**Ligation alone versus immediate revascularisation for femoral artery pseudoaneurysms secondary to intravascular drug use: a systematic review and meta-analysis**

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**Abstract**

Background

Femoral artery pseudoaneurysms (FA-PSAs) remain a common vascular aneurysmal pathology associated with intravascular drug use (IVDU). To date no internationally agreed consensus regarding optimal surgical management of FA-PSAs exists. The aim of this systematic review and meta-analysis was to determine the optimal surgical treatment of FA-PSAs associated with IVDU.

Methods

A systematic search was undertaken following PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines identifying original studies reporting outcomes of ligation-debridement and/or excision-revascularisation of FA-PSAs secondary to IVDU. Outcomes of interest were 30-day mortality, incidence of amputation at 12 months, chronic limb threatening ischaemia (CLTI) at any follow-up appointment, reintervention and bleeding.

Findings

A total of 39 cohort studies describing 1217 femoral artery pseudoaneurysm operative outcomes met inclusion criteria, 993 (81.6%) treated by ligation-debridement and 224 (18.4%) by excision-revascularisation. The incidence of 30-day mortality was 0.8% (n=8) and 1.3% (n=3) in the ligation-debridement and excision-revascularisation groups respectively, with only one study reporting mortality in both groups. This meta-analysis found no difference in amputation (8.89% vs 8.03%, OR 0.74 95% CI 0.35-1.56, P=0.42, 11 studies) or CLTI (21.5% vs 12.4%, OR 1.24 95% CI 0.35-4.38, P=0.74, 9 studies) following ligation and debridement compared with excision and revascularisation. There was a higher incidence of reintervention (24.7% vs 10.6%, OR 0.31 [ 95% CI 0.16, 0.62, P=0.0009, 13 studies) and rebleeding (7.1% vs 1.6%, (OR 0.61 [95% CI 0.16, 2.38], P=0.48, 5 studies) following excision and revascularisation compared with ligation alone.

Conclusion

For treatments of IVDU related FA-PSAs, this study suggests no significant difference in association of mortality, incidence of amputation, or chronic limb threatening ischaemia with ligation-debridement or excision-revascularisation, but a significantly higher reintervention rate and greater rebleeding rate for revascularized patients.

Key words: Femoral artery, pseudoaneurysm, false aneurysm, ligation, amputation, IVDU, drug abuse

**Ligation alone versus immediate revascularisation for femoral artery pseudoaneurysms secondary to intravascular drug use: a systematic review and meta-analysis**

**Introduction**

A femoral artery pseudoaneurysm (FA-PSA) is a common arterial consequence of repeated non-sterile puncture for recreational intravascular drug use (IVDU) and manifests in any combination of the common femoral, superficial femoral or profunda femoris arteries. The World Health Organisation estimate that 13 million people worldwide undertake IVDU and users are at a substantially higher risk of multiple health issues including contracting blood borne infections and endocarditis (1). In the UK, death from drug misuse is at the highest level since records began in 1993 (2). Repeated vessel wall trauma or periarterial injection leading to necrosis of vascular tissue allows pseudoaneurysm formation contributing to IVDU associated morbidity and mortality. Clinical presentation comprises of a pulsatile mass in the groin which can be associated with haemodynamic compromise from rupture or septic complications secondary to infective sequalae. Without prompt intervention this challenging patient group are at significant risk of limb loss, sepsis, catastrophic haemorrhage and death (3).

Non-surgical techniques to treat pseudoaneurysms include manual compression or ultrasonographic guided thrombin injection, however these are often inappropriate in this cohort of patients given widespread arterial wall damage (4). Surgical ligation of the affected vessel is an effective procedure but is associated with sequelae including chronic limb threatening ischemia and, at worst, major lower limb amputation. In attempt to avoid these complications, revascularisation can be performed at the time of index procedure, delayed, or not undertaken at all, and techniques include in situ reconstruction or extra anatomic bypass. However, a previous review by Coughlin et al (2006) suggested there is significant morbidity from immediate revascularisation with a high incidence of graft infection and major limb amputation when treating an infected pseudoaneurysm (5). Amputation in this review was 8% for ligation alone and 12% following revascularisation. Immediate reconstruction is challenging if there is concurrent infection and in this cohort of patients often no suitable autologous conduit is available. Globally both ligation and revascularisation methods are attempted in the management of FA-PSAs associated with IVDU, with differing local protocols on optimal surgical intervention (6). The modern era of vascular surgery benefits from more efficacious antibiotic management, imaging with increased sensitivity, newer synthetic conduits and the advent of biological material. Despite this there remains much debate regarding the optimal surgical approach and timing of intervention in IVDUs and no internationally agreed consensus exists.

