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Best evidence topic

Should patients with infrainguinal arterial bypasses using autologous vein conduit undergo follow-up surveillance with duplex ultrasound?

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HIGHLIGHTS

- Guidelines advocate routine use of duplex ultrasound (DUS) in vein graft bypass surveillance.
- The evidence for this approach is poor.
- This article provides a summary of the best available evidence on the topic.

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ABSTRACT

This best evidence topic was investigated according to a structured format. The question asked was: should duplex ultrasound (DUS) scanning be a routine component of surveillance following infrainguinal arterial bypass using vein conduit? We performed a systematic literature search and identified 4 studies (3 randomised controlled trials and 1 meta-analysis) that provided the best evidence.

The highest quality study was a multi-centre randomised controlled trial ($n = 594$). At 18 months following surgery, it found no difference in patency rates, amputations, vascular mortality or mortality. However it achieved just over half of anticipated recruitment and thus was underpowered. The remaining two randomised controlled trials had smaller sample sizes and methodological weaknesses and found conflicting results. Lundell et al. ($n = 106$) found improved primary assisted and secondary patency rates and fewer graft occlusions with a routine DUS policy. Ihlberg et al. ($n = 152$) found no difference in primary assisted patency or amputations although secondary patency was improved. A meta-analysis of mostly observational data ($n = 6649$) found fewer occlusions with routine DUS surveillance and no effect on amputations or mortality.

Results are conflicting. The strongest evidence comes from the single high quality multi-centre trial. It appears as though routine DUS surveillance does not yield benefits in patient important outcomes. Further studies are needed.

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1. Introduction

This best evidence topic was generated according to the structure outlined in *International Journal of Surgery* [1].

2. Clinical scenario

A patient who had a femoropopliteal bypass using a long saphenous vein conduit 6 weeks ago attends for routine follow-up at a vascular surgery clinic. Clinical examination and ankle brachial pressure index (ABPI) measurement are satisfactory. The vascular surgery consultant advises that the patient should undergo regular duplex ultrasound (DUS) as part of a surveillance program. You are unsure about the quality of the evidence underlying this strategy for vein grafts and you decide to assess the literature.

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Table 1
Summary of best evidence papers.

