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## Atherectomy for peripheral arterial disease (Review)

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Atherectomy for peripheral arterial disease (Review)

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[Intervention Review]

# Atherectomy for peripheral arterial disease

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## ABSTRACT

### Background

Symptomatic peripheral arterial disease may be treated by a number of options including exercise therapy, angioplasty, stenting and bypass surgery. Atherectomy is an alternative technique where atheroma is excised by a rotating cutting blade.

### Objectives

The objective of this review was to analyse randomised controlled trials comparing atherectomy against any established treatment for peripheral arterial disease in order to evaluate the effectiveness of atherectomy.

### Search methods

The Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched November 2013) and CENTRAL (2013, Issue 10). Trials databases were searched for details of ongoing or unpublished studies.

### Selection criteria

Randomised controlled trials (RCTs) comparing atherectomy and other established treatments were selected for inclusion. All participants had symptomatic peripheral arterial disease with either claudication or critical limb ischaemia and evidence of lower limb arterial disease.

### Data collection and analysis

Two review authors (GA and CT) screened studies for inclusion, extracted data and assessed the quality of the trials. Any disagreements were resolved through discussion.

### Main results

Four trials were included with a total of 220 participants (118 treated with atherectomy, 102 treated with balloon angioplasty) and 259 treated vessels (129 treated with atherectomy, 130 treated with balloon angioplasty). All studies compared atherectomy with angioplasty. No study was properly powered or assessors blinded to the procedures and there was a high risk of selection, attrition, detection and reporting biases.

The estimated risk of success was similar between the treatment modalities although the confidence interval (CI) was compatible with small benefits of either treatment for the initial procedural success rate (Mantel-Haenszel risk ratio (RR) 0.92, 95% CI 0.44 to 1.91, P =

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0.82), patency at six months (Mantel-Haenszel RR 0.92, 95% CI 0.51 to 1.66,  $P = 0.79$ ) and patency at 12 months (Mantel-Haenszel RR 1.17, 95% CI 0.72 to 1.90,  $P = 0.53$ ) following the procedure. The reduction in all-cause mortality with atherectomy was most likely due to an unexpectedly high mortality in the balloon angioplasty group in one of the two trials that reported mortality (Mantel-Haenszel RR 0.24, 95% CI 0.06 to 0.91,  $P = 0.04$ ). Cardiovascular events were not reported in any study. There was a reduction in the rate of bailout stenting following atherectomy (Mantel-Haenszel RR 0.45, 95% CI 0.24 to 0.84,  $P = 0.01$ ), and balloon inflation pressures were lower following atherectomy (mean difference  $-2.73$  mmHg, 95% CI  $-3.48$  to  $-1.98$ ,  $P < 0.00001$ ). Complications such as embolisation and vessel dissection were reported in two trials indicating more embolisations in the atherectomy group and more vessel dissections in the angioplasty group, but the data could not be pooled. From the limited data available, there was no clear evidence of different rates of adverse events between the atherectomy and balloon angioplasty groups for target vessel revascularisation and above-knee amputation. Quality of life and clinical and symptomatic outcomes such as walking distance or symptom relief were not reported in the studies.

### Authors' conclusions

This review has identified poor quality evidence to support atherectomy as an alternative to balloon angioplasty in maintaining primary patency at any time interval. There was no evidence for superiority of atherectomy over angioplasty on any outcome, and distal embolisation was not reported in all trials of atherectomy. Properly powered trials are recommended.

## PLAIN LANGUAGE SUMMARY

### Atherectomy for peripheral arterial disease

A person with diseased arteries in the legs can experience pain on walking (also known as intermittent claudication), pain at rest (especially at night), or ulcers due to poor blood flow. Established treatments include surgery, where a bypass is inserted to carry blood from an artery above the diseased (blocked or narrowed) section to below the diseased section, and balloon angioplasty, where a deflated balloon is inserted into the vessel and then blown up to stretch the artery thus opening up the narrow or blocked section. Stents may be inserted during angioplasty. In addition to these two established treatments, a less commonly used technique is to core out the artery, cutting or grinding away the disease which is causing the vessel to narrow or block. This is known as atherectomy.

In this review, we compared atherectomy to the more established treatments such as balloon angioplasty and bypass surgery. We identified four studies with a total of 220 participants. All studies compared atherectomy with balloon angioplasty. The studies were of low quality as there was no blinding of the procedures, the studies were not properly powered to show an effect, not all study outcomes were reported and a large number of the initial study populations did not complete the studies.

Although the results of the meta-analyses were imprecise, the average effect of the two treatments was similar in terms of initial success and unobstructed arteries (patency) at six months or 12 months following the procedure. There was a lower risk of death with atherectomy, most likely due to an unexpectedly high number of deaths in the balloon angioplasty group in one of the two trials reporting deaths. Cardiovascular events were not reported in any of the included studies. There was a reduction in the rate of emergency stenting procedures following atherectomy, and balloon inflation pressures were lower following atherectomy. Complications such as formation of clots (embolisation) and tears along the vessels (vessel dissection) were reported in two trials indicating more embolisations in the atherectomy group and more vessel dissections in the angioplasty group but the data could not be combined. The limited data available indicated that there was no clear evidence of a difference between the atherectomy and balloon angioplasty groups for adverse events such as the need for re-intervention due to obstruction of the treated vessel and above-knee amputation. Quality of life and clinical and symptomatic outcomes such as walking distance or symptom relief were not reported in the studies.

We showed that the limited evidence available does not support a significant advantage of atherectomy over conventional balloon angioplasty.

## BACKGROUND

### Description of the condition

Symptomatic peripheral arterial disease may be treated by a number of options including exercise therapy, angioplasty, stenting and bypass surgery (Fowkes 1998; Fowkes 2008; Watson 2008). Atherectomy is a competing technique where atheroma is excised by a rotating cutting blade (Garcia 2009). Due to the risk of vessel perforation, atherectomy tends to be performed only in the superficial femoral and popliteal arteries, though it may be used in infrapopliteal vessels. While established treatments have a strong evidence base and guidelines for their use (TASC II 2007), the outcomes for atherectomy are less well understood. Atherectomy has suffered from a relative paucity of published data, which led the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom to publish guidelines in early 2011 suggesting that it should only be used within the context of clinical trials (NICE 2011).

### Description of the intervention

Atherectomy is an endovascular procedure for revascularisation where pieces of atherosclerotic plaque are removed in order to increase the luminal diameter of the vessel (Schwarzwalder 2010). The procedure is normally performed percutaneously through a 7-French (F) or 8-F sheath unless vessel access is difficult, in which case an arterial cut-down is required. The mechanism used to remove pieces of plaque can involve a variety of techniques but usually involves some kind of rotating cutting blade, often together with a chamber for storing the cut pieces.

### Why it is important to do this review

A true systematic review and meta-analysis of published trials comparing atherectomy to more established treatments has never been performed. Therefore, the aim was to perform a meta-analysis of randomised trials comparing atherectomy with any established treatment for peripheral arterial disease in order to evaluate the effectiveness of atherectomy.

## OBJECTIVES

The objective of this review was to analyse randomised controlled trials comparing atherectomy against any established treatment for peripheral arterial disease in order to evaluate the effectiveness of atherectomy.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Only randomised controlled trials (RCTs) comparing atherectomy with other established treatments were selected for inclusion.

#### Types of participants

All participants had symptomatic peripheral arterial disease with either claudication or critical limb ischaemia and evidence of lower limb arterial disease. Arterial disease in any peripheral territory was considered.

Studies with participants who had previously had bypass, percutaneous transluminal angioplasty (PTA) or stents in the target lesion were excluded as the treatments might affect the primary patency rates.

#### Types of interventions

RCTs comparing atherectomy against any established treatment for peripheral arterial disease in order to evaluate the effectiveness of atherectomy were considered. The following trial comparisons were identified: atherectomy versus balloon angioplasty  $\pm$  stenting; atherectomy plus adjunctive balloon angioplasty versus balloon angioplasty; and atherectomy versus surgical bypass procedures.

#### Types of outcome measures

##### Primary outcomes

1. Primary vessel patency as assessed by ankle brachial index (ABI), arterial doppler ultrasound or angiography at six months and one year, and as data available in the studies
2. All-cause mortality at six months and one year, and as data available in the studies
3. Fatal and non-fatal cardiovascular events at six months and one year, and as data available in the studies

##### Secondary outcomes

1. Immediate procedural and angiographic outcomes
2. Target vessel revascularisation rates
3. Complication rates including thrombus, embolus, perforation and aneurysm
4. Morbidity assessment including (i) tissue healing, (ii) avoidance of any amputation and (iii) performance of less extensive amputation
5. Quality of life outcomes as measured in the included studies

6. Clinical and symptomatic outcomes e.g. improved walking distance, symptom relief

## Search methods for identification of studies

There was no language restriction.

### Electronic searches

The Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator (TSC) searched the Specialised Register (last searched November 2013) and the Cochrane Central Register of Controlled Trials (CENTRAL) (2013, Issue 10), part of *The Cochrane Library* ([www.thecochranelibrary.com](http://www.thecochranelibrary.com)). See [Appendix 1](#) for details of the search strategy used to search CENTRAL. The Specialised Register is maintained by the TSC and is constructed from weekly electronic searches of MEDLINE, EMBASE, CINAHL and AMED, and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used, are described in the [Specialised Register](#) section of the Cochrane Peripheral Vascular Diseases Group module in *The Cochrane Library* ([www.thecochranelibrary.com](http://www.thecochranelibrary.com)).

The following trial databases were searched by the TSC (November 2013) for details of ongoing and unpublished studies using the term atherectomy:

- World Health Organization International Clinical Trials Registry Platform (<http://apps.who.int/trialsearch/>);
- ClinicalTrials.gov (<http://clinicaltrials.gov/>);
- Current Controlled Trials (<http://www.controlled-trials.com/>);
- Netherlands Trials Register (<http://www.trialregister.nl/trialreg/admin/rctsearch.asp>).

### Searching other resources

Reference lists of relevant articles resulting from this search were searched to identify further trials. Proceedings from the British Vascular Surgical Society (Vascular Surgery abstract books from 1995 to 2011) and the European Vascular Surgical Society (ESVS) abstract books (from 2001 to 2011) were examined for relevant trials.