This systematic review and meta-analysis aimed to analyse the clinical outcomes of different surgical techniques for the treatment of infected and non-infected FA-PSA secondary to IVDU and report outcomes including incidence of mortality, amputation, chronic limb threatening ischemia (CLTI) and reintervention.

**Materials and methods**

This review adhered to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta‐Analysis) guidelines and recommendations for systematic reviews of observational studies (7).

***Data sources***

A search was undertaking through Embase and Medline without time constraint for all articles published until 1st April 2020 evaluating the operative management of femoral pseudoaneurysms in adults, with no language restriction.

***Search strategy and study selection***

The search was conducted using the following Medical Search Headings which were exploded as appropriate: ‘false\*’, ‘pseudo-an\*’ ‘pseudoan\*’, ‘femoral\*’, and ’ligation’. Studies were selected that were randomised controlled trials, case-control studies, and cohort studies that reported operative femoral pseudoaneurysm outcomes in any context. Studies were selected only if they contained a detailed report of operative outcomes in adults. Importantly, if femoral pseudoaneurysm operative outcomes were grouped with other anatomically located operative results or true aneurysm operative results which were not reported separately, the study was excluded. This review excluded non-English articles, literature reviews, case reports, conference abstracts, editorials, and letters. Duplicates were removed and two reviewers (AAS and JA) independently screened titles and abstracts to identify articles meeting inclusion criteria and any discrepancies were resolved by consensus with the senior author (PWS). References of included studies were reviewed to identify further articles for potential inclusion.

***Data extraction***

Two reviewers (AAS and JA) independently extracted relevant information from each operative report using a standardised data extraction proforma with one author (PWS) reviewing all extracted data. We captured: administrative information including authorship, institution, and year of publication; cohort data including participants demographics and operative methods; primary outcome measures of 30-day mortality, 12-month mortality; and secondary outcome measures including chronic limb threatening ischaemia, reintervention and rebleeding. Reintervention was defined as return to theatre and calculated per patient and rebleeding defined as bleeding requiring return to theatre. The quality of reporting of results was assessed using the Newcastle-Ottawa quality assessment form for non-randomised controlled trials (8).

***Analysis***

An initial descriptive analysis was performed assessing operative interventions for femoral pseudoaneurysms and their sequelae following data capture. Meta-analysis was performed on Review Manager Version 5.3. A P value of <0.05 was considered significant. Overall effect was calculated using a Z-test and random effects models and data is presented as odds ratios [95% confidence intervals]. Publication bias was assessed using funnel plots for meta-analysis which included more than 10 studies.

**Results**

A total of 489 articles were identified and after duplicates were removed 361 records were screened for eligibility. A total of 53 articles were reviewed in detail of which 39 studies were included in the quantitative synthesis (see Figure 1 for PRISMA flow diagram). Publication dates ranged from 1974-2020.

***Study characteristics***

Study size ranged from 4 to 387 participants with a total of 1652 patients. Once screened for presence of a FA-PSA secondary to IVDU a total of 1217 FA-PSA were included. 993 (81.6%) were treated by ligation-debridement and 224 (18.4%) by excision-revascularisation. All included studies were retrospective single centre case series and study characteristics are found in Table 1 (9–46). At presentation, 74% of patients had confirmed infection of the pseudoaneurysm and 33% presented with frank rupture.

Immediate revascularisation was performed in 21 studies. Six studies reported this approach as standard, four chose a ‘selective’ approach, non-selective approach was utilised in five studies and no rationale provided in six studies. The ‘selective’ approach involved either use of intraoperative doppler of pedal arteries following clamping (13,32), use of distal pulse oximetry after test clamp (11) or based on degree of preoperative ischemia (19).

***Outcomes***

The incidence of 30-day mortality was 0.8% (n=8) and 1.3% (n=3) in the ligation-debridement and excision-revascularisation groups respectively. There was no significant difference in the pooled amputation rate between ligation-debridement or ligation-revascularisation (6.6% vs 6.3%, P=0.8). This meta-analysis identified 11 eligible studies (n=270 v n=137) reporting amputation within the two groups and found no difference (8.89% vs 8.03%, OR 0.74 [95% CI 0.35, 1.56], P=0.42) following ligation-debridement compared with excision-revascularisation (Figure 2).

