Duplex scan surveillance during the first year after infrainguinal autologous vein bypass grafting surgery: costs and clinical outcomes compared with other surveillance programs

Visser K, Idu M M, Buth J, Engel G L, Hunink M

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 health technology examined in the study was duplex scan surveillance during the first year after infrainguinal autologous vein bypass grafting surgery. Duplex scan surveillance (based on peak systolic velocity (PSV)) was used to detect late occlusions caused by stenotic lesions that could result in the amputation of the limb.

Type of intervention
Screening; Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had undergone infrainguinal autologous vein bypass grafting surgery.

Setting
The setting was the community. The economic study was carried out in The Netherlands.

Dates to which data relate
Effectiveness and resource use data were gathered between 1993 and 1999. The price year was 1995.

Source of effectiveness data
The effectiveness evidence was derived from a literature review and from a single study. An observational study was used to derive the effectiveness data for the duplex scan surveillance strategy. The literature review provided data for the other two strategies.

Link between effectiveness and cost data
Part of the costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Subjects enrolled in the study were chosen from among all the patients who underwent infrainguinal autologous vein bypass grafting surgery at the three participating centres (Catharina Hospital, Sant Antonius Hospital, and the University Hospital Maastricht) between June 1993 and September 1995. Of the initial 340 patients, 47 were excluded. The reasons for exclusion were death within 30 days after surgery (n=6), irreversible graft occlusion within 30 days (n=20), amputation (n=7) and no duplex scan surveillance performed (n=14). Overall, 293 patients (mean age of 70.1 years; 58.7% male) participated into the study and were divided into two groups according to the presenting symptoms:
215 patients presented critical limb ischemia (73.4%) and 78 patients presented intermittent claudication (26.6%). Power calculations were not reported by the authors, but the study was also published in a different paper where more detailed information is available.

Study design
This was a prospective observational study, carried out in three centres (Catharina Hospital, Sint Antonius Hospital, and the University Hospital Maastricht) in The Netherlands. The duplex scan surveillance programme began between 4 and 6 weeks after the initial bypass grafting intervention and was then performed after 3, 6, 9, and 12 months. Patients were followed for 1 year (until September 1996) but 3 patients died before the end of the follow-up. Only one graft per patient was included in the study.

Analysis of effectiveness
Fourteen of the 293 subjects were excluded from the analysis because they did not have the duplex scan surveillance. The primary health outcomes used in the analysis were the overall one-year patency rate, the overall one-year assisted patency rate, and the number of major amputations (above the knee) among the two groups of patients in the sample. Statistical analysis to show the comparability of the groups was not relevant (and was not performed) given that individual analyses were carried out for each of the two groups.

Effectiveness results
Among the patients treated for critical limb ischaemia, the overall one-year patency rate was 0.63 (SE, 0.03), the overall one-year assisted patency rate was 0.86 (SE, 0.02), and 4 patients needed major amputations (1.9%).

Among the patients treated for intermittent claudication, the overall one-year patency rate was 0.66 (SE, 0.05), the overall one-year assisted patency rate was 0.88 (SE, 0.04), and 1 patient needed major amputation (1.3%).

Clinical conclusions
The effectiveness estimates provided in the study were quite similar for both groups of patients.

Modelling
A decision model was developed to estimate the costs and the clinical outcomes of duplex scan surveillance, ABI surveillance and clinical follow-up. The model assumed that duplex scan surveillance was the most sensitive means of identifying lesions from the three programmes. The data in the model (effectiveness outcomes and probability values) were derived from a literature review and from a single study.

Outcomes assessed in the review
The main outcomes assessed in the review were several probability values that were used as input parameters in the simulation model for the estimation of clinical outcomes related to ABI surveillance and clinical follow-up. These outcomes included the probability of interventions (surgical revascularisation, thrombolyses, and angioplasties), and the probability of major and minor amputations. Probabilities extracted from the literature were also included to identify the ranges of values used for the sensitivity analysis. These probability values were estimated for both groups of patients with critical limb ischaemia and intermittent claudication.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.
Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Two studies were used as the sources of effectiveness outcomes: the first study (1995) was used for the estimation of the probability values and the second study (1983) for the sensitivity analysis.

Methods of combining primary studies
Studies were not combined, given that each provided single estimations of probability values.

Investigation of differences between primary studies
Not reported.

Results of the review
In the group of patients with critical limb ischaemia, the probability of interventions (surgical revascularisation, thrombolyses, and angioplasties) was 0.59 (range: 0.44 - 0.89), and the probabilities of major and minor amputations were 0.30 and 0.34, respectively.

In the group of patients with intermittent claudication, the probability of interventions was 0.67 (range: 0.50 - 1), and the probabilities of major and minor amputations were 0.05 and 0, respectively.

In the first group, the probabilities used for the sensitivity analysis were 0.21 for further surgery, 0.31 for the interventions (surgical revascularisation, thrombolyses, and angioplasties), 0.31 for primary amputation, 0.13 for intervention followed by amputation, and 0.04 for death before further treatment.

In the second group, the probabilities for the sensitivity analysis were 0.62 for further surgery, 0.31 for the interventions (surgical revascularisation, thrombolyses, and angioplasties), 0.05 for primary amputation, 0.02 for intervention followed by amputation, and 0 for death before further treatment.