Author, date and country	Patient group	Study type and level of evidence	Outcomes	Key results	Comments
Davies [3] 2005 Ten European countries	594 patients who underwent femoropopliteal or femorocrural vein bypass and had patent grafts at 30 days after surgery. 290 were randomised to clinical follow-up and 304 were randomised to clinical follow-up with routine DUS. Follow-up for both groups was at 6 weeks and at 3, 6, 9, 12, and 18 months after surgery. Patients in both groups could undergo further imaging and procedures as necessary. Baseline characteristics were similar and similar numbers were lost to follow up. All patients were offered DUS at 18 months.	Multi-centre randomised controlled trial Level 2	Primary outcomes were time to amputation (above knee, through knee, below knee) and time to vascular mortality (myocardial infarction, heart failure, arrhythmia, cerebrovascular accident). Presence of stenoses, cost and quality of life scores at 18 months were secondary outcomes.	Primary patency, primary assisted patency and secondary patency rates at 18 months in clinical versus DUS groups were 69% versus 67% ($p = 0.516$), 76% versus 76% ($p = 0.916$) and 80% versus 79% ($p = 0.663$). At 18 months 39/204 in the clinical group versus 25/211 in the DUS group had graft stenoses detected. 46/290 clinical group patients had a therapeutic intervention within 18 months versus 66/304 DUS group ($p = 0.07$). There were 21 amputations in clinical group versus 21 in duplex (HR 1.01; 95%CI 0.55–1.86). Vascular death occurred in 10 clinical group patients and 12 DUS patients (HR 1.21; 95%CI 0.52–2.81). There were 31 cases of mortality in clinical group versus 26 in duplex group (HR 1.22; 95%CI 0.75–1.98). Duplex group patients incurred higher cost (mean difference £495; 95%CI £183–£807). There was no difference in quality of life.	This was a large multicentre trial that found no differences resulting from surveillance policies. Time to amputation, time to vascular death and quality of life were similar. There was no significant difference in requirements for therapeutic interventions between groups and patency rates at 18 months were similar. Notably the trial achieved just over half of anticipated recruitment leaving it prone to type 2 error. This trial had a published protocol, clear methodology on randomisation and prespecified outcome measures.
Lundell [5] 1995 Sweden	156 patients who underwent primary femoropopliteal or femorodistal bypass (vein or synthetic graft). 77 patients were randomised to “routine follow-up” (clinical examination and ABPI) at 1, 12, 24 and 36 months following surgery. 79 were randomised to “intensive follow-up” (clinical examination, ABPI and graft DUS) at 1, 3, 6, 9, 12, 15, 18, 24 and 36 months following surgery. There were 56 patients with vein grafts in the intensive group and 50 with vein grafts in the routine group. Baseline characteristics were similar and similar numbers were lost to follow-up.	Single centre randomised controlled trial Level 2	Outcomes were assisted primary patency, secondary patency, further interventions and occlusions at 3 years following surgery.	Regarding only those with vein grafts, 3 year primary assisted patency and secondary patency rates in “routine” versus “intensive” groups were 53% versus 78% ($p < 0.05$) for primary assisted patency and 56% versus 82% ($p < 0.05$) for secondary patency. During follow-up 4/50 grafts in the “routine” group underwent therapeutic intervention compared to 12/56 in the “intensive group” ($p = 0.062$). 20/50 grafts in the “routine” group occluded versus 11/56 in the “intensive” group ($p = 0.032$).	This was a small single centre trial and results at 3 years favoured “intensive” follow-up. Primary assisted and secondary patency rates at 3 years were significantly better with “intensive” surveillance. More therapeutic interventions were performed in the “intensive group”. Notably this trial compared “intensive” versus “routine” surveillance rather than routine DUS versus selective imaging – the increased number of follow-up visits in the DUS group is a source of bias. Furthermore, no protocol is available and aspects of methodology are unclear, especially for randomisation and treatment allocation. It is unclear whether outcomes were prespecified and there was no sample size justification.
Ihlberg [6] 1998 Finland	Patients who underwent primary infrainguinal arterial bypass using vein conduit. 76 patients were randomised to a follow-up schedule comprising clinical examination with ABPI measurement and 76 patients were randomised to a group that additionally underwent DUS at each visit. Follow-up visits for both groups were at 1, 3, 6, 9 and 12 months following surgery. Baseline characteristics were similar.	Single centre randomised controlled trial Level 2	Outcomes were primary assisted patency, secondary patency and limb salvage rates at one year.	At one year, primary assisted patency rates were 74% in the clinical group and 65% in the DUS group ($p = 0.21$), secondary patency rates were 84% and 71% respectively ($p = 0.04$) and limb salvage rates were 88% and 81% respectively ($p = 0.23$).	This was a small single centre trial that found no difference between policies in terms of primary assisted patency, secondary patency or amputation rates. Notably, no protocol is available and it was pseudo-randomised. It is unclear whether outcomes were prespecified and there was no sample size justification.
Colledge [8] 1996 United Kingdom	Studies evaluating occlusion rates of lower limb arterial bypass with vein grafts were included. Eligible	Systematic review and meta-analysis Level 2	Occlusion, amputation and death rates.	Mean follow-up was 49 months in the clinical follow-up group versus 40 in the DUS	This meta-analysis found lower rates of graft occlusion and death in series that reported

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Table 1 (continued)

Author, date and country	Patient group	Study type and level of evidence	Outcomes	Key results	Comments
	studies provided outcomes within DUS surveillance programs and/or within clinical surveillance programs. In total 17 studies (2680 patients) evaluated outcomes with DUS surveillance. 26 studies (3969 patients) evaluated outcomes with clinical follow-up only. 43 cohort studies and one randomised controlled trial were included.			surveillance group. 583/3677 grafts ^a in the clinical group occluded after 30 days from surgery compared with 165/1332 ^a in the DUS group ($p < 0.01$). 357/2842 limbs required amputation in the clinical group versus 85/664 in the DUS group ($p > 0.5$). 718/3677 patients died during follow-up in the clinical group versus 96/843 in the DUS surveillance group ($p < 0.001$).	results from DUS surveillance programs compared to series that reported outcomes from clinical follow-up programs. There was no difference in amputation rates. As it is mostly based upon observational data it is prone to bias. Death and amputation were infrequently reported in DUS surveillance program series. Notably patency rates were not evaluated. The principle message from this review was that there was strong rationale for a large randomised controlled trial.