Reintervention rates (Figure 3) were significantly higher following excision-revascularisation versus ligation and debridement (24.7% vs 10.6%, OR 0.31 [95% CI 0.16, 0.62, P=0.0009, 13 studies). Chronic limb threatening ischaemia in the two groups was reported in 9 studies (n=209 vs n=121) with no significant difference (21.5% vs 12.4%, OR 1.24 [95% CI 0.35, 4.38], P=0.74) following ligation-debridement compared with excision-revascularisation (Figure 4). There was a higher incidence of rebleeding following excision and revascularisation (7.1% vs 1.6%, n=16 vs n=16) but meta-analysis of five eligible studies revealed no significant difference (OR 0.61 [95% CI 0.16, 2.38], P=0.48).

A total of 17 studies reported the number of vessels ligated. Triple ligation of the common femoral, superficial femoral and profunda femoris artery was the most common (53.1%, 220/414) followed by single (12.8%, 153/414) and double (9.9%, 41/414) ligation. Only 10 of these studies reported results based on location and number of ligations. Four studies reported a trend of increasing incidence of amputation with higher number of ligations, especially if the common femoral bifurcation was involved (9,17,30,32). Two studies reported triple ligation was associated with higher incidence of claudication (18,35). However, four studies reported no significant difference in amputation, claudication or CLTI between those with single, double or triple ligation (19,36,42,44).

Following ligation-debridement a total of 38 patients required emergent revascularisation due to limb ischemia. Artificial conduits (PTFE or Dacron) were used in all of these cases. There was a high incidence of graft infection (12.5%, 28/224) and graft occlusion (10.3%, 23/224) following immediate revascularisation.

Infection of the femoral pseudoaneurysm was reported in 33 studies. In total, 901 cases were described as infected and microbiology results were described in 49.5%. The predominant isolated pathogen on wound culture was S*taphylococcus species* (77.8%) followed by *Escherichia coli* (4.7%), *Streptococcus species* (4.3%) and *Pseudomonas species* (1.3%). Mixed growth was described in 8.3%.

***Quality Assessment***

All included studies were case-control or cohort studies and were assessed for risk of bias using the Newcastle-Ottawa Quality Assessment Form as displayed in Supplementary Table 1. The overall quality of studies was fair to poor. All included studies selected relevant cases and comparators when possible however, the vast majority of these participants were enrolled retrospectively through medical record review. Measurement of outcomes was performed well throughout studies, with operative complications and outcomes being described when possible. Overall missing data bias was moderate as the majority of studies had some form of loss to follow up due to a challenging patient cohort and were not able to adjust for this in their analyses. Furthermore, a select few studies had limited reporting of results and pooling of results with no clear matching of patient specific operative factors and outcomes. No publication bias was detected for meta-analysis which included more than 10 studies (Supplementary Figure 1).

**Discussion**

This systematic review and meta-analysis reports no difference in 30-day mortality or amputation rates between patients undergoing ligation and debridement or excision and revascularisation for FA-PSA in intravenous drug users. Historically, early acute limb ischemia or chronic limb threatening ischemia are perceived to be a risk of ligation and debridement alone, with amputation rates reported up to 33% in the general population (30). We found no evidence to support this in the FA-PSA associated with IVDU cohort, with ligation with debridement alone representing a feasible, safe and efficacious initial intervention. Chronic IVDU is hypothesised to lead to development of collateral arterial circulation which could be important if ligation alone is undertaken. The potential presence of distal embolization from intraarterial inject could also impact revascularisation success. This may explain why rates of CLTI were not significantly different between both approaches in this study.

The indication for undertaking immediate revascularisation is poorly reported. Intraoperative doppler assessment after test clamp was performed by some authors (13,32) and similarly distal tissue oxygen saturation was performed by Jaiswal et al (11). Commonly ‘non-selective’ revascularisation was performed with no explanation of rationale for this approach. It is possible some of those with ‘selective revascularisation’ were patients with triple vessel ligation who were at higher risk of limb complications, partly explaining higher incidence of postoperative complications.

A limitation of this review is only 10 studies stratified results based on site and number of ligations, with no clear association determined. The location of the FA-PSA is important as it determines how many vessels may require ligation and the potential resulting ischemic sequalae. An isolated ligation of the profunda femoris will undoubtably lead to less distal ischemia than that of the common femoral but it was not possible to determine this due to poor reporting of data. Future work in this field must report these parameters to allow more meaningful analysis.

