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ORIGINAL ARTICLE

What is the impact of endoscopic vein harvesting on clinical outcomes following coronary artery bypass graft surgery?

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ABSTRACT

Objective Endoscopic vein harvesting (EVH) is increasingly used as an alternative to open vein harvesting (OVH) for coronary artery bypass graft (CABG) surgery. Concerns about the safety of EVH with regard to midterm clinical outcomes following CABG have been raised. The objective of this study was to assess the impact of EVH on short-term and midterm clinical outcomes following CABG.

Design This was a retrospective analysis of prospectively collected multi-centre data. A propensity score was developed for EVH and used to match patients who underwent EVH to those who underwent OVH.

Setting Blackpool Victoria Hospital, Plymouth Derriford Hospital and the University Hospital of South Manchester were the main study settings.

Patients There were 4709 consecutive patients who underwent isolated CABG using EVH or OVH between January 2008 and July 2010.

Main outcome measures The main outcome measure was a combined end point of death, repeat revascularisation or myocardial infarction. Secondary outcome measures included in-hospital morbidity, in-hospital mortality and midterm mortality.

Results Compared to OVH, EVH was not associated with an increased risk of the main outcome measure at a median follow-up of 22 months (HR 1.15; 95% CI 0.76 to 1.74). EVH was also not associated with an increased risk of in-hospital morbidity, in-hospital mortality (0.9% vs 1.1%, p=0.71) or midterm mortality (HR 1.04; 95% CI 0.65 to 1.66).

Conclusions This multi-centre study demonstrates that at a median follow-up of 22 months, EVH was not associated with adverse short-term or midterm clinical outcomes. However, before the safety of EVH can be clearly determined, further analyses of long-term clinical outcomes are required.

INTRODUCTION

Coronary artery bypass graft (CABG) surgery is a recommended treatment option for patients with ischaemic heart disease and has been performed for over 40 years.[1] During this time, a number of different arterial and venous conduits have been used for CABG. Despite evidence that multiple arterial grafts may improve outcomes,[2 3] venous conduits are still used in approximately 90% of CABG procedures in the UK.[4]

The long saphenous vein is the most commonly used venous conduit. The open technique of harvesting the long saphenous vein involves a linear incision, often along the whole length of the lower extremity. This long incision can result in significant postoperative pain and is associated with a number of complications.[5 6]

Endoscopic vein harvesting (EVH) was developed as a minimally invasive method of harvesting the long saphenous vein and is now performed in approximately 70% of CABG cases in the USA.[7] EVH has been shown to reduce the donor site morbidity associated with open vein harvesting (OVH).[8–13] However, there are concerns among some surgeons that, during EVH, the vein may become damaged, increasing the risk of subsequent graft occlusion.

A recent analysis of data from the PREVENT (PRoject of Ex-vivo Vein graft ENgineering via Transfection) IV trial found EVH to be independently associated with vein graft failure and adverse clinical outcomes at 3 years.[7] As a consequence, the UK National Institute for Health and Clinical Excellence issued guidelines for EVH.[14] The guidelines recommended that EVH should only be performed if special arrangements have been made for clinical governance and that patients should be informed about the possible risks of inferior cardiac clinical outcomes. Further research into the use of EVH through prospective and retrospective studies was also recommended.

A number of single-centre studies have found no association between EVH and midterm adverse clinical outcomes, and a subsequent multi-centre study found EVH to be associated with reduced long-term mortality.[13 15 16] However, an analysis of data from the ROOBY (Randomised On/Off Bypass) trial found EVH to be associated with lower rates of vein graft patency and higher rates of repeat revascularisation.[17] Given these conflicting reports and with the increasingly widespread use of EVH for CABG, it is important that the safety of this technique is evaluated further. The aim of this multi-centre study was to assess the impact of EVH on short-term and midterm clinical outcomes following CABG.

METHODS

Study population

Data were collected prospectively during clinical practice at three centres: Blackpool Victoria

Hospital, Plymouth Derriford Hospital and the University Hospital of South Manchester. Consecutive isolated CABG procedures performed from 1 January 2008 to 31 July 2010 were included for analysis. All three centres used the Maquet Vasoview EVH system. The decision to perform EVH was made in each case by the consultant surgeon responsible for the care of the patient.

Data collection

Data relating to cardiac surgical procedures were collected at each centre using local software systems. Each patient had a data set collected as part of routine clinical practice. The data set included preoperative, operative and in-hospital clinical outcome variables. Validation of the data is carried out regularly at each centre.

