Is duplex surveillance of value after leg vein bypass grafting: principal results of the Vein Graft Surveillance Randomised Trial (VGST)

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of duplex ultrasound scanning to detect stenoses or lesions following a vein bypass graft. The duplex group received the same treatment as the clinical group (i.e. the comparator), but also a routine duplex scan.

Type of intervention
Secondary prevention.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients undergoing femoropopliteal or femorocrural vein bypasses. Patients receiving synthetic grafts, such as polytetrafluoroethylene grafts, were excluded from the study. The design of the Vein Graft Surveillance Trial (VGST) was reported in Kirby et al. 1999 (see ‘Other Publications of Related Interest’ below for bibliographic details).

Setting
The setting was secondary care in 22 centres within the UK and 7 centres in Europe.

Dates to which data relate
The effectiveness data were collected during April 1998 and December 2001. The health care costs related to the 2002/03 financial year.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study. It appears that the costing has been undertaken retrospectively.

Study sample
The authors stated that they had originally planned to recruit 1,200 patients but, owing to the increased use of percutaneous endovascular treatments, this was not possible. Instead, a sample size of 600, which would yield a standard error for the difference in amputation rates between the two groups of approximately 2.5%, was aimed for. All patients who underwent a femoropopliteal or femorocrural vein bypass during the study period were recruited into the study.
The authors of this paper did not justify the choice of the patient sample, with respect to the characteristics of the treatment under investigation, in terms of the generalisability of the findings. They also did not report whether anyone refused to participate in the trial. A total of 594 patients participated in the trial.

Study design
This was a multi-centred randomised controlled trial. A central computer-based randomised service was used to allocate patients to each group. The authors reported that this used randomly sized allocation blocks stratified by centre and presenting symptoms. The authors did not report whether blinding was undertaken. Follow-up appointments were made at the time of recruitment (6 weeks), and 3, 6, 9, 12 and 18 months. Eleven per cent of the clinical group died and 11% withdrew, compared with 12% (died) and 13% (withdraw) in the duplex group. Forty-five per cent of all withdrawals were due to amputations. At 18 months, of those remaining in the clinical group, 93% attended the assessment, 90% attended the duplex scan, 77% completed the SF-36 questionnaire and 83% completed the EQ-5D questionnaire. Of those remaining in the duplex group, 93% attended the assessment, 93% attended the duplex scan, 78% completed the SF-36 questionnaire and 82% completed the EQ-5D questionnaire. At 18 months, patients in both groups received a duplex scan to identify the incidence of stenoses.

Analysis of effectiveness
The primary health outcomes used in the analysis were time to amputation and time to vascular death. The groups were comparable at analysis.

Effectiveness results
The results over 18 months were as follows:

7% of the clinical group and 7% of the duplex group had an amputation (hazard ratio 1.01, confidence interval, CI: 0.55 - 1.86);

3% of the clinical group and 4% of the duplex group had a vascular death (hazard ratio 1.21, CI: 0.52 - 2.81);

10% of the clinical group and 11% of the duplex group had an amputation or vascular death (hazard ratio 1.15, CI: 0.70 - 1.90); and

11% of the clinical group and 12% of the duplex group died (hazard ratio 1.22, CI: 0.75 - 1.98).

There were 204 patients in the clinical group with an 18-month duplex scan, compared with 211 in the duplex group. Nineteen per cent of patients in the clinical group were found to have a stenosis in the graft, compared with 12% in the duplex group, (p=0.04).

Clinical conclusions
The clinical conclusions were that amputations, vascular mortality and overall mortality were equally distributed between the two groups. The 18-month duplex scan revealed that the proportion of patients with a stenosis in the graft was greater in the clinical group.

Estimates of effectiveness and key assumptions
The measure of health benefit used was health-related quality of life. This was measured using the SF-36 (36-item short form health survey) and the EuroQol (EQ-5D) questionnaire.

Direct costs
The cost perspective adopted appears to have been that of the health care provider. The health care costs were obtained for each patient. This was done by applying health resource group costs for the financial year 2002/03 to the duplex
scans, angiograms, angioplasties, thrombolysis and surgical interventions performed. The costs and the quantities were not reported separately.

Statistical analysis of costs
The costs were treated in a stochastic manner with a standard t-test being used.

Indirect Costs
The indirect costs were not recorded.

Currency
UK pounds sterling ( ).

Sensitivity analysis
A sensitivity analysis was not carried out.

Estimated benefits used in the economic analysis
At the 6-month follow-up:
the SF-36 physical score was 47 (+/- 27) for the clinical group and 50 (+/- 30) for the duplex group, (p=0.19);
the SF-36 mental score was 71 (+/- 20) for the clinical group and 71 (+/- 21) for the duplex group, (p=0.93); and
the EQ-5D utility score was 0.59 (+/- 0.30) for the clinical group and 0.63 (+/- 0.30) for the duplex group, (p=0.06).
At the 18-month follow-up:
the SF-36 physical score was 48 (+/- 29) for the clinical group and 50 (+/- 28) for the duplex group, (p=0.51);
the SF-36 mental score was 71 (+/- 21) for the clinical group and 74 (+/- 21) for the duplex group, (p=0.15); and
the EQ-5D utility score was 0.62 (+/- 0.29) for the clinical group and 0.64 (+/- 0.29) for the duplex group, (p=0.28).
These results do not show any clear indication of a difference between the two groups at 6 and 18 months.

Cost results
The health service cost per patient over the 18 months was 876 (+/- 2,035) (median 111) for the clinical group and 1,371 (+/- 1,837) (median 666) for the duplex group, (p=0.002).

The average health service cost per patient was higher in the duplex group than in the clinical group. The mean difference was 495 (95% CI: 183 - 807).

Synthesis of costs and benefits
The costs and benefits were not synthesised.

Authors’ conclusions
There was no clinical benefit or quality of life improvement in patients who receive the duplex surveillance in comparison with clinical examination with ankle brachial pressure index measurements. Duplex surveillance was associated with an increased financial cost.
CRD COMMENTARY - Selection of comparators
It was unclear why the comparator used was chosen, and the authors did not provide a justification for their choice. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial, which was appropriate for the study design. The study sample was representative of the study population. The patients were shown to be comparable at baseline. Appropriate statistical analyses were undertaken to take potential biases and confounding factors into consideration.

Validity of estimate of measure of benefit
The estimation of benefit was obtained directly from the effectiveness analysis. No justification was given for the choice of estimates.

Validity of estimate of costs
The authors did not explicitly state what the perspective adopted in the study was, although it appears to have been that of the health care provider. If the perspective was, in fact, that of the healthcare provider, then all the categories of costs relevant to this perspective appear to have been included in the analysis. The costs and the quantities were not reported separately. A statistical analysis of the costs was performed.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively.

Implications of the study
The authors no longer recommend the widespread use of duplex vein graft surveillance in the presence of close clinical follow-up.

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Other publications of related interest

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MeSH
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