Several revascularisation techniques were reported including in situ versus extra anatomic bypass using conduits including vein, synthetic or internal iliac artery. The most common extra anatomic bypass routes were lateral femoral and obturator. However, reintervention rates were significantly higher in the excision and revascularisation group. Prosthetic conduit material is susceptible to infection and high rates of this complication were seen – even in extra-anatomic bypass (6,37). A graft should only be placed through a field where infective control has been achieved but this is often difficult in infected FA-PSA patients and lack of infective source control could have contributed to the high incidence for graft infection reported. Rebleeding rates were reported between 13-25% where an infected field was present (37,45). Immediate revascularisation can also be a technically challenging procedure requiring a longer operative time and advanced wound management techniques such as sartorius pedicled flap in the presence of extensive debridement (47), which may not be appropriate in an unstable patient. Due to repeated iatrogenic injury, superficial veins are generally unavailable in this cohort with a high degree of artificial conduits used. It has also been reported that bypass conduits have been used for ongoing recreational drug access (13).

Given the high proportion of concurrent infection reported, empirical antimicrobial therapy is indicated. The predominant pathogen by far was *Staphylococcus aureus* but clinicians must be aware of patients with methicillin resistant species. Most studies did not include a definition of criteria for classifying a FA-PSA as infected and this diagnosis was predominantly clinical. Certainly, both preoperative blood samples and intraoperative tissue samples should be sent for extended microbiological analysis to tailor antimicrobial regimens. Whilst awaiting sensitivities broad spectrum cover should be initiated and those with bypass conduits a prolonged course should be considered.

The results of the present meta-analysis need to be interpreted in the context of limitations. This analysis is limited by the quality of included studies and the paucity of robust evidence within this field. No randomised or blinded design trials were identified, and all studies were prone to the inherent bias associated with retrospective reviews. Indeed, it would be very challenging to undertake a randomised prospective trial in these patients which may explain the lack of these studies. The retrospective studies included were undertaken in countries across the world reflecting different clinical settings, with an expected heterogeneity across the populations included in this meta-analysis. In this analysis it was not feasible to attempt to control for confounders such as clinical and demographic patient factors, institute level service factors, and timing of surgery. There was significant variation in indication for revascularisation and six studies did not provide any rationale for the approach. While these findings suggest that there is no detrimental impact to the patient of undertaking ligation alone, further work needs to be conducted focusing on the individual criteria for revascularisation in this patient cohort beyond unit or surgeon preference, in addition to establishing robust follow up methods. Further prospective studies assessing which patients are at risk of amputation, which revascularisation techniques are most appropriate, and which graft materials provide the optimum outcomes should be undertaken.

**Conclusion**

This systematic review and meta-analysis suggests that there is no significant difference in mortality, incidence of amputation or chronic limb threatening ischaemia in intravascular drug users following ligation-debridement or excision-revascularisation for femoral artery pseudoaneurysms. Ligation-debridement is a safe, feasible initial operative strategy and immediate revascularisation is associated with a significantly higher incidence of reintervention. There is a shortage of high-quality unbiased studies reporting outcomes in femoral artery pseudoaneurysms in IVDU.

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**Author contributions**

AAS – study design, systematic review, meta-analysis, writing and editing manuscript

JA - study design, systematic review, meta-analysis, editing manuscript

PWS – editing and final approval of manuscript

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**Figures and Tables**

**Figure 1**

309 articles excluded

Reasons:

* Written in non-English language (45)
* Article investigating true aneurysm or false aneurysm in alternative anatomical location (147)
* Letters, conference abstracts, case reports, review articles (109)
* Full text unavailable (8)

Identification of relevant records using the databases of EMBASE and MEDLINE with search terms ‘false\*’, ‘pseudo-an\*’ ‘pseudoan\*’, ‘femoral\*’, and ’ligation’ (n = 487)

Records after duplicates removed (n = 361)

Records screened for full text review (n = 361)

Additional records identified through reference lists (n = 2)

Full text articles assessed for eligibility (n = 52)

13 articles excluded

Reasons:

* Pooled analysis of outcomes at different anatomical sites (10)
* Surgical technique not meeting inclusion criteria (2)
* Anatomical site not meeting inclusion criteria (1)