Patient survival data were obtained by linkage of patients' National Health Service numbers to the Office of National Statistics, which records the date of death for all patients in the UK. Data on readmission to hospital due to myocardial infarction (MI) were obtained from the Myocardial Ischaemia National Audit Project (MINAP).[18] The MINAP database collects data from all hospitals in England and Wales that admit patients with MI. Data on repeat revascularisation by percutaneous coronary intervention were obtained from the British Cardiovascular Intervention Society database.[19] The British Cardiovascular Intervention Society database collects data from all hospitals in the UK that perform percutaneous coronary intervention. All databases used are part of the Central Cardiac Audit Database, and all processes are compliant with UK data protection legislation.

Study outcomes

The main outcome measure for the study was a combined end point of midterm death, MI or repeat revascularisation. The in-hospital secondary outcomes for this study were mortality, stroke, dialysis and reoperation. The midterm secondary outcome measure was mortality.

Statistical methods

Due to non-normality of data, continuous variables are shown as median with 25th and 75th percentiles. Categorical data are shown as percentages. If a patient factor was missing, the factor was assumed to be absent for categorical variables or replaced with the median value for continuous variables (occurred in <2% of cases). Univariate comparisons were made with Wilcoxon rank-sum tests, χ^2 tests or Fisher's exact tests as appropriate.

A propensity score for EVH was developed using multivariable logistic regression to account for differences in case mix between groups.[20] The propensity score included all variables listed in table 1 and was a full non-parsimonious model. Patients who underwent EVH were then matched (1 to 4 matching) to patients who underwent OVH using an identical eight-digit propensity score. If this could not be done, a seven-, six-, five-, four-, three-, two- or one-digit match was identified.

In-hospital outcomes between EVH and OVH matched groups were compared using χ^2 tests. Mortality and other follow-up events occurring over time were described using the Kaplan–Meier survival curve methodology and associated log-rank tests for significance.

A forward stepwise Cox proportional hazards analysis was performed to identify risk factors for the combined main outcome measure and late mortality in the propensity-matched patients. All variables listed in table 1 were offered to the Cox proportional hazards analyses as potential risk factors. Hospital and year of operation were also offered to the Cox models to assess the association of these variables with each outcome. Potential interactions between year and EVH, as well as between hospital and EVH, were tested. In all cases, a p value <0.05 was considered significant. All statistical analysis was performed with SAS for Windows V.9.1 (SAS).

RESULTS

Study population and baseline characteristics

During the study period, 4709 patients underwent isolated CABG at the three centres, with 586 (12.4%) having EVH. The

Table 1 Comparison of EVH and OVH patient characteristics before and after propensity matching

	Unmatched cohort (n=4709)			Propensity-matched cohort (n=2665)		
Patient characteristic	**EVH (n=586)**	**OVH (n=4123)**	**p Value**	**EVH (n=533)**	**OVH (n=2132)**	**p Value**
Age (years)*	66.2 (59.6–73.5)	67.3 (60.4–74.0)	0.23	66.3 (60.2–73.8)	66.9 (60.1–73.9)	0.94
Female	14.0	18.7	0.005	15.0	15.8	0.65
BMI (kg/m^2)*	28.0 (25.4–30.7)	28.1 (25.4–31.1)	0.39	28.0 (25.5–30.6)	28.0 (25.4–30.9)	0.88
Angina CCS class ≥3	38.2	38.6	0.86	37.7	37.8	0.97
Dyspnoea NYHA class ≥3	23.6	23.7	0.94	22.3	23.3	0.66
Smoking history	64.8	64.7	0.93	64.5	62.9	0.48
Hypertension	71.0	68.5	0.23	69.8	69.6	0.93
Previous MI	44.2	49.5	0.017	47.3	45.5	0.47
Diabetes	18.8	20.9	0.24	19.5	19.9	0.83
Renal disease	2.7	1.8	0.15	2.4	2.3	0.89
Respiratory disease	7.9	12.6	<0.001	8.6	9.0	0.81
Peripheral vascular disease	10.8	15.0	0.006	11.6	12.3	0.66
Triple-vessel disease	74.1	72.0	0.29	74.1	74.3	0.93
LMS stenosis >50%	24.6	26.3	0.37	25.1	25.6	0.82
Ejection fraction <50%	20.5	22.3	0.32	21.2	22.5	0.51
Previous cardiac surgery	0.7	1.7	0.065	0.8	0.9	0.21
Non-elective	25.6	26.5	0.66	25.1	26.2	0.63
CPB used	98.3	87.7	<0.001	98.1	97.9	0.78
Number of grafts*	3 (3–3)	3 (2–3)	0.006	3 (3–3)	3 (3–4)	0.37
Consultant led	62.5	80.2	<0.001	68.3	70.3	0.36

