} and thus one of the most significant confounding variables in comparing the techniques of open and endoscopic vein harvest may be the exact level from which the vein has been taken. Poorer results that follow the use of a large diameter vein may be the result of low-velocity flow within the conduit.¹¹ Endoscopically removed vein is classically taken from above the knee where the vein is larger, less uniform and may have more side branches, whereas open vein harvest is normally taken from the ankle upwards. Some subscribe to the concept of the 'privileged vein',¹² the lowest portion of the saphenous vein that runs

from the medial malleolus to below the knee and may be superior in terms of size and homogenous calibre.

If the endoscopic technique leads to an inferior vein how is this? One explanation could relate to trauma inflicted on the vein during endoscopic handling. The nature of endoscopic harvest applies traction stresses across the walls of the saphenous vein and its side branches and may cause disruption of the endothelium.^{9 10} Could there be other explanations? Might it be related to the diathermy used to dissect free side branches? Might it relate to the longer time it takes to remove the vein endoscopically and the learning curve of the operator? Answers to these questions might help us understand the increased incidence of saphenous vein graft failures in the endoscopically harvested vein group, and in a well-designed study would help to devise a strategy harnessing the strengths of the technique and avoiding the pitfalls.

In terms of the conduct of the operation, endoscopic harvesting requires special equipment and detailed training and mentoring. There does not appear to be any increased intra-operative mortality, but one specific hazard highlighted by NICE relates to the insufflation of carbon dioxide into the leg incision to help develop the plane in which the vein lies. There are several reports of patients having massive carbon dioxide embolisation,^{11 12} and one group have reported that minimal, moderate and massive carbon dioxide embolisms occur in 13.1%, 3.5% and 0.5% of endoscopic vein harvests, respectively, prompting them to recommend the transoesophageal echocardiographic monitoring of carbon dioxide bubbles in the inferior vena cava for patients having endoscopic vein harvesting.

The NICE guidance should reinvigorate all of us involved in the field of cardiac surgery to strive to improve our results in terms of vein graft patency and leg wound freedom from complication. Whereas there has been tremendous effort placed on the development of the most efficacious stent, the question of how to improve patency of the saphenous vein, which remains the mainstay of all coronary artery bypass operations, remains largely unanswered. Previously there was a lot of work characterising the endothelial proliferation that occurs when the saphenous vein is placed in the arterial circulation.¹³ In recent years there has been further work on gene activation^{14 15} in veins, but as yet how to ameliorate effectively the complex pathophysiology of the degeneration of the saphenous vein bypass conduit eludes us. Furthermore, we in cardiac surgery have paid great attention to auditing our results, but have concentrated, almost exclusively, on postoperative mortality.¹⁶ An area of major concern to patients and primary care services, the healing of the leg incision, has been largely ignored. We await the audit into postoperative infection conducted by the Health Protection Authority looking into the issue of wound infection. If this audit process leads to improvements in rates of complications, this in turn could level the playing field between the options of open or endoscopic vein harvest, and if patency is then proved to be inferior in endoscopic vein harvest in a well-designed and conducted study this could trigger the decline of the endoscopic technique. There are other minor refinements that might have an important impact on improving the established technique of open harvest in terms of subsequent wound problems. Mapping of the saphenous vein is usually only performed when there are perceived problems in the leg (eg, varicose veins). More routine use of such techniques might help direct attention to the better leg to harvest from and to a more appropriate portion of the leg so that a long incision leading to no useable vein might be avoided.

Endoscopic saphenous vein harvest for CABG: NICE guidance

1. This procedure should be used only with special arrangements for clinical governance, consent and audit or research.
2. Clinicians undertaking endoscopic saphenous vein harvest for CABG should:
 - ▶ Inform the clinical governance leads in their Trusts.
 - ▶ Ensure that patients and their carers understand the uncertainty about the benefits of minimal access graft harvesting balanced against the possible risks of inferior cardiac clinical outcomes and provide them with clear written information.
3. Clinicians should enter details about all patients undergoing endoscopic saphenous vein harvest for CABG onto the UK Central Cardiac Audit Database (<http://www.ccad.org.uk>).

The new NICE guidance should not lead to the abandonment of the endoscopic harvest technique but should lead to it being conducted in an environment in which particular arrangements are made to ensure that patients are appropriately counselled and consented, and results are collected and monitored so that outcome data can be compiled and learnt from. In the new environment in the NHS in England, where there is to be an increased emphasis on commissioning and patient satisfaction, this new approach might be timely. More research is required to give definitive guidance on recommending or discounting this technique at this stage. Ideally, a large randomised controlled study is required to compare open vein harvest with endoscopic vein harvest for CABG, which should include postoperative graft studies so that the questions regarding patency can be answered.

Competing interests None.

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