## Data collection and analysis

### Selection of studies

For this review, two review authors (GA and CT) selected trials for inclusion in the review. Disagreements were resolved through discussion. The section '[Criteria for considering studies for this review](#)' details the inclusion criteria used for the selection process.

## Data extraction and management

Data were extracted by GA then cross checked by CT. Disagreements were resolved through discussion. The following information was extracted for each trial.

- Trial methods: method of randomisation, method of allocation.
- Participants: country of origin, age, sex distribution, severity of disease as measured by the ABI and using the European Consensus definition of critical ischaemia (Consensus document), inclusion and exclusion criteria.
- Interventions: type of procedure (atherectomy, angioplasty or bypass).
- Outcomes: primary and secondary outcomes as listed in [Types of outcome measures](#).

Data were extracted from the published reference papers directly. No attempt was made to obtain additional unpublished data. All analyses were based on endpoint data from the individual clinical trials, which all provided intention-to-treat results. The data were synthesised by comparing group results. Individual patient data from different trials were not amalgamated.

## Assessment of risk of bias in included studies

Risk of bias of the included studies was assessed by two review authors independently (GA, CT), according to the guidelines given in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1 ([Higgins 2011](#)).

The following domains were assessed as 'low risk of bias', 'unclear risk of bias' or 'high risk of bias':

- sequence generation;
- allocation concealment;
- blinding;
- incomplete outcome data;
- selective outcome reporting.

These assessments were reported for each individual study in the [Risk of bias in included studies](#) tables.

## Measures of treatment effect

Treatment effects for dichotomous quantities were measured using risk ratios (RR) with 95% confidence intervals (CI). For continuous quantities, treatment effects were measured by mean difference with 95% CI.

## Unit of analysis issues

Two of the trials ([Shammas 2011](#); [Shammas 2012](#)) included multiple treated vessels per participant in some cases. This means that the observations from these trials will not be totally independent, and therefore should have less emphasis placed on them in the meta-analysis. However, as most participants (88%) in these trials had only one treated vessel and very few had more than two treated

vessels (15%), it is not likely that this will have a large impact on the results presented below. The data could not be re-examined to an individual participant level.

For the outcomes mortality, fatal and non-fatal cardiovascular events, complications, quality of life, and clinical and symptomatic outcomes the unit of analysis was the individual participant rather than the treated vessel.

### Dealing with missing data

Analysis was performed on a complete case basis and no attempt was made to contact study authors for further follow-up data. It was not necessary to contact authors for additional data.

### Assessment of heterogeneity

Chi<sup>2</sup> tests were used to assess for heterogeneity between trials, with P values greater than 0.2 being used as an indication of the possibility of the presence of significant heterogeneity. Since trials contained low participant numbers the power of this test is likely to be low if a small P value is used (Higgins 2011).

### Assessment of reporting biases

There were insufficient studies identified to create a funnel plot to assess reporting bias.

### Data synthesis

As the devices used for atherectomy were different in the included trials, analysis was performed using both Mantel-Haenszel fixed-effect models and inverse-variance random-effects models (Dersimonian 1986), and the sensitivity of the analysis to the use of these two methods was assessed. Review Manager (RevMan) version 5.1 software (RevMan 2012) was used.

Many participants in the atherectomy arm of the included studies underwent additional angioplasty. Details of this were not specified exactly in all studies and these participants were therefore not

analysed separately. The result from atherectomy is still considered successful even with additional angioplasty, so these participants were included in the atherectomy arm for analysis. Only one trial did not perform routine angioplasty with atherectomy (Vroegindewij 1995) and sensitivity analyses were performed to assess the effect of including this study in the overall meta-analyses.

### Subgroup analysis and investigation of heterogeneity

No subgroup analysis was performed as no suitable subgroups were presented in the selected studies.

Previously planned subgroup analyses were the presence or absence of concomitant illness such as diabetes, hypertension, hyperlipidaemia, chronic kidney disease, smoking, gender of participants, lesion location, length and percentage of stenosis including whether any studies classified lesion length and percentage of stenosis by the Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC II) (TASC II 2007).

### Sensitivity analysis

Sensitivity analysis was performed in two ways. Firstly, each meta-analysis was performed using both fixed-effect and random-effects models to assess whether the results were robust to changes in this modelling assumption. Secondly, meta-analysis was repeated after excluding the study where adjunctive balloon angioplasty was not routinely performed (Vroegindewij 1995).

## RESULTS

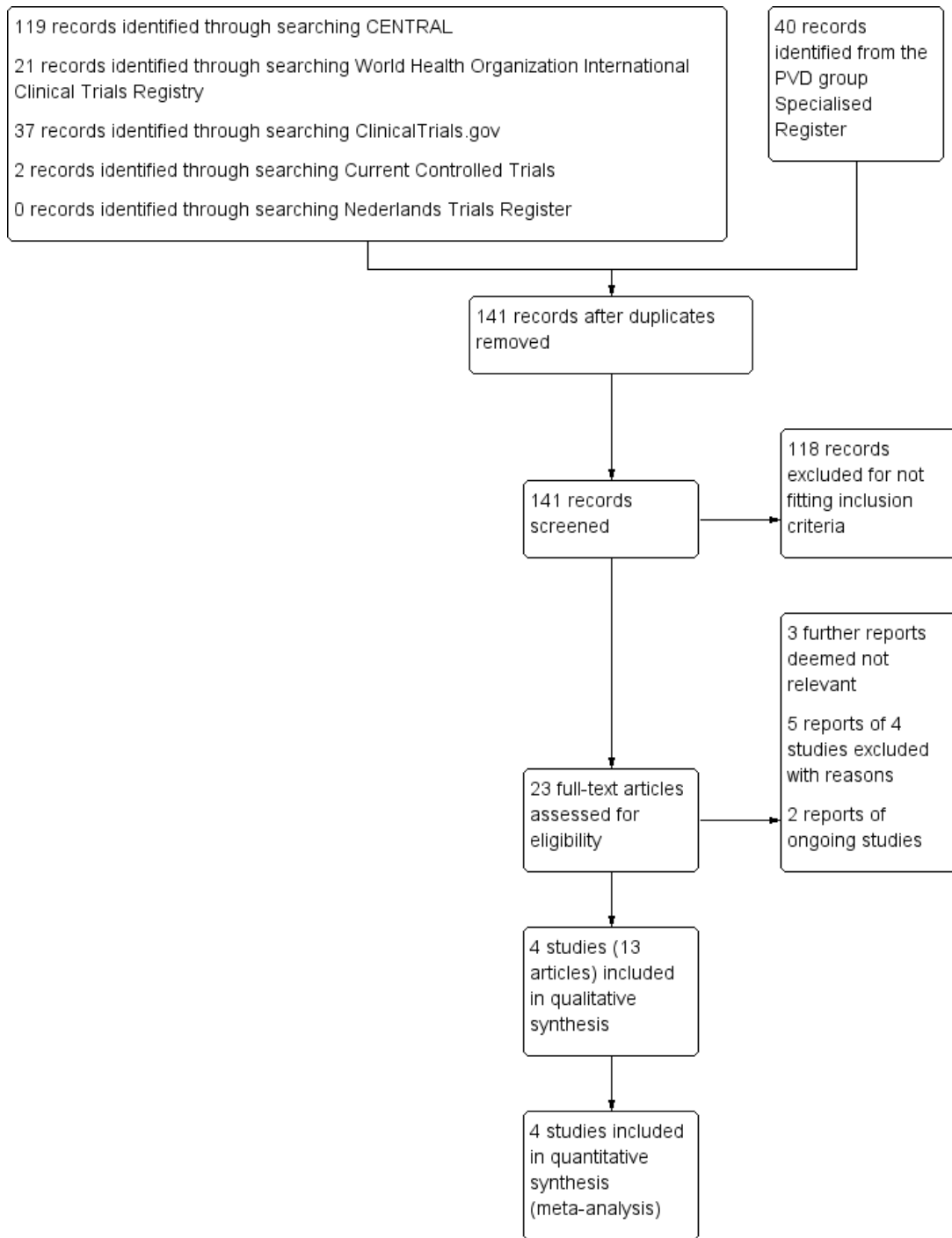
### Description of studies

### Results of the search

See Figure 1



**Figure 1. Study flow diagram.**



## Included studies

Summarised details of the included studies are included in the [Characteristics of included studies](#) table.

Four studies met the selection criteria ([Nakamura 1995](#); [Shammas 2011](#); [Shammas 2012](#); [Vroegindeweyj 1995](#)). Primary patencies were reported initially in all studies ([Nakamura 1995](#); [Shammas 2011](#); [Shammas 2012](#); [Vroegindeweyj 1995](#)). Follow-up was reported at three month intervals in [Vroegindeweyj 1995](#) up until two years. [Nakamura 1995](#) reported patencies at six months follow-up only. [Shammas 2011](#) reported follow-up patencies at 12 months only. [Shammas 2012](#) reported follow-up at three months, six months and 12 months. A total of 220 participants (118 atherectomy, 102 angioplasty) were treated in these trials. Some trials treated multiple vessels in each participant, so in total 259 vessels (129 atherectomy, 130 angioplasty) were treated in these trials. Two trials ([Shammas 2011](#); [Shammas 2012](#)) also reported rates of bailout stenting and amputation. This bailout stenting was said to be indicated in the presence of severe dissection, perforation, > 30% residual stenosis or significant vessel recoil in one paper ([Shammas 2012](#)) but only indicated in the presence of severe dissection or > 30% residual stenosis in the other ([Shammas 2011](#)).

[Nakamura 1995](#) compared balloon angioplasty to transluminal extraction catheter (TEC) atherectomy ([Stack 1988](#)) followed by adjunctive balloon angioplasty in 39 participants with intermittent claudication. TEC atherectomy utilises an over the wire device with a conical motorised cutting head with triangular blades which rotate at 700 rpm, together with a proximal suction apparatus which removes excised plaque. The assembly is controlled by a large hand-held controller which incorporates the motor, triggers to activate the motor and suction, and a sliding advancement control. There was no difference in primary patency either initially ( $P = 0.16$ ) or at six months ( $P = 0.16$ ). No medication protocol was specified.