*Categorical data are presented as percentages, and continuous or ordinal data are presented as median with 25th and 75th percentiles.
BMI, body mass index; CCS, Canadian Cardiovascular Society; CPB, cardiopulmonary bypass; EVH, endoscopic vein harvesting; LMS, left main stem; MI, myocardial infarction; NYHA, New York Heart Association; OVH, open vein harvesting.

propensity score was used to match 533 patients who underwent EVH to 2132 patients who underwent OVH. All patients were able to be tracked for follow-up purposes. Among the matched patients, there were a total of 51 502 follow-up months and the median follow-up duration was 22 months. The characteristics of patients who underwent EVH or OVH in the unmatched and matched cohorts are shown in table 1. Before matching, patients who underwent EVH were more likely to be male and less likely to have had a previous MI, respiratory disease or peripheral vascular disease. Patients having EVH were also more likely to receive a higher number of grafts, to undergo surgery with cardiopulmonary bypass and to have non-consultant-led procedures. Following propensity matching, there were no significant differences in the patient characteristics between the EVH and the OVH groups.

The unmatched patients who underwent OVH were significantly different to the matched patients who underwent OVH (online appendix 1). The unmatched patients who underwent OVH were more likely to be female; to have a history of smoking, respiratory disease or peripheral vascular disease; or to have had a previous MI. The unmatched patients who underwent OVH were also more likely to have had previous cardiac surgery or to have a consultant-led procedure. The unmatched patients who underwent OVH were less likely to have renal disease, triple-vessel disease and surgery with cardiopulmonary bypass. The unmatched patients also had fewer grafts.

In-hospital clinical outcomes

The in-hospital clinical outcomes in the propensity-matched cohort are shown in table 2. The overall in-hospital death rate was 1.1%. There was no difference in the rate of in-hospital mortality, stroke, dialysis or reoperation between the EVH and the OVH groups.

Long-term clinical outcomes

There was no difference between the propensity-matched EVH and OVH groups with regard to the main outcome measure of midterm mortality, repeat revascularisation and MI combined (HR 1.15; 95% CI 0.76 to 1.74; p=0.51; figure 1). Risk factors for the main outcome measure are shown in table 3 and included age, peripheral vascular disease, dyspnoea (New York Heart Association class ≥3) and ejection fraction <50%. EVH was not a risk factor for the main outcome measure in the Cox model (HR 1.17; 95% CI 0.75 to 1.58; p=0.47).

There was no difference in midterm mortality between the propensity-matched EVH and OVH groups (HR 1.04; 95% CI 0.65 to 1.66; p=0.88) (online appendix 2). Risk factors identified for midterm mortality were the same as those identified for the main outcome measure (results not shown), except for the addition of diabetes (HR 1.81; 95% CI 1.39 to 2.22; p=0.005). EVH was not a risk factor for midterm mortality in the Cox model (HR 0.90; 95% CI 0.41 to 1.39; p=0.68).

Table 2 In-hospital outcomes in propensity-matched patients (n=2665)

	EVH (n=533)	OVH (n=2132)	p Value
Mortality (%)	0.9	1.1	0.71
Stroke (%)	0.6	0.4	0.66
Dialysis support (%)	3.6	2.6	0.22
Reoperation (%)	2.8	3.1	0.78

EVH, endoscopic vein harvesting; OVH, open vein harvesting.