Measure of benefits used in the economic analysis
The benefit measure used in the economic analysis was the number of major amputations avoided per 1,000 patients examined during the first postoperative year. A strategy was considered more effective when it produced fewer amputations, compared to the other interventions.

Direct costs
Discounting was not carried out. Quantities and costs were reported separately. The quantity/cost boundary adopted was that of the health service. Costs included personnel, equipment, disposables, hospitalisation and overhead, duplex scan examination, ABI, SDA, outpatient visits, and several interventions (surgical revascularisation of the graft, thrombosis, angioplasty, major and minor amputations). The costs of complications relating to the procedures performed and other illnesses were not considered. The estimation of the total costs of each intervention was derived by modelling. The source of costs and resources was the cost accounting system of Catharina Hospital in Eindhoven. Only the costs of thrombosis were available from the literature. Resource use data were collected between June 1993 and September 1995. The price year was 1995.
Statistical analysis of costs
No statistical analysis of costs was reported.

Indirect Costs
Indirect costs were not included.

Currency
Dutch guilders (Dfl). The authors performed a conversion from Dutch guilders to US dollars ($) (Dfl 1.61 = $1.00).

Sensitivity analysis
One-way sensitivity analyses were performed to investigate variability in the data. The ranges used were derived from the literature. The parameters used were costs, relative risks, the proportion of thrombolyses, the number of major amputations, and the number of outpatient visits, among others.

Estimated benefits used in the economic analysis
Of 293 patients, 134 underwent duplex scan surveillance, 130 underwent ABI surveillance, and 52 underwent clinical follow-up. For the entire patient population the number of major amputations per 1,000 patients examined was 17 for duplex scan surveillance, 77 for ABI surveillance, and 77 for clinical follow-up. For patients treated for critical limb ischemia, the number of major amputations per 1,000 patients examined was 19 for duplex scan surveillance, and 100 for both ABI surveillance and clinical follow-up. For patients treated for intermittent claudication, the number of major amputations per 1,000 patients examined was 13 with the three strategies.

Cost results
For the entire patient population, the average total costs were $2,823 for duplex scan surveillance, $5,411 for ABI surveillance, and $5,072 for clinical follow-up.

In the group of patients treated for critical limb ischaemia, the average total costs were $2,974 for duplex scan surveillance, $6,664 for ABI surveillance, and $6,340 for clinical follow-up.

In the group of patients treated for intermittent claudication, the average total costs were $2,404 for duplex scan surveillance, $1,959 for ABI surveillance, and $1,577 for clinical follow-up.

Synthesis of costs and benefits
An incremental cost-effectiveness analysis was performed in order to combine costs and benefits of each strategy.

In the group of patients treated for critical limb ischaemia, the duplex scan strategy was dominant over the other strategies because it was more effective (fewer major amputations) and less expensive than ABI surveillance and clinical follow-up.

In the group of patients treated for intermittent claudication, clinical follow-up was dominant because it was as effective as the other strategies, but less costly.

The results of the base case analysis were quite robust when several parameters were changed. However, the main result of the sensitivity analysis was that in the groups of patients treated for intermittent claudication, if duplex scan surveillance could have avoided 6 major amputations, it would have been cost-effective.

Authors’ conclusions
The authors concluded that, for patients treated for critical limb ischaemia, duplex scan surveillance is the most cost-
effective strategy. For patients treated for intermittent claudication, the choice of duplex scan surveillance is probably justified, based on the results of the sensitivity analysis.

**CRD COMMENTARY - Selection of comparators**
The reason for the selection of the comparators was clear. They represented the routine surveillance programmes for patients who received infrainguinal autologous vein bypass grafting surgery. You should consider whether they represent widely used technologies in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness measures were derived from a single study (for the evidence regarding duplex scan surveillance) and a previously published paper (for the ABI surveillance and the clinical follow-up). These estimates were then combined through a decision model and some problems could arise in the combination process, given that the populations of the two sources could present different baseline characteristics. Moreover, the effectiveness measures derived from a single study were not based on a randomised design, therefore the internal validity of the analysis could have been reduced.

**Validity of estimate of measure of benefit**
The benefit measure adopted in the study was the number of major amputations avoided per 1,000 patients. The choice of this measure was properly justified by the authors, who highlighted the advantages of this approach, by comparing it with the widely used quality-adjusted life years measure.

**Validity of estimate of costs**
Costs and quantities were reported separately and it appears that all the categories of costs relevant to the perspective adopted in the study were included in the analysis. The costs estimated in the analysis appear to be quite specific to the setting (The Netherlands). However, different ranges of costs were used in the sensitivity analysis, therefore the generalisability of the study was enhanced. The authors also made appropriate currency conversions.

**Other issues**
The issue of the generalisability of the study to other settings was partially addressed by performing sensitivity analyses on several parameters of the model. The authors recognised that a longer time horizon for the analysis, and a different benefit measure for the patients treated for intermittent claudication, could have improved the analysis results.

**Implications of the study**
The authors recommended the adoption of duplex scan surveillance, especially for patients treated for clinical limb ischaemia. The authors suggested that further research should be based on a randomised trial, with particular attention to patients treated for intermittent claudication.

**Source of funding**
Supported in part by a grant (OG-93/037) from the Commission of Investigative Medicine of the Dutch National Health Insurance Council.

**Bibliographic details**

**PubMedID**
11137932