



**PROPOSED REVIEW OF SIGN GUIDELINE
CONSULTATION FORM**

Title of guideline	SIGN 89: Diagnosis and management of peripheral arterial disease
Date of publication	October 2006
SIGN scoping search – sources	<p>MeSH headings for the condition specified and any common variations as free text, plus terms for the interventions and care processes discussed in the guideline</p> <p>Sources: Guidelines: NICE; National Library for Health guidelines finder; National Guidelines Clearinghouse; GIN Web site; CKS Knowledge Summaries. Technology appraisals: NICE; UK HTA database (Southampton); INAHTA database. Cochrane reviews: Cochrane Library. Other good quality systematic reviews: UK HTA database (Southampton); DARE.</p> <p>Search dates: 2006- 2009</p>
SIGN scoping search - summary	<p>Guidelines – 1 HTAs – 2 Cochrane reviews – 13</p>
Other guidelines/HTAs	<p>Sobel M, Verhaeghe R; American College of Chest Physicians; American College of Chest Physicians. Antithrombotic therapy for peripheral artery occlusive disease: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). <i>Chest</i>. 2008 Jun;133(6 Suppl):815S-843S http://www.chestjournal.org/content/133/6_suppl/815S.full.pdf+html</p> <p>HTAs</p> <p>Collins R, Cranny G, Burch J, Aguiar-Ibáñez R, Craig D, Wright K, Berry E, Gough M, Kleijnen J and Westwood M. A systematic review of duplex ultrasound, magnetic resonance angiography and computed tomography angiography for the diagnosis and assessment of symptomatic, lower limb peripheral arterial disease. <i>Health Technol Assess</i> 2007;11(20):1–202</p> <p>Institut fuer Qualitaet und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) 2007. Clopidogrel vs. acetylsalicylic acid in the secondary prophylaxis of vascular diseases http://www.iqwig.de/index.356.en.html</p>
Main conclusions from new evidence	<ul style="list-style-type: none"> ▪ Computed tomography angiography is an accurate modality to assess presence and extent of PAD in patients with intermittent claudication; however, methodological weaknesses of examined studies prevent definitive conclusions from the pooled data. <i>CT angiography is discussed in SIGN 89 but it is recommended that non-invasive imaging modalities should be employed first (A).</i> ▪ Antiplatelet therapy with aspirin had a slight beneficial effect on the patency of peripheral bypass grafts but seemed to have an inferior effect on venous graft patency compared with artificial grafts. The effect of aspirin on cardiovascular outcomes and survival was small and not statistically significant. This was also demonstrated in another systematic review. <i>SIGN 89 includes a general recommendation on antiplatelet therapy for patients with symptomatic peripheral arterial disease.</i> ▪ Cilostazol has been shown to be of benefit in improving walking distance in people with intermittent claudication. There are no data on whether it results in a reduction of adverse cardiovascular events. <i>It is recommended that patients with intermittent claudication should be considered for treatment</i>

with cilostazol.

- A Cochrane review on the use of betablockers in patients with PAD found that none of the trials showed a clear worsening effect of beta blockers on time to claudication, claudication and maximal walking distances measured on a treadmill, calf blood flow, calf vascular resistance and skin temperature when compared with placebo. The trials did not report any adverse events or issues regarding taking the medication with the beta blockers studied. Most of the trials were old, small and of poor quality. *Betablockers are not discussed in SIGN 89.*
- Lipid-lowering therapy is effective in reducing cardiovascular mortality and morbidity in people with PAD. It may also improve local symptoms. Until further evidence on the relative effectiveness of different lipid-lowering agents is available, use of a statin in people with PAD and a blood cholesterol level ≥ 3.5 mmol/litre is most indicated. *This is recommended in SIGN 89 (A).*
- Naftidrofuryl has a statistically significant and clinically meaningful effect of improving walking distance in the six months after initiation of therapy for people with intermittent claudication. *It is recommended that patient with intermittent claudication and a poor quality of life should be considered for treatment with naftidrofuryl (A).*
- A Cochrane review found there is little evidence available to evaluate the efficacy of buflomedil for patients with intermittent claudication. Most trials were excluded due to poor quality. Buflomedil's benefit is small in relation to safety issues and its narrow therapeutic range. *Not discussed in SIGN 89.*
- Omega-3 fatty acids appear to have limited haematological benefits in people with intermittent claudication but there is no evidence of consistent improved clinical outcomes (quality of life, pain free walking distance, maximal walking distance, ankle brachial pressure index, angiographic findings). Supplementation may also cause adverse effects such as increased total and LDL cholesterol levels. *Omega-3 not discussed in SIGN 89*
- A systematic review concluded that despite the poor quality of the studies found subintimal angioplasty can play an important role in the treatment of patients with peripheral arterial disease, especially in the case of critical limb ischemia. Despite the moderate patency rates after one year, SA may serve as a "temporary bypass" to provide wound healing and limb salvage. *No recommendation given in SIGN 89, due to lack of evidence.*
- There is a small benefit to adding a stent when performing balloon angioplasty in certain patients with superficial femoral artery narrowing. However, this could not be recommended as routine practice in all patients. *SIGN 89 states there is a lack of evidence for stenting.*
- No evidence was found to favour bypass surgery over angioplasty in terms of the effect on walking distance, complications and disease progression, amputation rate or death in patients with chronic lower limb ischaemia. Surgery was associated with increased surgical complications and longer hospital stays than for those that received angioplasty. *No recommendations on bypass surgery given in SIGN 89.*
- A meta-analysis of randomized controlled trials comparing Dacron and PTFE as bypass materials for peripheral vascular surgery showed no evidence of an advantage of one synthetic material over the other. *Not discussed in SIGN 89*
- The benefit of cryoplasty over conventional angioplasty has not been established as no randomised controlled trials exist. *Not discussed in SIGN 89*
- Exercise programmes can have significant benefit compared with placebo or usual care in improving walking time and distance in selected patients with leg pain from intermittent claudication. A further Cochrane Review reported that supervised exercise therapy showed statistically significant and clinically relevant differences in improvement of maximal treadmill walking distance compared with non-supervised exercise therapy regimens, with an overall effect size of 0.58 (95% confidence interval 0.31 to 0.85) at three months. This translates to a difference of approximately 150 meters increase in walking distance in favour of the supervised group. The authors concluded that more studies are needed to demonstrate whether this improves patients'

	<p>quality of life. <i>SIGN 89</i> includes a recommendation that patients with intermittent claudication should be encouraged to exercise.</p> <ul style="list-style-type: none"> ▪ There is no evidence that Ginkgo biloba has a clinically significant benefit for patients with peripheral arterial disease. <i>Ginkgo biloba</i> is discussed but no recommendations on its use are given. ▪ Gene therapy confers no benefit on patients with PVD. <i>Not discussed in SIGN 89</i>
New areas that could be added to the guideline	<ul style="list-style-type: none"> ▪ Use of angioplasty and stenting ▪
Summary of the recommendations that could be updated	<ul style="list-style-type: none"> ▪

This report has been reviewed by SIGN Senior Management who do not consider that the new evidence provides justification for updating of the guideline at this stage, and the guideline remains current. This report will be updated and reconsidered in 2011.