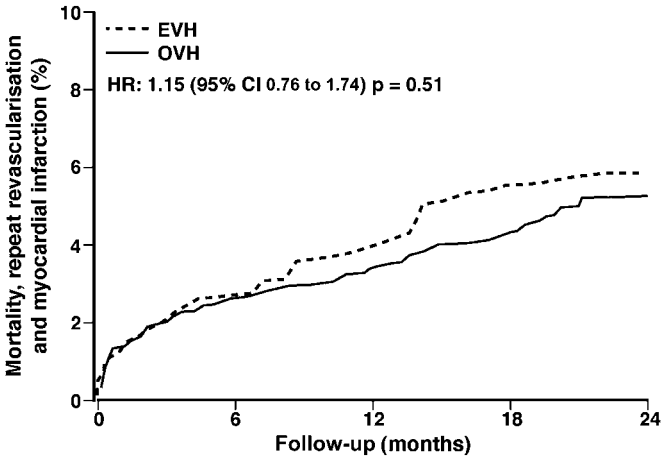

Figure 1 Follow-up combined mortality, repeat revascularisation and MI by vein harvesting approach in propensity-matched patients. The HR is for EVH relative to OVH related to outcome. Numbers of patients at risk at 12 and 24 months are 479 and 256 for EVH and 1805 and 1156 for OVH, respectively. EVH, endoscopic vein harvesting; MI, myocardial infarction; OVH, open vein harvesting.

DISCUSSION

This contemporary multi-centre study comparing EVH with OVH for isolated CABG surgery has demonstrated no difference in short-term and midterm clinical outcomes. Patients who had EVH were not more likely to require reoperation or dialysis, have a stroke or die in-hospital. At a median follow-up of 22 months, EVH was not associated with an increase in mortality or the main outcome measure of death, repeat revascularisation or MI combined.

This study was based on robust data that have been validated internally but not externally. The data also have the advantage of being collected prospectively. The data represent good contemporary cardiac surgical practice with a low in-hospital mortality of 1.1%. Follow-up data were available for all patients, with the main outcome measure obtained by combining multiple separate databases. It is recognised that follow-up events may potentially not be captured by these clinical databases. The MINAP database is thought to have accurate data on ST-elevation MIs but is thought to underestimate the number of non-ST-elevation MIs.[18] This potential under-reporting of follow-up events is unlikely to introduce systematic bias but may lead to an underestimation of the main outcome measure rates.

There are limitations to this non-randomised study. As with any retrospective cohort analysis, it is impossible to control for all confounders that may potentially influence the results. However, the two cohorts created following propensity

Table 3 Predictors of mortality, repeat revascularisation and MI combined in propensity-matched patients

	HR* (95% CI)	p Value
Age†	1.04 (1.02 to 1.06)	<0.001
Peripheral vascular disease	1.84 (1.40 to 2.27)	0.006
Dyspnoea NYHA class ≥3	1.56 (1.19 to 1.93)	0.019
Ejection fraction <50%	1.52 (1.15 to 1.89)	0.028
EVH	1.17 (0.75 to 1.58)	0.47

*Adjusted for the propensity score (HR 0.32; p=0.48).
†For each additional year.
EVH, endoscopic vein harvesting; MI, myocardial infarction; NYHA, New York Heart Association.

matching are well matched with regard to the observed patient characteristics. The short-term results do not change on propensity regression analysis and the midterm results of the study do not change when analysed using Cox proportional hazards. This study is also limited by the lack of angiographic data available, meaning no conclusions regarding the impact of EVH on graft patency directly can be drawn. Although data on the clinical midterm outcomes of requirement for revascularisation and MI following CABG were available, no data regarding symptom recurrence were available. Another potential limitation is that the follow-up time currently available for this group of patients is relatively short. In an analysis by Lopes *et al*,[7] differences in clinical outcomes between EVH and OVH groups became apparent 12–18 months following surgery. This study has, however, demonstrated no difference in the combined main outcome measure or mortality at a median follow-up of 22 months.

In this study, EVH was performed in a smaller percentage of patients than in other published observational studies.[7 13 16] EVH is now used in more than 70% of CABG cases in North America and has become standard practice at a number of centres.[7 21] Uptake in the UK has been slower, and despite this study including only enthusiastic EVH centres, EVH was performed in only 12.4% of cases. At each centre in this study, EVH was performed by an experienced surgeon or surgical assistant. OVH, however, was performed by both trainee surgeons and surgical assistants. There is evidence that EVH is associated with a learning curve and that inexperienced practitioners may be more likely to cause both intimal and deep vessel injury to saphenous vein grafts, which may increase graft failure risk.[22] The experience of the healthcare practitioner performing vein harvesting has not been taken into consideration as part of this study and may be a potential confounder.