[Vroegindeweyj 1995](#) compared balloon angioplasty to Simpson atherectomy ([Simpson 1988](#)) in 73 participants with intermittent claudication. The Simpson atherectomy device consists of cylindrical housing with a longitudinal opening down one side and a balloon on the other side. The device is passed over a guide wire to the region of stenosis and then the balloon is inflated in order to both fix the device in place and press the longitudinal opening up against the wall of the vessel. A rotating cutting blade (2000 rpm) is then advanced through the cylinder so that any part of the vessel wall projecting through the longitudinal window will be cut away. These pieces are pushed into a distal collecting chamber, which can hold enough for between four and eight passes of the blade. The balloon is then deflated and the device either repositioned for further passes or removed, and the collecting chamber emptied.

There was no difference in primary patency between groups at any time point (log rank  $P = 0.07$ ). The day before the procedure, all participants were commenced on low dose aspirin therapy.

[Shammas 2011](#) compared balloon angioplasty to Silverhawk atherectomy ([Zeller 2004](#)) followed by adjunctive balloon angioplasty in 58 participants with claudication, rest pain or minor tissue loss. The Silverhawk atherectomy device is similar to the Simpson device, described above, except that instead of using a balloon to push the cutting window against the wall of the vessel the cylindrical housing is hinged in the region of the window, with the device flexing away from the window causing the tip and tail of the device to press up against one side of the vessel wall while the window is pressed up against the other side. The remainder of the procedure is similar. There was no difference in primary patency either initially or at 12 months, but bailout stenting was performed significantly less often following atherectomy ( $P = 0.01$ ). One participant in the balloon angioplasty arm required an amputation. In this trial, a distal embolism filter was used in approximately half of the participants. This filter caught macroembolic material significantly more frequently following atherectomy than following balloon angioplasty ( $P = 0.001$ ). If participants were not already established on dual anti-platelet therapy (aspirin and clopidogrel), they were given loading doses of aspirin and clopidogrel immediately prior to the procedure. Participants on established therapy continued on their regular doses.

The final included trial ([Shammas 2012](#)) compared balloon angioplasty to Diamondback atherectomy ([Heuser 2008](#)) followed by adjunctive balloon angioplasty in 50 participants with rest pain or tissue loss and stenosed, calcified vessels. Rather than cutting plaque away from the vessel wall, the Diamondback atherectomy device incorporates an eccentrically mounted abrasive crown on a catheter that rotates at high speed (100,000 rpm) causing plaque to be filed rather than cut away. As a result, individual pieces of plaque are likely to be extremely small, so no system for removing the resulting debris is used. There was no difference in primary patency at any time point (log rank test  $P = 0.14$ ) or rates of bailout stenting ( $P = 0.44$ ). There were no device or procedure related above-knee amputations in either group. Unexpectedly, 6/25 participants in the balloon angioplasty had died by the 12 month follow-up point, though no good explanation of this could be found by the trialists. No participants in the atherectomy arm died. No medication protocol was specified.

## Excluded studies

See [Characteristics of excluded studies](#)

Four studies were excluded. In [Gabrielli 2012](#) and [Gisbertz 2009](#) remote endarterectomy was performed rather than rotational atherectomy. [NCT01579123](#) was excluded as a laser atherectomy

device was used as opposed to the mechanical cutting devices included in this review. The results were therefore not directly comparable. In [Brodmann 2013](#) the patients had a first in-stent reobstruction.

### Ongoing studies

See [Characteristics of ongoing studies](#)

Two studies were ongoing (NCT00986752; NCT01366482), comparing drug coated balloon angioplasty with atherectomy.

### Risk of bias in included studies

The summarised data are included in the [Characteristics of included studies](#) table and [Figure 2](#); [Figure 3](#).

**Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**

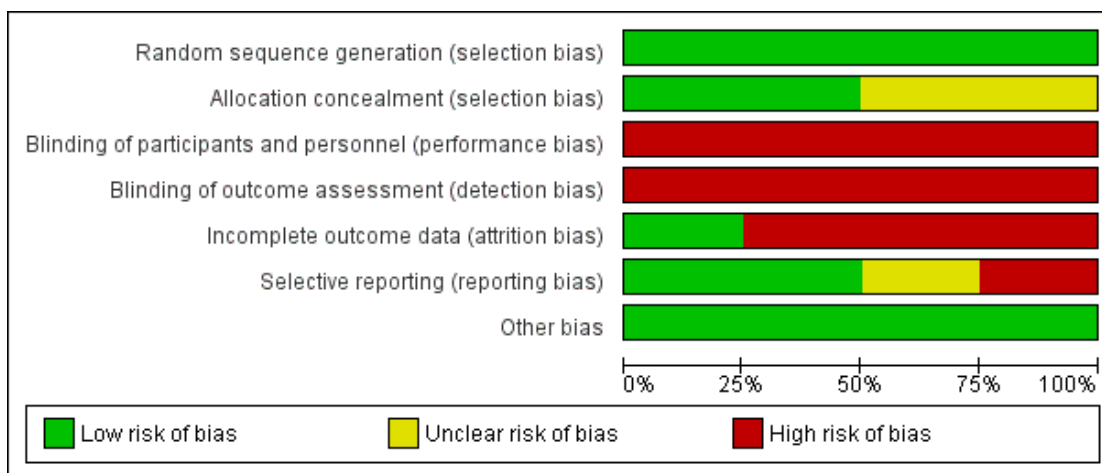


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Nakamura 1995	+	?	-	-	+	?	+
Shammas 2011	+	?	-	-	-	-	+
Shammas 2012	+	+	-	-	-	+	+
Vroegindeweij 1995	+	+	-	-	-	+	+

## Allocation

Nakamura 1995 used a random number table but it was unclear whether confirmation of suitability of participants in terms of inclusion and exclusion criteria were assessed before randomisation. Shammass 2011 used sealed envelopes for randomisation and stated that “randomisation was done after crossing total occlusions”, implying that allocation concealment was unclear. Shammass 2012 and Vroegindeweij 1995 both used sealed envelopes for randomisation and allocated participants only after the inclusion and exclusion criteria were evaluated, implying that allocation concealment was acceptable.

## Blinding

Blinding operators for procedure type is not possible in trials of this nature. Blinding for post-procedure follow-up is possible but does not appear to have been performed in any of the four trials. There was, therefore, significant risk of both performance and detection bias in all four trials.

## Incomplete outcome data

Outcome data at six and 12 months follow-up were incomplete in three of the four studies (Shammass 2011; Shammass 2012; Vroegindeweij 1995) as significant numbers of the initial study population were not followed up to later time points. There was, therefore, significant concern about the presence of attrition bias but patency rates were reported for those participants who were followed up for the appropriate periods of time in all four studies.

## Selective reporting

Primary patencies were fully reported in all studies but some studies failed to completely report all secondary outcomes. Nakamura 1995 reported initial and six month patencies, but only reported ABIs for participants whose vessels remained patent. Shammass 2011 also failed to completely report follow-up ABIs and did not fully report major adverse events. The remaining two studies (Shammass 2012; Vroegindeweij 1995) reported all outcomes fully.

## Other potential sources of bias

No further sources of bias were identified.

## Effects of interventions

All included studies compared atherectomy versus balloon angioplasty. Three studies compared atherectomy plus balloon angioplasty with balloon angioplasty (Nakamura 1995; Shammass 2011; Shammass 2012) and one study compared atherectomy with angioplasty (Vroegindeweij 1995).

Each meta-analysis was performed using both fixed-effect and random-effects models to assess whether the results were robust to changes in this modelling assumption. In no case did this change a significant result to a non-significant result, or vice versa. The values presented below are those obtained using fixed-effect models.

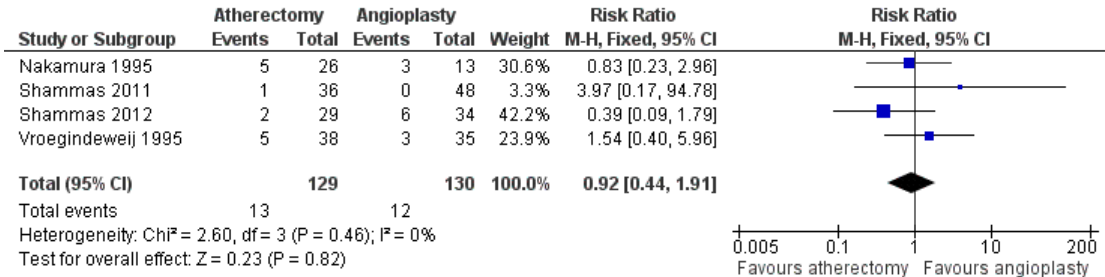
Meta-analyses were also repeated after excluding the study where adjunctive balloon angioplasty was not routinely performed (Vroegindeweij 1995). Again, there was no change in the significance of the results.

## Primary outcomes

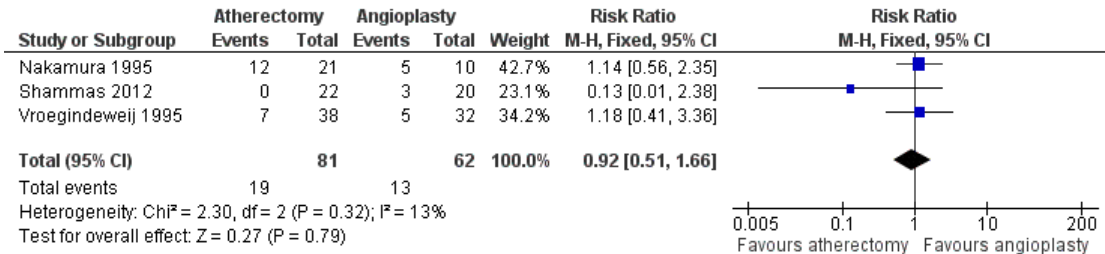
### Primary vessel patency

All four included trials reported initial procedural success rates. None found a between-treatment difference and this was reflected in the meta-analysis, which also found no significant difference between interventions (Mantel-Haenszel RR 0.92, 95% CI 0.44 to 1.91,  $P = 0.82$ ; Figure 4). Three of the studies reported primary patency at six months (Nakamura 1995; Shammass 2012; Vroegindeweij 1995), again without finding significant between-treatment differences. Meta-analysis also failed to find a significant between-procedure difference (Mantel-Haenszel RR 0.92, 95% CI 0.51 to 1.66,  $P = 0.79$ ; Figure 5). Three of the studies reported primary patency at 12 months (Shammass 2011; Shammass 2012; Vroegindeweij 1995) but all found no statistically significant difference between interventions, which was again reflected in the meta-analysis (Mantel-Haenszel RR 1.17, 95% CI 0.72 to 1.90,  $P = 0.53$ ; Figure 6). In all of these cases heterogeneity was low, so fixed-effect models were used and presented.

