



Endoscopic saphenous vein harvest for coronary artery bypass grafting

Interventional procedures guidance Published: 25 June 2014

www.nice.org.uk/guidance/ipg494

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG343.

1 Recommendations

- 1.1 Current evidence on the efficacy and safety of endoscopic saphenous vein harvest for coronary artery bypass grafting (CABG) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians should enter details of all patients undergoing endoscopic saphenous vein harvest for CABG onto this database.

2 Indications and current treatments

- 2.1 Coronary artery disease refers to hardening and narrowing of the coronary arteries as a result of atherosclerosis. This can cause angina and myocardial infarction, and result in heart failure. One treatment option for coronary artery disease is coronary artery bypass grafting, which is normally done using autologous vein or arterial grafts. Vein grafts are most commonly done using the great saphenous vein.
- 2.2 The conventional method of harvesting the saphenous vein is an 'open' technique

using 1 or more incisions in the leg. This technique may result in local complications including wound infection, dehiscence and persistent pain. Endoscopic saphenous vein harvest aims to reduce these problems by using much smaller incisions.

3 The procedure

3.1 The procedure is carried out with the patient under general anaesthesia, at the same time as coronary artery bypass grafting. An endoscope is usually inserted through a short incision near the knee, to visualise the subcutaneous plane in which the great saphenous vein lies. Carbon dioxide insufflation may be used to open this space. The vein is mobilised by blunt dissection and its tributaries are clipped and divided before removing the dissected segment of vein. The subcutaneous tunnel may be packed with an antibiotic-soaked swab, which is removed before wound closure. A compression bandage is applied to the leg to minimise haematoma.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

A systematic review and meta-analysis of 44 studies including 269,474 patients reported no statistically significant difference in mid-term mortality between patients treated by endoscopic or open saphenous vein harvest for coronary artery bypass grafting (CABG; log-relative risk 0.90, 95% confidence interval [CI] 0.79 to 1.03, p=0.12, median follow-up 22.5 months). A non-randomised comparative study of 4,709 patients treated by endoscopic or open saphenous vein harvest reported that there was no difference between the groups for the main outcome measure of mid-term mortality, repeat revascularisation and myocardial infarction combined (hazard ratio [HR] 1.15, 95% CI 0.76 to 1.74, p=0.51) in 2,665 propensity-matched patients (533 versus 2,132). A non-randomised comparative study of 1,988 patients treated by endoscopic or open

saphenous vein harvest reported overall rates of revascularisation, death and myocardial infarction of 6% and 7% respectively (p=0.18) with a mean follow-up of 22 months.

- The systematic review of 44 studies reported an increased incidence of vein graft stenosis in the endoscopic group compared with the open group (3 studies, n=3,229, log-rate ratio 1.19, 95% Cl 1.05 to 1.34, p=0.005). In 2 of the studies reporting this outcome, angiography was done at 3 and 6 months; in the third study, angiograms were done at a median of 12.6 months. Neither of the randomised controlled trials included in this analysis showed any statistically significant difference between the groups.
- The systematic review of 44 studies reported less postoperative pain in patients following endoscopic saphenous vein harvesting than after open saphenous vein harvest (12 studies, n=663, unstandardised mean difference -1.48, 95% CI -2.38 to -0.59, p=0.001, I2=98% [significant heterogeneity]). A similar result was obtained when the analysis was limited to randomised controlled trials only (unstandardised mean difference -1.75, 95% CI -3.17 to -0.32, p=0.02). Significant heterogeneity was observed in both analyses, partly because of differences in the device system used across studies.
- The specialist advisers listed key efficacy outcomes as reduced hospital stay, reduced risk of leg wound infections, early mobility, early rehabilitation and return to normal activities after CABG, reduced rate of readmissions, freedom from myocardial infarction, freedom from re-intervention, and patient satisfaction.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

The systematic review and meta-analysis of 44 studies reported a lower incidence of 30-day mortality in patients treated by endoscopic saphenous vein harvest than in patients who had open saphenous vein harvest (log-relative risk 0.71, 95% confidence interval [CI] 0.56 to 0.90, p=0.005). This difference was no

longer statistically significant when only randomised controlled trials were analysed (log-relative risk 0.75, 95% CI 0.27 to 2.11, p=0.58). In-hospital mortality was 1% after both endoscopic and open saphenous vein harvest in the non-randomised comparative study of 4,709 patients (2,665 propensity-matched patients [533 versus 2,132]). Mortality within 30 days occurred in 2% of patients treated by endoscopic saphenous vein harvest and 4% of patients treated by open saphenous vein harvest in the non-randomised comparative study of 1,988 patients (478 propensity-matched patients, p=0.26).

- Wound infection was reported in a lower proportion of patients treated by endovascular vein harvest than in patients treated by open saphenous vein harvest in the systematic review of 44 studies (log-relative risk 0.31, 95% CI 0.23 to 0.42, p<0.0001, I²=43%). A similar result was reported from the analysis of randomised controlled trials only (log-relative risk 0.26, 95% CI 0.15 to 0.44, p<0.0001). Wound infection was reported in less than 1% of patients treated by endoscopic saphenous vein harvest and 2% of patients treated by open saphenous vein harvest in the non-randomised comparative study of 1,988 patients (p=0.03).
- Severe leg wound complications needing surgical revision were reported in 1% and 2% of patients treated by endoscopic and open saphenous vein harvest respectively (p=not significant) in the non-randomised comparative study of 885 patients.
- Necrotising fasciitis was reported in 1 patient in a case report. The patient developed symptoms 3 weeks after the procedure, and surgical exploration of the wound showed extensive necrosis. Treatment included radical debridement, intravenous antibiotics followed by oral antibiotics, and a split-thickness skin graft.
- Compartment syndrome was reported in 1 patient in a case report. Symptoms of leg tightness, swelling and tenderness occurred 4 days after the procedure. A fasciotomy was performed to decompress all 4 compartments of the lower leg. By 3 months, the patient had recovered without any neurological sequelae.
- 5.6 Massive carbon dioxide (CO₂) embolisation was reported in 2 patients in a case series of 405 patients: 1 patient was successfully treated pharmacologically and

the other needed emergency cardiopulmonary bypass support to complete the coronary artery bypass graft surgery.

- A case report described scrotal distension due to CO₂ and signs of cellulitis in 1 patient following endoscopic saphenous vein harvesting. The patient was treated with antibiotics and discharged after 14 days.
- 5.8 Pneumoperitoneum was reported in 1 patient in a case report. Postoperative chest X-ray showed a complete resorption of CO₂.
- The specialist advisers described the possibility that endoscopic saphenous vein harvest might result in damage to the vein, which could decrease patency and lead to increased rates of postoperative myocardial infarction, mid-term myocardial infarction, mid-term mortality, recurrence of angina, repeat revascularisation rates and decreased survival over the long term.

6 Committee comments

- 6.1 When it considered endoscopic saphenous vein harvest for coronary artery bypass grafting in 2010 (see section 7), the Committee had concerns about safety in the short and medium term. These concerns were related to the possible reduction in patency rates of endoscopically harvested vein grafts, with increased risks of re-intervention, myocardial infarction and death compared against open harvesting techniques. Evidence published since that time included large numbers of patients, and the Committee judged that it did not show increased occlusion rates or incidences of re-intervention, myocardial infarction or death for endoscopically harvested grafts.
- The Committee noted the importance of training and regular experience for any clinician doing this procedure.
- The Committee noted positive comments from patients about their experiences of the procedure.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN 978-1-4731-0617-8

Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.