International Journal of Surgery 13 (2015) 38–41

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.journal-surgery.net

Best evidence topic

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

D.A. Healy [a, *], C. Keogh [a], K. Bashar [a], S.M. Sahebally [a], M. Clarke Moloney [b], S.R. Walsh [c]

[a] Department of Surgery, University Hospital Limerick, Limerick, Ireland
[b] Clinical Research Support Unit, Health Research Institute, University of Limerick, Limerick, Ireland
[c] Department of Vascular Surgery, University College Hospital Galway, Galway, Ireland

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.

ARTICLE INFO

Article history:
Received 21 April 2014
Received in revised form
13 November 2014
Accepted 18 November 2014
Available online 25 November 2014

Keywords:
Peripheral vascular disease
Bypass
Infrainguinal bypass
Duplex ultrasound
Vein graft

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.

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.

* Corresponding author.
E-mail address: donagh1@hotmail.com (D.A. Healy).

http://dx.doi.org/10.1016/j.ijsu.2014.11.024
1743-9191/

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.
Golledge [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

(*continued on next page*)