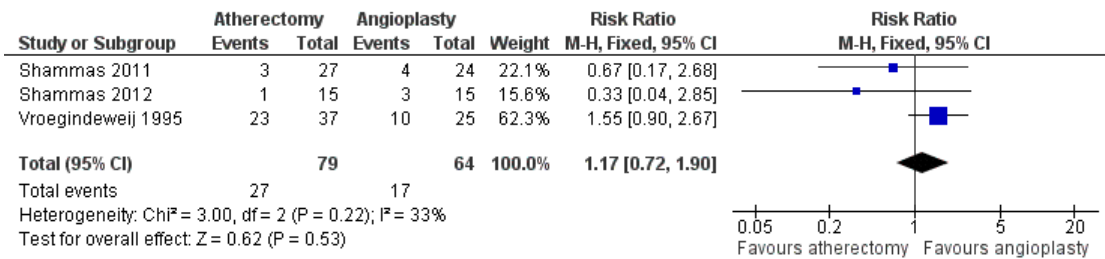
**Figure 4. Forest plot of comparison: I Balloon angioplasty versus atherectomy, outcome: I.1 Initial technical failure rates.**



**Figure 5. Forest plot of comparison: I Balloon angioplasty versus atherectomy, outcome: I.2 6 month vessel occlusion rates.**



**Figure 6. Forest plot of comparison: I Balloon angioplasty versus atherectomy, outcome: I.3 12 month vessel occlusion rates.**



**All-cause mortality**

Two studies (Shammas 2011; Shammas 2012) reported mortality rates at one year. In one of the trials (Shammas 2012) there were an unexpectedly high number of deaths in the balloon angioplasty

arm (6/25 participants), with no deaths in the atherectomy arm, though no good explanation of this could be found by the trialists. In the other trial, there were 4/29 deaths in the balloon angioplasty arm and 2/29 deaths in the atherectomy arm. Meta-analysis of

this endpoint showed that this effect reached significance (Mantel-Haenszel RR 0.24, 95% CI 0.06 to 0.91,  $P = 0.04$ ; Figure 7).

**Figure 7. Forest plot of comparison: I Balloon angioplasty versus atherectomy, outcome: 1.6 Mortality.**



#### Fatal and non-fatal cardiovascular events

No fatal or non-fatal cardiovascular events were reported in any of the included studies. Shammas 2011 declared embolic stroke and myocardial infarction to be secondary outcomes, but none were seen in either the treatment or control arm of the study.

#### Secondary outcomes

#### Immediate procedural and angiographic outcomes

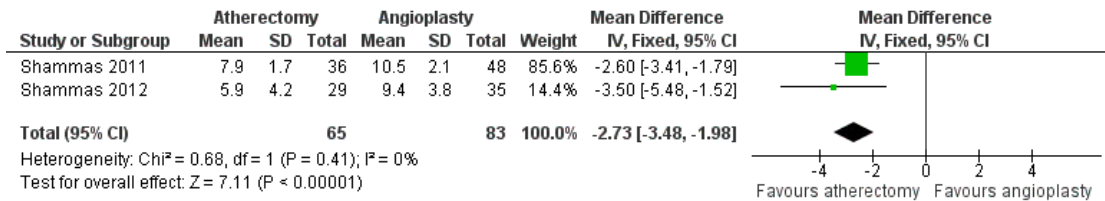
Two studies (Shammas 2011; Shammas 2012) reported rates of bailout stenting with fairly similar indications (presence of severe dissection or > 30% residual stenosis in both studies, also perforation or significant vessel recoil in one of the studies (Shammas 2012)). One of the studies (Shammas 2012) showed a trend towards a greater need for bailout stenting after angioplasty, while the other (Shammas 2011) showed a dramatic reduction in the need for stenting with atherectomy. Meta-analysis confirmed this result (Mantel-Haenszel RR 0.45, 95% CI 0.24 to 0.84,  $P = 0.01$ ; Figure 8). Tests of heterogeneity again did not suggest significant between-study differences.

**Figure 8. Forest plot of comparison: I Balloon angioplasty versus atherectomy, outcome: 1.4 Bailout stenting.**



Two studies (Shammas 2011; Shammas 2012) reported balloon inflation pressures during angioplasty (in both studies balloon angioplasty was routinely performed following atherectomy). Both studies reported significantly lower inflation pressures following atherectomy than during stand-alone balloon angioplasty. Meta-analysis confirmed this finding (mean difference -2.73 mmHg, 95% CI -3.48 to -1.98,  $P < 0.00001$ ; Figure 9).

**Figure 9. Forest plot of comparison: I Balloon angioplasty versus atherectomy, outcome: I.7 Balloon inflation pressure.**



### Target vessel revascularisation rates

Shammas 2011 reported target vessel revascularisation rates at one year, reporting 6/28 vessels in the angioplasty arm and 3/27 in the atherectomy arm. This difference was not statistically significant. None of the other studies reported this outcome separately.

### Complication rates

Shammas 2012 reported that one participant in the atherectomy arm and six participants in the angioplasty arm experienced vessel dissection. Five of these were treated by stent placement, and two (both in the angioplasty arm) were treated with dilatation. One participant in the atherectomy arm received a stent for slow flow and one participant in the angioplasty arm received a stent for vessel recoil. One participant in the angioplasty arm experienced vessel perforation, treated by balloon dilatation, and one participant in the angioplasty arm experienced distal embolisation.

Shammas 2011 reported that one participant in the atherectomy arm who was not treated with a distal embolisation filter had clinically significant distal embolisation requiring mechanical and pharmacological therapy. Seventeen participants in the atherectomy arm were treated with a distal embolisation filter, of whom 11 had macroembolisation with debris larger than 2 mm captured in the filter. None of the 10 participants in the angioplasty group who were treated with a filter had significant debris caught in the filter. No participants treated with a filter had clinically significant embolisation distal to the filter and all filters were removed without further complications.

### Morbidity assessment

Two studies (Shammas 2011; Shammas 2012) reported rates of above-knee amputation at one year. There was only one event in either of the trials (in the angioplasty arm of Shammas 2011) so, given the low event rate and small numbers, it is difficult to draw any meaningful conclusions about this adverse event (Mantel-Haenszel RR 0.33, 95% CI 0.01 to 7.80).

### Quality of life outcomes

The included studies did not report on quality of life outcomes.

### Clinical and symptomatic outcomes

The included studies did not report on clinical and symptomatic outcomes such as walking distance or symptom relief.

### Other outcomes

Vroegindewij 1995 performed a post hoc analysis to assess the effect of lesion length on patency. Using life-table analysis, they showed that atherectomy was equivalent to balloon angioplasty for short lesions (< 2 cm), but for longer lesions long-term patency was significantly better following balloon angioplasty (P = 0.007). Shammas 2011 also reported 30 day and 12 month ABI and Rutherford class, high sensitivity C-reactive protein (CRP) and post-procedural Thrombolysis in Myocardial Infarction (TIMI) flow grade, reporting no significant difference between any of these outcomes in the two treatment arms. Shammas 2012 reported an aggregate major adverse events endpoint, which included amputation, all-cause mortality and need for target lesion revascularisation. Participants in the balloon angioplasty arm were significantly more likely to suffer one of these major adverse events (P = 0.006), although this was affected by the unexpectedly high number of deaths in this trial.

## DISCUSSION

### Summary of main results

The main finding from the four RCTs identified was that there was no primary patency benefit to atherectomy over balloon angioplasty. There was a statistically significant difference in all-cause mortality, likely to be caused by an unexpectedly high mortality in the angioplasty arm of one of the two trials reporting mortality. Cardiovascular events were not reported in any of the trials. There was a reduction in the need for bailout stenting associated with a



reduction in the inflation pressure necessary to achieve an optimal balloon inflation. Complications such as embolisation and vessel dissection were reported in two trials, indicating more embolisations in the atherectomy group and more vessel dissections in the angioplasty group, but the data could not be pooled. No statistically significant differences were found between the atherectomy and balloon angioplasty groups for adverse events, such as data on target vessel revascularisation and above-knee amputation, but the data were limited. Quality of life and clinical and symptomatic outcomes such as walking distance or symptom relief were not reported in the studies. The trials were not adequately powered, had low participant numbers and poor overall quality relating to blinding and poor reporting of outcomes resulting in high risks of bias.

### Overall completeness and applicability of evidence

This represents the only meta-analysis of atherectomy versus any other therapy for peripheral arterial disease to date.

The indication for intervention was claudication in two studies (Nakamura 1995; Vroegindeweyj 1995); claudication, rest pain or tissue loss in another trial (Shammas 2011); and rest pain or tissue loss only in the final study (Shammas 2012). Results of angioplasty and bypass surgery are known to vary between these patient groups (TASC II 2007) and therefore may bias the results between studies. The severity of claudication was impossible to assess in some included studies, which may mean that the results are for patient groups treated conservatively in many UK centres (Frans 2012), so the results should be interpreted with a degree of caution. Unfortunately we were not able to separate results by symptoms (claudication or critical ischaemia) because of the way study results were reported. In addition, the majority of included studies did not report on all of the pre-specified outcomes of this review, so the results of this review are based in most cases on results from only one or two studies.

### Quality of the evidence

All four included studies were of poor quality. In addition, there were differences in patient groups, trial protocols and target vessels. Only one trial (Shammas 2011) showed power calculations to assess the required number of participants. Overall study numbers were low and meta-analysis of such small participant number randomised trials can be unreliable (Rerkasem 2010). As a result, the lack of difference in primary patency that was found could easily be type II error. Medication protocols were not stated in two of the trials (Nakamura 1995; Shammas 2012). This may be important as it is known that antiplatelet, cilostazol, and heparin use are all associated with lower restenosis rates after angioplasty (Robertson 2012). Important clinical endpoints such as secondary patency,

limb survival, and complication rates between techniques were not included in all trials to analyse in detail.