ABPI – ankle–brachial pressure index; CI – confidence interval; DUS – duplex ultrasound; HR – hazard ratio.

^a Data were provided in numbers of grafts rather than number of patients.

3. Three part question

In [patients with infrainguinal arterial bypasses with vein conduits] does [routine DUS surveillance in addition to clinical examination] improve [outcomes].

4. Search strategy

We searched Medline up to 19th April 2014 using the following search strategy [(duplex ultrasound surveillance) AND (vein graft OR bypass)]. The search was limited to English language studies. We identified additional studies by examining included article references. Eligible studies involved patients who underwent infrainguinal arterial bypasses using vein grafts. Eligible studies compared follow-up strategies comprising clinical examination and routine DUS with follow-up strategies comprising clinical examination and selective imaging. The outcomes of interest were primary patency, primary assisted patency, secondary patency, occlusions, amputations and mortality. There was no restriction on length of follow-up. The definitions for patency outcomes were those specified by the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery [2]: primary patency is patency without intervention, primary assisted patency is patency without intervention plus patency after intervention for graft stenosis, secondary patency is patency without intervention plus patency after intervention for graft stenosis plus patency after intervention for graft occlusion. We excluded studies that involved synthetic conduits unless studies reported on both vein and synthetic conduits and provided separate results for each.

5. Search outcome

The search identified 319 Medline citations. 4 studies provided the best evidence to answer the question.

6. Results

3 randomised controlled trials and one meta-analysis were included. These are summarised in Table 1.

7. Discussion

Davies et al. [3] performed a multi-centre randomised controlled trial involving 594 patients. Eligible patients had undergone femoropopliteal or femorocrural vein bypass and had a patent graft at 30 days after surgery. Patients were randomised to “clinical” follow-up, comprising clinical examination and ABPI measurement at each visit or “DUS” follow-up, comprising clinical examination, ABPI measurement and additional DUS scanning at each visit. Follow-up appointments for both groups were are 6 weeks and at 3, 6, 12 and 18 months following surgery. All patients were offered DUS at study completion (18 months). Outcomes were time to amputation and vascular mortality, patency rates, quality of life and costs. The groups were well matched at baseline – median age was 70 in each group and 72% were males; median ABPI at baseline was 0.48 in the clinical group and 0.49 in the DUS group; 37% in both groups had below knee grafts and 66% of operations in both groups were for critical ischaemia. There were no significant differences in terms of outcomes. There were 21 amputations in the clinical group versus 21 in the DUS group (HR 1.01; 95%CI 0.55–1.86). Vascular death occurred in 10 clinical group patients versus 12 DUS group patients (HR 1.21; 95%CI 0.52–2.81). Corresponding figures for all-cause mortality were 31 in the clinical group and 36 in the DUS group (HR 1.22; 95%CI 0.75–1.98). Patency rates and quality of life were also similar although the DUS group incurred more cost. This was a high quality trial – it had a published protocol [4] with pre-specified outcome measures, the methodology for random sequence generation and allocation concealment was robust, there were few patients lost to follow-up and all outcomes were reported. However, the trial achieved just over half of anticipated recruitment leaving it prone to type 2 error – it was terminated prematurely due to recruitment difficulties arising from increased use of percutaneous revascularisation techniques.

Lundell et al. [5] performed a single-centre randomised controlled trial that evaluated the effects of “routine” versus “intensive” surveillance programs. Eligible patients underwent primary femoropopliteal or femorodistal bypass using either vein or synthetic grafts (results were provided separately for both types of grafts). “Routine” surveillance comprised clinical examination and ABPI measurement at 1, 12, 24 and 36 months after surgery and “intensive” surveillance comprised clinical examination, ABPI measurement and DUS scanning at 1, 3, 6, 9, 12, 15, 18, 24 and 36 months following surgery. Outcomes were assisted primary patency and secondary patency rates. The groups were well