There is little doubt that EVH is preferred to OVH by patients as it results in smaller donor site incisions. A number of randomised trials have found that, as a consequence, EVH is associated with reduced rates of donor site morbidity.[8–11] Meta-analyses have also been performed, concluding that minimally invasive vein harvesting reduces donor site morbidity, although some of these analyses included both endoscopic and non-endoscopic, minimally invasive techniques.[6 23–25]

While it is generally accepted that EVH reduces donor site morbidity compared to OVH, it is important to ensure that the EVH technique does not have a significant negative effect on conduit function as this may impact on clinical outcomes. A number of groups have studied the impact of EVH on harvested conduit. The histological properties of vein harvested using EVH have been analysed and compared to vein harvested using OVH with no significant difference demonstrated.[26 27] However, a potential detrimental impact of EVH on the structure and function of vein endothelium has been reported.[28] Short-term vein graft patency has been studied and found to be similar between EVH and OVH,[10 29] although reduced vein graft patency following EVH has been demonstrated in two more recent analyses of data from randomised trials.[7 17]

The PREVENT IV study was a multi-centre trial of the ex vivo treatment of vein grafts with edifoligide in patients undergoing CABG.[7] This study was not originally designed to assess the impact of EVH on clinical outcomes;[30] however, an analysis of data from this trial found that 46.7% of patients who had EVH had vein graft failure compared to 38.0% of patients who had OVH.[7] The study also found that a significantly higher number of EVH vein grafts failed or became occluded. At 3-year follow-up, EVH was associated with higher rates of death, MI or revascularisation (20.2% vs 17.4%; adjusted HR 1.22, 95% CI 1.01 to 1.47).[7] A planned analysis of the ROOBY trial, which was a multi-centre trial of on-pump versus off-pump CABG, also demonstrated reduced vein graft patency rate for the patients who underwent EVH compared to those who underwent OVH (74.5% vs 85.2%, $p<0.0001$).[17] The need for repeat revascularisation rate was also significantly higher in the EVH group (6.7% vs 3.4%, $p<0.05$).[17]

Although both the PREVENT IV and ROOBY trials were randomised, the primary aim of both studies was not to assess the impact of EVH on clinical outcomes. The conclusions of both of these studies regarding EVH therefore need to be interpreted with caution. A large, prospective randomised trial comparing clinical outcomes between patients having EVH and those having OVH is required but has not been performed to date. A number of other retrospective cohort studies in addition to the present study have therefore provided evidence regarding the impact of EVH on clinical outcomes.

Two single-centre studies and one multi-centre cohort study have found that EVH does not increase the rate of adverse clinical outcomes following CABG.[13 15 16] The multi-centre analysis of the Northern New England data from 2001 to 2004 found EVH to be associated with a significant reduction in long-term mortality (adjusted HR 0.74, 95% CI 0.60 to 0.92).[16] Unlike this present study, Dacey *et al* found EVH to be associated with an increased adjusted risk of requiring a return to the operating theatre (2.4 vs 1.7; $p=0.03$).[16] The single-centre analysis by Ouzounian *et al* found EVH to have no association with either in-hospital (OR 0.93, $p=0.56$) or midterm adverse outcomes (HR 0.93, $p=0.22$), and the patients from the UK single-centre study were included in this grouped analysis.[13 15]

CABG will continue to have a role to play in the management of patients with ischaemic heart disease as recommended by the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery joint guidelines on myocardial revascularisation.[1] Identifying how to provide the ideal conduit to improve clinical outcomes is essential. We feel that EVH should continue to be studied and that a prospective randomised controlled trial of EVH is warranted. If possible, the trial should assess the impact of EVH on graft patency, clinical outcomes and cost-effectiveness. Research should also be undertaken to try and improve the rates of vein graft patency in patients undergoing CABG.

This study provides evidence that with regard to short-term and midterm clinical outcomes, EVH is not inferior to OVH and can be safely performed. We endorse the UK National Institute for Health and Clinical Excellence guidelines recommending clinical governance and audit of patients undergoing EVH and feel that before the safety and efficacy of EVH can be clearly determined, the long-term results with regard to graft patency and clinical outcomes should be assessed.

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Competing interests BB is chairman of the Society for Cardiothoracic Surgery of GB and Ireland Database Committee. JZ has received speaker honoraria and travel grants for academic meetings from Maquet. MJRD-H has received honoraria for lectures and

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Ethics approval The Central Cardiac Audit Database has been granted section 251 approval by the National Information Governance Board.

Contributors BB had the idea for the study. BB, JZ, MRD-H and PDW contributed data. SWG and ADG designed the study, cleaned the data and performed the analysis. All authors contributed to the preparation of the manuscript. BB will act as guarantor for the study.

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