Several factors may contribute to heterogeneity between studies even though from the forest plots this was non-significant. One included study compared atherectomy alone with balloon angioplasty (Vroegindeweyj 1995), whereas the other three trials (Nakamura 1995; Shammas 2011; Shammas 2012) compared atherectomy plus adjunctive balloon angioplasty with balloon angioplasty alone. Superficially this creates concern about heterogeneity, however three participants in the atherectomy arm of Vroegindeweyj 1995 crossed over and had subsequent balloon angioplasty after failure of atherectomy alone. Additionally, balloon pressures reported in two of the other studies following atherectomy were usually very low, so it is likely that these interventions were more similar than they might appear. Sensitivity analysis excluding the Vroegindeweyj 1995 study did not change the statistical significance of the results.

One concern with atherectomy devices is the risk of distal embolisation, since the devices physically cut or grind plaques (Briguori 2003). In one of the included studies (Shammas 2011) this was found to be a particular issue and a distal embolic filter was deployed in 17/29 of participants, which caught macroembolic debris (defined as debris greater than 2 mm in the longest axis) in 11/17 cases. The filter was deployed in 10/29 of the participants in the balloon angioplasty arm but did not catch macroemboli in any cases. In addition, one participant in the atherectomy arm who was treated without a filter had a clinically significant distal embolic event. In contrast, only one other case of distal embolisation was reported in the other three trials (Shammas 2012: one participant in the balloon angioplasty arm had a clinically significant embolic event). As no other studies reported rates of distal embolic filter deployment or macroembolisation, this could not be analysed but remains a specific concern.

Mortality is commonly reported in trials of lower limb revascularisation, which is why it was considered a primary outcome measure. However, the mortality from angioplasty is much lower than is primary patency or limb loss rates (Laird 2010; Schillinger 2006), so trials would not be expected to show a difference if powered to detect primary patency. The results presented may be a consequence of random error due to small sample sizes. There was a statistically significant difference in all-cause mortality that was likely to be caused by an unexpectedly high mortality in the angioplasty arm of one of the two trials reporting all-cause mortality.

The poor overall quality of the included trials is a major limitation of this review. A lack of power calculations, protocol uniformity and heterogeneity between trials means that the conclusions that can be drawn from the analyses are limited. However, what is clear from this review is that there is currently no evidence to support the use of atherectomy as a treatment for peripheral vascular disease.

### Potential biases in the review process

The review process identified only four small trials, so it is difficult to assess the impact of reporting bias. Given the general trend towards the publication of positive findings, especially in the context of new technologies, it is possible that the analysis actually overestimates the benefits of atherectomy over the more established balloon angioplasty.

Some trials (Shammas 2011; Shammas 2012) treated more than one vessel per participant or limb. Failure of patency of any of the treated vessels increases the chances that other treated vessels will cease to be patent, so these observations will be correlated. It is possible, therefore, that the outcomes of these trials are given greater weight in the meta-analysis than is appropriate in the analysis of six month and 12 month patency. As both the angioplasty and atherectomy arms of these trials included multiple vessels per participant it is unlikely that the magnitude of the observed effect has been affected significantly, though our degree of confidence in this effect may be overstated.

### Agreements and disagreements with other studies or reviews

While there were no previous meta-analyses of atherectomy for peripheral arterial disease, atherectomy has been more thoroughly investigated in the coronary arteries. A large meta-analysis comparing multiple randomised trials of atherectomy or other plaque debulking procedures with balloon angioplasty in percutaneous coronary intervention showed no benefit for atherectomy (Bittl 2004). The studies in the analysis by Bittl 2004 were almost all performed in the 1990s, when coronary stenting was still evolving. A meta-analysis of trials comparing coronary stenting with atherectomy followed by stenting has shown that debulking procedures may indeed confer long-term benefit (Niccoli 2006). However, the majority of trials that were analysed were small case-control studies rather than RCTs, and the one large RCT that was analysed failed to show benefit (Stankovic 2004).

Balloon angioplasty for peripheral vascular disease is widely practised, has a clear evidence base and is constantly evolving, with the use of covered stents and drug eluting devices, to improve results (Schillinger 2009; TASC II 2007). As the technique has evolved so has the evidence base for its place compared to exercise therapy and bypass surgery (Bradbury 2010; Mazari 2012). Based on the results of this review the routine use of atherectomy, against balloon angioplasty, cannot be recommended. Performing a properly powered randomised trial of atherectomy versus balloon angioplasty to look at primary patency or limb survival may be inappropriate considering the lack of difference in this analysis, increased technical difficulty, complication rates and the existing 'gold standard' practice of angioplasty. The exception to this may be in patients with TASC C or D lesions who are not fit for bypass surgery. Atherectomy may offer benefit over the relatively poor results of long segment subintimal angioplasty in this patient

group, although results from cohort studies imply that subintimal angioplasty may be superior in this setting (Indes 2010).

Stenting in peripheral arterial disease has been the focus of significant recent attention. Several randomised trials comparing stenting to angioplasty alone have been reported recently, the majority favouring stenting (Dake 2011; Krankenberg 2007; Laird 2010; Schillinger 2006). All of these trials contained significant crossover, with rates of bailout stenting in the control arm ranging from 32% to 50%. In this context, it was unsurprising to find that the rate of bailout stenting in the angioplasty arm of one of the more recent studies was 50%, and 22% in the atherectomy arm (Shammas 2011). More surprising was the unexpectedly low rate of bailout stenting in the angioplasty and stenting arms of the most recent included study (14% and 7% respectively) (Shammas 2012) despite the more permissive indications used in this trial. This may suggest treatment of more minor lesions in the latter study, a possibility which is difficult to verify as summary TASC lesion categories were not published.

In conclusion, there were no high quality trials comparing atherectomy with any other established intervention for peripheral vascular disease. Meta-analysis of four low quality trials comparing atherectomy with balloon angioplasty showed no difference in primary patency rates at any time interval. Given the widespread practice, clear evidence base, and established gold standard guidelines for balloon angioplasty, atherectomy has no place in the routine treatment of people with peripheral arterial disease who are amenable to standard angioplasty. There was no evidence for atherectomy versus bypass surgery, but the use of atherectomy for more severe (TASC C or D) disease when bypass surgery is contraindicated or inappropriate should be limited to clinical trials.

## AUTHORS' CONCLUSIONS

### Implications for practice

This review has identified poor quality evidence to support atherectomy as an alternative to balloon angioplasty in maintaining primary patency at any time interval. With the exception of mortality, there was no evidence for superiority of atherectomy over angioplasty for any outcome, and distal embolisation was not reported in all trials of atherectomy.

The findings of this review are not sufficient to challenge the current widespread practice, clear evidence base, and established gold standard guidelines for balloon angioplasty in the routine treatment of people with peripheral arterial disease who are amenable to standard angioplasty.

### Implications for research

Current evidence in this area is poor. Larger and better designed trials in selected subgroups of participants are needed.

Future trials should be as follows.

1. Better powered to detect smaller differences. Existing evidence is sufficient to say that there is no large overwhelming benefit of atherectomy but a more moderate benefit could still exist.
2. Have participants separated into claudicant and critically ischaemic groups.
3. More rigorous with follow-up. Existing studies rate poorly in terms of outcome assessment blinding and subject attrition. It

is important that future studies have both longer follow-up and blinded outcome assessment. As the procedures are often performed by interventional radiologists but followed up by vascular surgeons, this latter point should not be too difficult to achieve.

## ACKNOWLEDGEMENTS

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Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FGR, et al. on behalf of the TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease. *International Angiology* 2007;**26**(2):81–157.

**Watson** 2008

Watson L, Ellis B, Leng GC. Exercise for intermittent claudication. *Cochrane Database of Systematic Reviews* 2008, Issue 4. [DOI: 10.1002/14651858.CD000990.pub2]

**Zeller** 2004

Zeller T, Rastan A, Schwarzwälder U, Frank U, Bürgelin K, Amantea P, et al. Percutaneous peripheral atherectomy of femoropopliteal stenoses using a new-generation device: six-month results from a single-center experience. *Journal of Endovascular Therapy* 2004;**11**(6):676–85.

\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

Nakamura 1995

Methods	Randomisation: random number table	
Participants	Country: United States of America No. of participants: 39: - 2.7 mm TEC atherectomy plus balloon angioplasty: 13 - 4.0 mm TEC atherectomy plus balloon angioplasty: 13 - balloon angioplasty: 13. Age (mean (years) $\pm$ SD): - 2.7 mm TEC: 64 $\pm$ 6 - 4.0 mm TEC: 70 $\pm$ 6 - balloon angioplasty: 61 $\pm$ 4.1 Inclusion criteria: occluded SFA with 1 - 2 block claudication Exclusion criteria: those with previous femoro-popliteal graft or "insufficient run-off vessels"	
Interventions	Balloon angioplasty versus 2.7 mm TEC atherectomy plus balloon angioplasty versus 4.0 mm TEC atherectomy plus balloon angioplasty	
Outcomes	Initial and 6 month vessel patency Pre-procedure and 6 month ankle-brachial pressure index (6 month ABI only reported for participants with primary patency at 6 months)	
Notes		
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Random number table used for randomisation
Allocation concealment (selection bias)	Unclear risk	Not specifically stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Neither participants nor personnel were blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	No mention of blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Complete data available to 6 months

**Nakamura 1995** (Continued)

Selective reporting (reporting bias)	Unclear risk	Initial and 6 month patencies reported. Ankle-brachial pressure index only reported for subjects whose vessels remained patent at 6 months
Other bias	Low risk	No other potential source identified