matched at baseline (but baseline data were not available separately for vein graft patients) – median age was 74 years in the intensive group versus 76 in routine surveillance group; 49% were male in the intensive group versus 42% in the routine group; 72/79 intensive group patients had critical ischaemia versus 74/77 routine group patients. 56 patients in the intensive group and 50 in the routine group had vein grafts – at 3 years intensive surveillance lead to significantly better primary assisted patency rates (78% in intensive group versus 53% in routine group, $p < 0.05$) and secondary patency rates (82% in intensive group versus 56% in routine group, $p < 0.05$). Importantly, this trial compared “intensive” with “routine” surveillance rather than routine DUS with selective imaging – the increased number of follow-up visits in the DUS group is a major source of confounding as it may account for the improved patency results. A further limitation is that several aspects of methodological quality are unclear – there is no available protocol, the methodology for randomisation and allocation concealment is unclear, it is unclear whether outcomes were prespecified and there was no justification for the chosen sample size.

Ihlberg et al. performed a single centre randomised controlled trial that was reported in two different publications [6,7]. The first related to recruitment from 1991 to 1993, involving 179 patients [6], and the second related to recruitment from 1991 to 1995, involving 344 patients [7]. The second publication dealt solely with patients who attended all follow-up visits – for the purposes of this review the first publication [6] provided more relevant data although patient numbers were smaller. Eligible patients underwent primary infrainguinal bypasses with vein conduits. Once patency was confirmed at 30 days patients were randomised to clinical follow-up comprising clinical examination and ABPI measurement or to a follow-up program that additionally involved DUS scanning at each visit. Follow-up visits for both groups were at 1, 3, 6, 9 and 12 months following surgery. Outcomes were primary assisted patency, secondary patency and limb salvage rates at one year. The groups were well matched at baseline – mean age was 69.8 years in the clinical group versus 68.8 in the DUS group, 74% were male in the clinical group versus 62% in the DUS group; 62/76 clinical group patients had critical ischaemia versus 66/76 in the DUS group. No significant differences were found in primary assisted patency (74% in the clinical group and 65% in the DUS group, $p = 0.21$) or limb salvage rates (88% and 81% respectively, $p = 0.23$) although secondary patency rates were improved (84% and 71% respectively, $p = 0.04$). A major limitation is that several aspects of methodology are unclear or inadequate – no protocol is available, it was pseudo-randomised based on odd or even dates of birth, it is unclear whether outcomes were prespecified and there was no sample size justification.

The final study was a systematic review and meta-analysis by Golledge et al. [8]. The authors compared pooled data from studies involving DUS surveillance with pooled data from studies with clinical follow-up programs. This was achieved through a Medline search from 1987 to 1995. Eligible studies provided data on occlusion rates. Additional outcomes that were included were amputations and deaths during follow-up. 17 studies (2680 patients) evaluated outcomes within DUS surveillance programs and 26 studies (3969 patients) evaluated outcomes within clinical follow-up programs. Though not all studies reported all relevant baseline and outcome data, the groups were similar at baseline – similar proportions of patients in both groups had critical ischaemia (2842/3969 (72%) in clinical surveillance versus 1342/1838 (73%) in DUS surveillance, $p = 0.3$) and similar ratios of femoropopliteal to crural surgery (2049:1365 in the clinical group versus 1216:800 in the DUS group, $p > 0.5$). However mean follow-up was 49 months in the clinical follow-up group versus 40 in the DUS surveillance

group (no p value available). Results suggested that DUS surveillance had a favourable effect on occlusion rates but no effect on amputations or mortality. The main strength of this review is the large sample size – at the time of its publication it provided a strong rationale for the completion of a large randomised control trial [4]. However as it involved mostly observational data, conclusions based upon the review are prone to bias and confounding.

8. Clinical bottom line

Results from available data are conflicting. The strongest evidence comes from the trial by Davies et al. [3] as the smaller trials and observational studies have major limitations. It appears as though routine DUS surveillance does not yield benefits in patient important outcomes. Further high quality studies are needed.

Ethical approval

None required.

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Author contribution

DA Healy: data collection, analysis, drafting the manuscript.
C Keogh: data collection, analysis, revising manuscript.
K Bashar: data collection, revising manuscript.
SM Sahebally: data collection, analysis, revising manuscript.
M Clarke-Moloney: analysis, revising manuscript.
SR Walsh: design, revising manuscript.

Conflicts of interest

None.

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