**Shammas 2011**

Methods	Randomisation: sealed envelopes
Participants	<p>Country: United States of America</p> <p>No. of participants: participants: 58; vessels: 84</p> <ul style="list-style-type: none"> <li>- Silverhawk atherectomy plus balloon angioplasty: participants: 29; vessels: 36</li> <li>- balloon angioplasty: participants: 29; vessels: 48</li> </ul> <p>Age (mean (years) ± SD):</p> <ul style="list-style-type: none"> <li>- atherectomy: 67.4 ± 9.1</li> <li>- balloon angioplasty: 70.9 ± 13.9</li> </ul> <p>Inclusion criteria: adults with claudication, rest pain or minor tissue loss</p> <p>Exclusion criteria: (i) heavily calcified vessels; (ii) total occlusions longer than 10 cm or any total occlusion with suspicion of subintimal wire recanalisation, (iii) inability to take aspirin or adenosine diphosphate receptor antagonists, (iv) bleeding disorder or platelet count less than 100,000/L, (v) creatinine level greater than 2.5 mg/dL, (vi) unwillingness to give consent or return for future follow-up visits, (vii) ongoing active infection, (viii) decompensated congestive heart failure or acute coronary syndrome, or (ix) a staged vascular procedure during the same hospital stay or 1 week after the index procedure</p>
Interventions	Balloon angioplasty versus Silverhawk atherectomy with adjunctive balloon angioplasty
Outcomes	<p>Primary: Target lesion revascularisation at 1 year</p> <p>Secondary:</p> <ul style="list-style-type: none"> <li>(i) The rate of “bailout” stent implantation because of suboptimal acute angiographic results, defined as a residual stenosis of more than 30% or the presence of type C-F dissection</li> <li>(ii) Final acute angiographic results in each arm at the end of the procedure</li> <li>(iii) Target vessel revascularisation at 1 year</li> <li>(iv) Major adverse events including major amputation, death, distal embolisation, vascular complications (arteriovenous fistula, pseudoaneurysm, or perforation), major bleeding (loss of 3U of packed red blood cells with a source of bleeding, or intracranial or retroperitoneal bleeding), unplanned urgent revascularisation of the treated vessel in the same hospital stay, myocardial infarction, embolic stroke, and renal failure (i.e., increase in creatinine clearance by 25% versus pre-procedure baseline)</li> <li>(v) Change in the ankle-brachial index at 1 month, 6 months, and 1 year after the procedure versus baseline</li> </ul>
Notes	
<i>Risk of bias</i>	

**Shammas 2011** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sealed envelopes used for randomisation
Allocation concealment (selection bias)	Unclear risk	Not specifically stated, but appears to have been acceptable: Authors state "Randomization was performed after total occlusions were crossed"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated, but impractical in trials of this type
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not stated, probably not done
Incomplete outcome data (attrition bias) All outcomes	High risk	Primary outcome only reported for 51/84 vessels
Selective reporting (reporting bias)	High risk	Secondary outcomes (iv) and (v) incompletely reported
Other bias	Low risk	No other potential source identified

**Shammas 2012**

Methods	Randomisation: sealed envelopes
Participants	<p>Country: United States of America</p> <p>No. of participants: participants: 50; vessels: 64</p> <ul style="list-style-type: none"> <li>- Diamondback atherectomy plus balloon angioplasty: participants: 25; vessels: 29</li> <li>- balloon angioplasty: participants: 25; vessels: 35</li> </ul> <p>Age (mean (years) ± SD):</p> <ul style="list-style-type: none"> <li>- atherectomy: 70.7 ± 13.4</li> <li>- balloon angioplasty: 71.8 ± 10.9</li> </ul> <p>Inclusion criteria: adults with rest pain or tissue loss (Rutherford class 4 - 6). Also angiographic stenosis &gt; 50%, fluoroscopically-visible calcium &gt; 25% of the treated segment, atherectomy wire must cross all lesions with no subintimal wire passage, main target vessel reference diameter &gt; 1.5 mm, more than one patent distal runoff vessel with brisk flow for any treated popliteal segment, distal portion of anterior tibial or posterior tibial target vessel must reconstitute to the ankle or foot and only proximal one third of the peroneal artery to be treated; distal two thirds must reconstitute</p> <p>Exclusion criteria: (i) inability to understand study or history of non-compliance with medical advice, (ii) unwilling or unable to sign informed consent form, (iii) currently enrolled in another study that may interfere with study endpoints, (iv) unsuccessful treatment of target leg superficial femoral artery or proximal vessel on procedure day, (v) pregnant or planning to become pregnant within study period, (vi) known sensitivity</p>



	to contrast media that cannot be adequately premedicated, (vii) chronic renal failure/creatinine level > 2.0 mg/dL unless on chronic dialysis, (viii) one or more of the popliteal or below-knee lesions to be treated are within a stent, (ix) known allergy to heparin, aspirin, or clopidogrel, (x) history of bleeding disorders or platelet count < 80,000 cells/mL, (xi) ongoing cardiac problems that would interfere with study procedures, (xii) stroke or transient ischaemic attack within 4 weeks prior to procedure, (xiii) anticipated lifespan < 1 year, (xiv) known or suspected active systemic infection, (xv) thrombus present or suspected in the target vessel, (xvi) concomitant thrombectomy/other atherectomy device treatment in target vessel, (xvii) investigator's medical judgment excludes subject from the study
Interventions	Balloon angioplasty versus Diamondback atherectomy with adjunctive balloon angioplasty
Outcomes	Primary: ability to achieve adequate lumen diameter, defined as < 30% residual stenosis with no bailout stenting or dissection Secondary: rate of bailout stenting; limb salvage at 30 days, 6 months and 12 months; target lesion and vessel revascularisation (TLR/TVR) at 6 and 12 months; and major adverse events (a composite of above-knee amputation, mortality from all causes, and TLR/TVR)
Notes	

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sealed envelopes provided to all centres for randomisation
Allocation concealment (selection bias)	Low risk	Randomisation performed only after inclusion and exclusion criteria assessed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated, but impractical in trials of this type
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not stated, probably not done
Incomplete outcome data (attrition bias) All outcomes	High risk	Secondary outcomes reported for only 33/50 participants
Selective reporting (reporting bias)	Low risk	All outcomes reported, though significant attrition present
Other bias	Low risk	No other potential source identified

## Vroegindewei 1995

Methods	Randomisation: Numbered envelopes opened sequentially
Participants	Country: Netherlands No. of participants: 73 Simpson atherectomy: 38 Balloon angioplasty: 35 Age (mean (years) range): Atherectomy: 64 (range 49 - 77) Balloon angioplasty: 64 (range 46 - 80) Inclusion criteria: intermittent claudication of at least 3 months duration and obstructive lesions of the femoropopliteal arteries with a maximum length of 5 cm or complete occlusions shorter than 2 cm Exclusion criteria: any previous ipsilateral femoropopliteal endovascular or operative intervention; participant unable to comply with the frequent follow-up visits required by the protocol
Interventions	Balloon angioplasty versus Simpson atherectomy
Outcomes	(i) Primary patency during follow-up (ii) Restenosis as determined by duplex ultrasound
Notes	Four participants crossed over to the other treatment group: three participants had angioplasty following atherectomy, one participant had atherectomy in addition to angioplasty. Results were presented in an intention-to-treat format

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Numbered envelopes opened sequentially
Allocation concealment (selection bias)	Low risk	Randomisation not performed until after inclusion and exclusion criteria evaluated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated, but impractical in trials of this type
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not stated, probably not done
Incomplete outcome data (attrition bias) All outcomes	High risk	Three participants in the balloon angioplasty group were not followed up to six months. One participant in the atherectomy group and 10 in the balloon angioplasty group were not followed up to one year

**Vroegindewij 1995** (Continued)

Selective reporting (reporting bias)	Low risk	Primary patency reported fully in life-table format; restenosis presented graphically
Other bias	Low risk	No other potential source identified

ABI: ankle brachial index

SD: standard deviation

SFA: superficial femoral artery

TEC: transluminal extraction catheter

TLR: target lesion revascularisation

TVR: target vessel revascularisation

**Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
Brodmann 2013	Patients with a first in-stent reobstruction
Gabrielli 2012	Remote endarterectomy rather than atherectomy
Gisbertz 2009	Remote endarterectomy rather than atherectomy
NCT01579123	Laser atherectomy versus angioplasty

**Characteristics of ongoing studies** [ordered by study ID]

**NCT00986752**

Trial name or title	Efficacy study of stenting, paclitaxel eluting balloon or atherectomy to treat peripheral artery disease (ISAR-STATH)
Methods	RCT Allocation: randomised Intervention model: parallel assignment Masking: single blind (outcomes assessor)
Participants	Peripheral vascular disease Male or female 18 years and older Inclusion criteria: <ul style="list-style-type: none"> <li>● symptomatic <math>\geq</math> 70% stenosis of the SFA (Rutherford stage 2 - 6)</li> <li>● written informed consent</li> </ul> Exclusion criteria:

**NCT00986752** (Continued)

	<ul style="list-style-type: none"> <li>● acute ischaemia and/or acute thrombosis of the SFA</li> <li>● untreated ipsilateral iliac artery stenosis &gt; 70%</li> <li>● previous stenting of the SFA</li> <li>● popliteal stenosis &gt; 70%</li> <li>● severe renal insufficiency</li> </ul>
Interventions	<p>Arm 1: stenting (Smart stent) (Due to randomisation one nitinol stent will be implanted after dilation with a conventional balloon)</p> <p>Arm 2: stenting after paclitaxel eluting balloon (Smart stent, Invatec) (Due to randomisation one nitinol stent will be implanted after dilation with a paclitaxel eluting balloon)</p> <p>Arm 3: atherectomy (SilverHawk device)</p>
Outcomes	<p>Primary outcome measures:</p> <ul style="list-style-type: none"> <li>● percentage diameter stenosis (time frame: 6 months) (designated as safety issue: no)</li> </ul> <p>Secondary outcome measures:</p> <ul style="list-style-type: none"> <li>● all-cause mortality (time frame: 6 and 24 months) (designated as safety issue: yes)</li> <li>● major adverse peripheral events (MAPE) defined as acute thrombosis of SFA or ipsilateral amputation or revascularisation (PTA or bypass surgery) (time frame: 6 months) (designated as safety issue: yes)</li> <li>● time to onset of any of MAPE (time frame: 3 - 24 months) (designated as safety issue: yes)</li> <li>● binary restenosis rate (time frame: 6 months) (designated as safety issue: no)</li> <li>● percentage diameter stenosis in duplex ultrasound (time frame: 6 and 24 months) (designated as safety issue: no)</li> <li>● change from baseline in functional status and health related quality of life (Walking Impairment Questionnaire) (time frame: 3 and 6 months)</li> </ul>
Starting date	July 2009
Contact information	Klaus Tiroch
Notes	

**NCT01366482**

Trial name or title	Atherectomy followed by a drug coated balloon to treat peripheral arterial disease (DEFINITIVE AR)
Methods	<p>RCT</p> <p>Allocation: randomised</p> <p>Intervention model: parallel assignment</p> <p>Masking: double blind (subject, outcomes assessor)</p>
Participants	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> <li>● Rutherford clinical category 2 - 4</li> <li>● at least 18 years of age</li> <li>● is able and willing to provide written informed consent prior to study specific procedures</li> </ul> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> <li>● has a life expectancy of less than 24 months</li> <li>● is pregnant, of childbearing potential not taking adequate contraceptive measures, or nursing</li> <li>● has one or more of the contraindications listed in the SilverHawk/TurboHawk or Cotavance</li> </ul>

	instructions for use
Interventions	<p>Arm 1: Cotavance drug-eluting balloon (treatment with a paclitaxel coated angioplasty balloon (without preceding plaque excision))</p> <p>Arm 2: TurboHawk/SilverHawk device followed by a Cotavance drug eluting balloon (plaque excision followed by treatment with a paclitaxel coated angioplasty balloon)</p> <p>Arm 3: TurboHawk/SilverHawk device followed by a Cotavance drug eluting balloon (non-randomised arm; subjects with severe calcification will be assigned to a non-randomised arm and treated with plaque excision followed by a drug eluting balloon)</p>
Outcomes	<p>Primary outcome measures:</p> <ul style="list-style-type: none"> <li>target lesion percent stenosis (time frame: 1 year) (designated as safety issue: no)</li> </ul>
Starting date	July 2011
Contact information	Professor Thomas Zeller
Notes	

PTA: percutaneous transluminal angioplasty

RCT: randomised controlled trial

SFA: superficial femoral artery

## DATA AND ANALYSES

### Comparison 1. Balloon angioplasty versus atherectomy

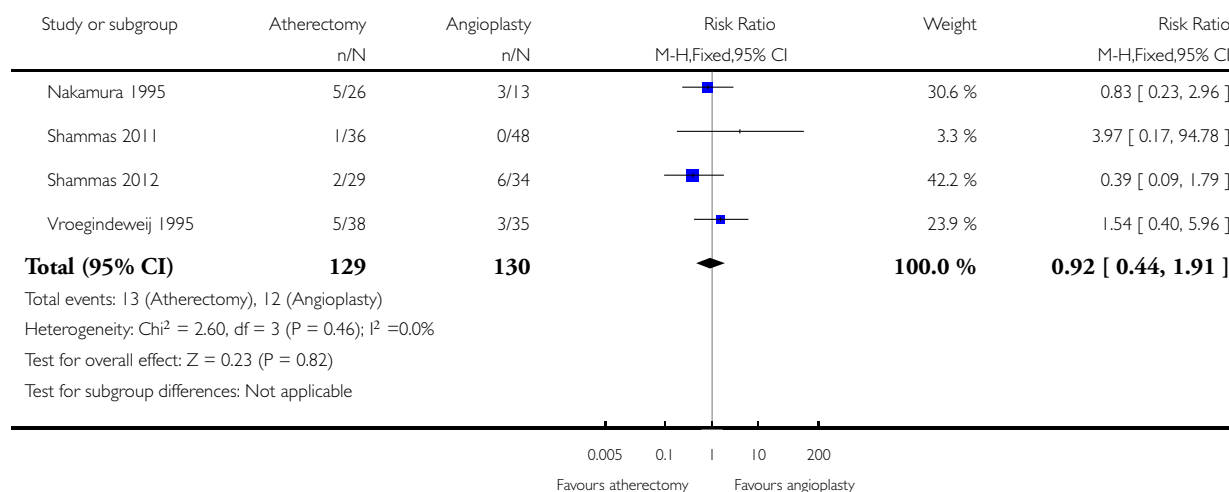
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Initial technical failure rates	4	259	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.44, 1.91]
2 6 month vessel occlusion rates	3	143	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.51, 1.66]
3 12 month vessel occlusion rates	3	143	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.72, 1.90]
4 Mortality	2	108	Risk Ratio (M-H, Fixed, 95% CI)	0.24 [0.06, 0.91]
5 Amputation	2	76	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.80]
6 Bailout stenting	2	148	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.24, 0.84]
7 Balloon inflation pressure	2	148	Mean Difference (IV, Fixed, 95% CI)	-2.73 [-3.48, -1.98]

#### Analysis 1.1. Comparison 1 Balloon angioplasty versus atherectomy, Outcome 1 Initial technical failure rates.

Review: Atherectomy for peripheral arterial disease

Comparison: 1 Balloon angioplasty versus atherectomy

Outcome: 1 Initial technical failure rates

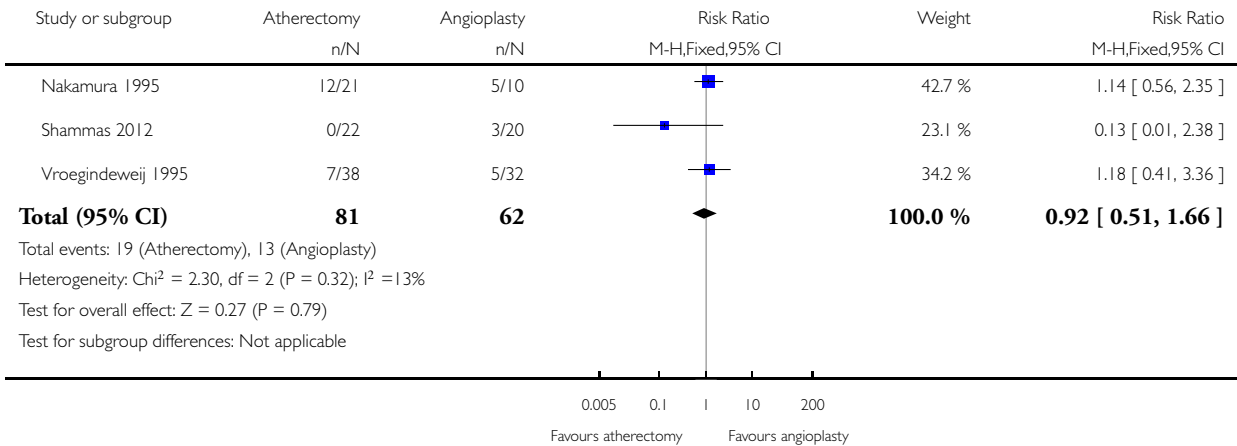


**Analysis 1.2. Comparison 1 Balloon angioplasty versus atherectomy, Outcome 2 6 month vessel occlusion rates.**

Review: Atherectomy for peripheral arterial disease

Comparison: 1 Balloon angioplasty versus atherectomy

Outcome: 2 6 month vessel occlusion rates

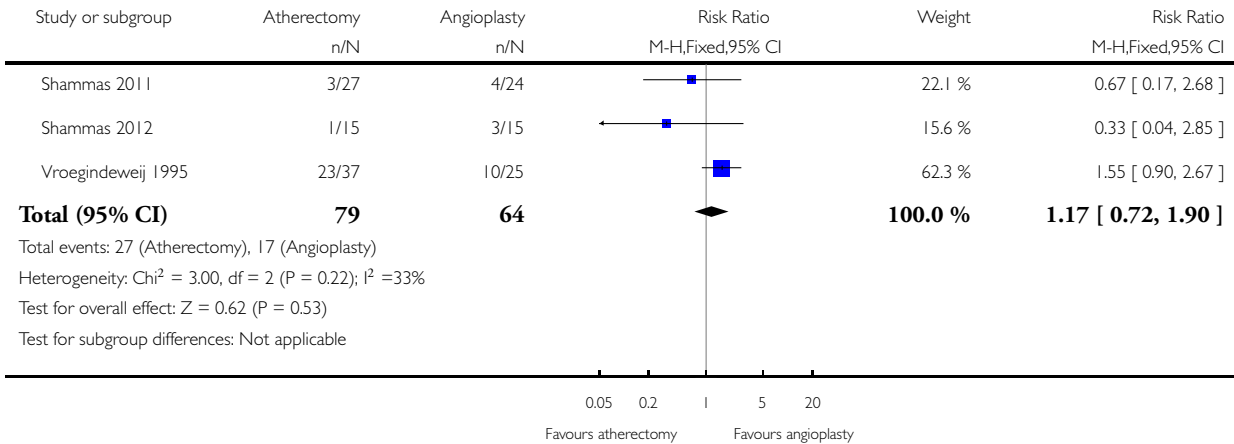


### Analysis I.3. Comparison I Balloon angioplasty versus atherectomy, Outcome 3 12 month vessel occlusion rates.

Review: Atherectomy for peripheral arterial disease

Comparison: I Balloon angioplasty versus atherectomy

Outcome: 3 12 month vessel occlusion rates

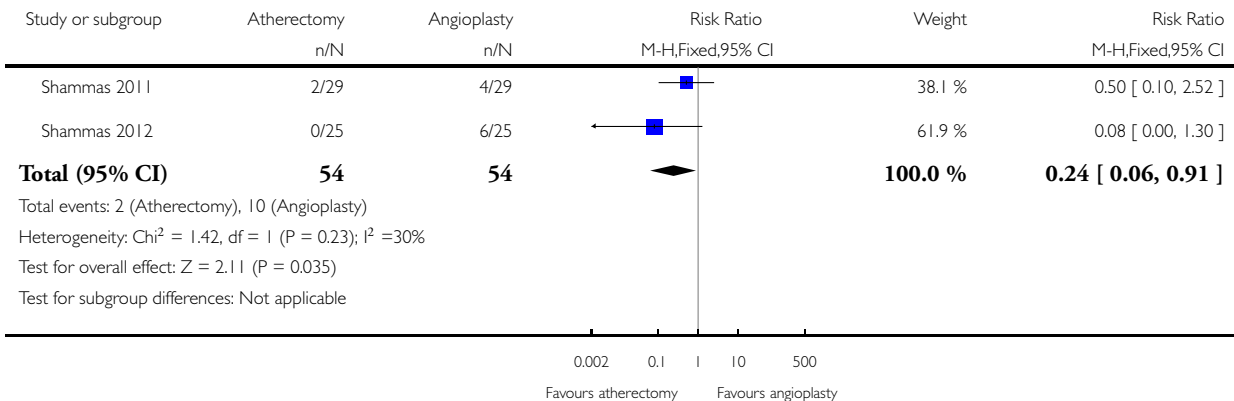


### Analysis I.4. Comparison I Balloon angioplasty versus atherectomy, Outcome 4 Mortality.

Review: Atherectomy for peripheral arterial disease

Comparison: I Balloon angioplasty versus atherectomy

Outcome: 4 Mortality



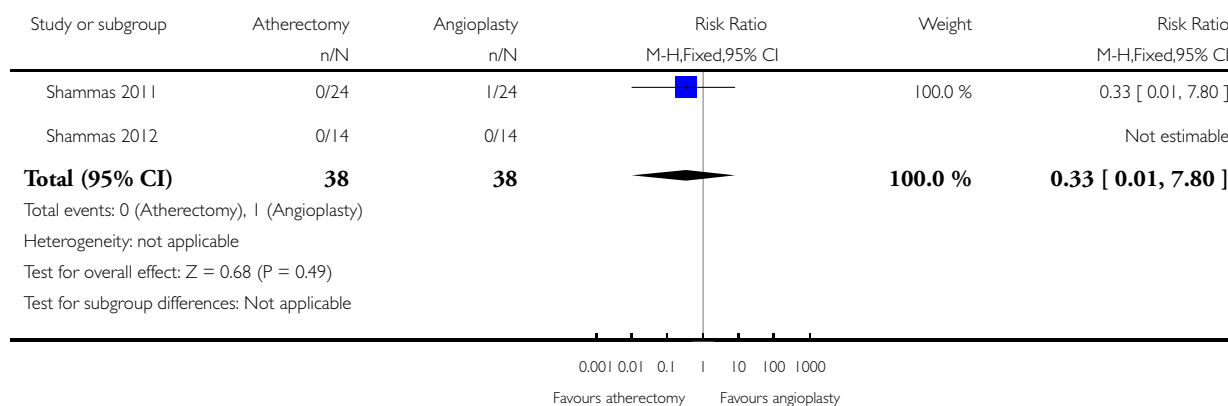


### Analysis 1.5. Comparison 1 Balloon angioplasty versus atherectomy, Outcome 5 Amputation.

Review: Atherectomy for peripheral arterial disease

Comparison: 1 Balloon angioplasty versus atherectomy

Outcome: 5 Amputation

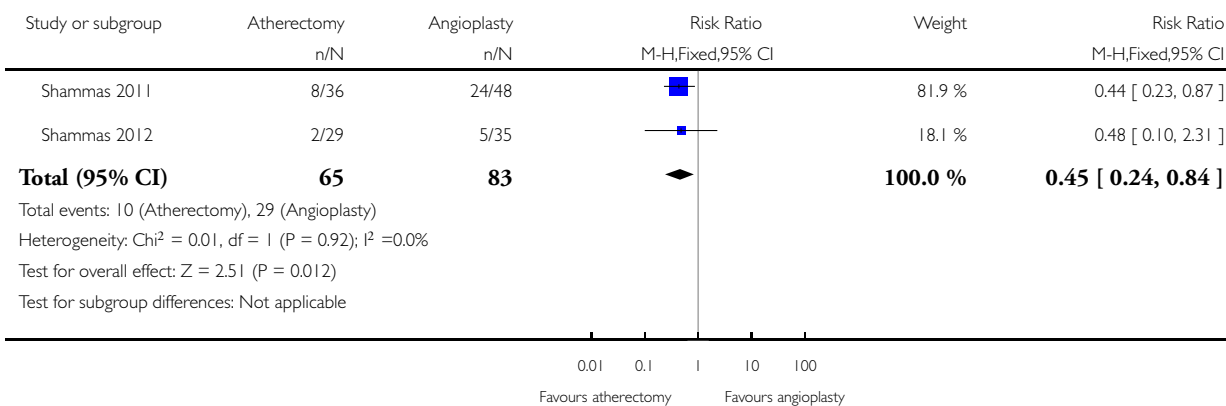


### Analysis 1.6. Comparison 1 Balloon angioplasty versus atherectomy, Outcome 6 Bailout stenting.

Review: Atherectomy for peripheral arterial disease

Comparison: 1 Balloon angioplasty versus atherectomy

Outcome: 6 Bailout stenting

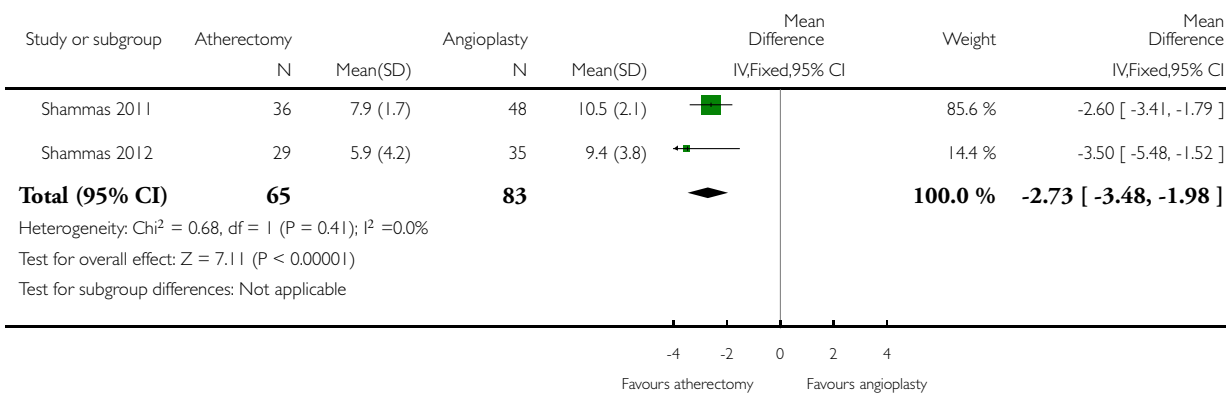


### Analysis 1.7. Comparison 1 Balloon angioplasty versus atherectomy, Outcome 7 Balloon inflation pressure.

Review: Atherectomy for peripheral arterial disease

Comparison: 1 Balloon angioplasty versus atherectomy

Outcome: 7 Balloon inflation pressure



## APPENDICES

### Appendix I. CENTRAL search strategy

#1	MeSH descriptor: [Arteriosclerosis] this term only	894
#2	MeSH descriptor: [Arteriolosclerosis] this term only	0
#3	MeSH descriptor: [Arteriosclerosis Obliterans] this term only	72
#4	MeSH descriptor: [Atherosclerosis] this term only	423
#5	MeSH descriptor: [Arterial Occlusive Diseases] this term only	775
#6	MeSH descriptor: [Intermittent Claudication] this term only	729
#7	MeSH descriptor: [Ischemia] this term only	771
#8	MeSH descriptor: [Peripheral Vascular Diseases] explode all trees	2202
#9	MeSH descriptor: [Vascular Diseases] this term only	396
#10	MeSH descriptor: [Leg] explode all trees and with qualifiers: [Blood supply - BS]	1092
#11	MeSH descriptor: [Femoral Artery] explode all trees	739
#12	MeSH descriptor: [Popliteal Artery] explode all trees	263
#13	MeSH descriptor: [Iliac Artery] explode all trees	152
#14	MeSH descriptor: [Tibial Arteries] explode all trees	30
#15	(atherosclero* or arteriosclero* or PVD or PAOD or PAD)	18024
#16	(arter*) near (*occlus* or steno* or obstuct* or lesio* or block* or obliter*)	5003
#17	(vascular) near (*occlus* or steno* or obstuct* or lesio* or block* or obliter*)	1437
#18	(vein*) near (*occlus* or steno* or obstuct* or lesio* or block* or obliter*)	756
#19	(veno*) near (*occlus* or steno* or obstuct* or lesio* or block* or obliter*)	1012

(Continued)

#20	(peripher*) near (*occlus* or steno* or obstruct* or lesio* or block* or obliter*)	1393
#21	peripheral near/3 dis*	3407
#22	arteriopathic	20
#23	(claudic* or hinken*)	1497
#24	(isch* or CLI)	17493
#25	dysvascular*	29
#26	leg near/4 (obstruct* or occlus* or steno* or block* or obliter*)	191
#27	limb near/4 (obstruct* or occlus* or steno* or block* or obliter*)	244
#28	(lower near/3 extrem*) near/4 (obstruct* or occlus* or steno* or block* or obliter*)	149
#29	(aort* or iliac or femoral or popliteal or femoro* or fempop* or crural) near/3 (obstruct* or occlus*)	340
#30	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29	41325
#31	MeSH descriptor: [Atherectomy] this term only	25
#32	atherect*:ti,ab,kw (Word variations have been searched)	199
#33	SilverHawk or "Silver Hawk"	7
#34	Jetstream:ti,ab,kw (Word variations have been searched)	1
#35	plaque near/3 excis*:ti,ab,kw (Word variations have been searched)	7
#36	atheroablation or rotational or orbital:ti,ab,kw (Word variations have been searched)	648
#37	angle near/3 blade*:ti,ab,kw (Word variations have been searched)	8
#38	cut near/3 blade*:ti,ab,kw (Word variations have been searched)	8

(Continued)

#39	blade near/3 cathet*:ti,ab,kw (Word variations have been searched)	0
#40	EV3:ti,ab,kw (Word variations have been searched)	11
#41	#31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40	824
#42	#30 and #41 in Trials	119

## HISTORY

Protocol first published: Issue 3, 2007

Review first published: Issue 3, 2014

Date	Event	Description
29 October 2008	Amended	Converted to new review format.

## CONTRIBUTIONS OF AUTHORS

Graeme Ambler: decided which trials should be included, assessed trial quality, extracted data, wrote the review text.

Rami Radwan: identified all possible trials.

Paul Hayes: reviewed review text.

Christopher Twine: decided which trials should be included, cross checked data extraction, assessed trial quality, reviewed and edited review text.

## DECLARATIONS OF INTEREST

None known

## SOURCES OF SUPPORT

### Internal sources

- No sources of support supplied

### External sources

- Chief Scientist Office, Scottish Government Health Directorates, The Scottish Government, UK.  
The PVD Group editorial base is supported by the Chief Scientist Office.

- National Institute for Health Research (NIHR), UK.  
The PVD Group editorial base is supported by a programme grant from the NIHR.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The quality of the trials has been assessed using the risk of bias assessments as per current recommendations from The Cochrane Collaboration ([Higgins 2011](#)).

## INDEX TERMS

### Medical Subject Headings (MeSH)

Angioplasty, Balloon [\*methods; mortality]; Atherectomy [\*methods; mortality]; Peripheral Arterial Disease [mortality; \*therapy]; Randomized Controlled Trials as Topic; Stents

### MeSH check words

Humans