Studies included in quantitative synthesis (n = 39)

Screening

Identification

Eligibility

Included

**Figure 2**

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**Figure 3**

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**Figure 4**

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**Table 1**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study | Total patients | FA-PSA included | Infection | Rupture | Intervention | Newcastle-Ottawa score |
| Al Shakari 2019 | 25 | 27 | 27 | 0 | Ligation and debridement n=27 | 4 |
| Anderson 1974 | 16 | 3 | 3 | 3 | Ligation and debridement n=3 | 4 |
| Arora 2001 | 6 | 6 | 6 | 0 | Ligation and debridement n=6 | 6 |
| Behera 2003 | 46 | 34 | 34 | 28 | Ligation and debridement n=30, excision and revascularisation n=4 | 6 |
| Benjamin 1999 | 7 | 5 | 5 | 0 | Excision and revascularisation n=5 | 6 |
| Cheng 1992 | 19 | 21 | 21 | 3 | Ligation and debridement n=19, excision and revascularisation n=2 | 6 |
| Elahwal 2019 | 26 | 26 | 26 | 16 | Ligation and debridement n=26 | 4 |
| Gan 2000 | 34 | 37 | 37 | 14 | Ligation and debridement n=37 | 6 |
| Georgiadis 2007 | 26 | 15 | - | - | Excision and revascularisation n=15 | 6 |
| Hu 2010 | 55 | 54 | 54 | 54 | Ligation and debridement n=54 | 6 |
| Jaiswal 2020 | 32 | 10 | 10 | - | Ligation and debridement n=7, excision and revascularisation n=3 | 3 |
| Klonaris 2007 | 14 | 14 | 14 | 4 | Ligation and debridement n=1, Excision and revascularisation n=13 | 6 |
| Kozelj 2006 | 4 | 4 | 4 | 3 | Excision and revascularisation n=4 | 4 |
| Lasikarizedeh 2011 | 21 | 16 | - | 5 | Ligation and debridement n=14, excision and revascularisation n=2 | 4 |
| Levi 1997 | 8 | 7 | 3 | 1 | Ligation and debridement n=2, excision and revascularisation n=5 | 3 |
| Li 2014 | 387 | 88 | - | - | Ligation and debridement n=56, excision and revascularisation n=32 | 5 |
| Mcilroy 1989 | 60 | 55 | 55 | 5 | Ligation and debridement n=43, excision and revascularisation n=12 | 4 |
| Mohammedzade 2009 | 32 | 32 | 32 | - | Ligation and debridement n=32 | 4 |
| Moini 2008 | 50 | 23 | 23 | - | Ligation and debridement n=20, excision and revascularisation n=3 | 4 |
| Mousavi 2010 | 134 | 134 | 134 | 57 | Ligation and debridement n=134 | 5 |
| Naqi 2006 | 17 | 16 | - | 9 | Ligation and debridement n=16 | 6 |
| Naqi 2010 | 40 | 40 | - | - | Ligation and debridement n=40 | 4 |
| Padberg 1992 | 23 | 15 | 9 | 2 | Ligation and debridement n=6, excision and revascularisation n=9 | 6 |
| Patel 1988 | 16 | 15 | 15 | 0 | Excision and revascularisation n=15 | 5 |
| Peirce 2009 | 9 | 8 | 7 | 2 | Ligation and debridement n=8 | 5 |
| Qiu 2016 | 81 | 83 | 8 | 65 | Ligation and debridement n=83 | 4 |
| Quanming 2009 | 63 | 63 | 63 | 52 | Ligation and debridement n=14, excision and revascularisation n=49 | 5 |
| Rabbani 2008 | 9 | 8 | 8 | 5 | Excision and revascularisation n=8 | 6 |
| Rammell 2017 | 4 | 4 | 4 | 1 | Ligation and debridement n=4 | 6 |
| Reddy 1986 | 53 | 54 | 54 | 7 | Ligation and debridement n=44, excision and revascularisation n=10 | 4 |
| Salimi 2008 | 57 | 55 | - | - | Ligation and debridement n=55 | 6 |
| Samarakoon 2020 | 27 | 25 | 25 | 3 | Ligation and debridement n=23, excision and revascularisation n=2 | 4 |
| Stevenson 2017 | 55 | 55 | 55 | 27 | Ligation and debridement n=55 | 5 |
| Tan 2009 | 15 | 13 | 13 | - | Ligation and debridement n=8, excision and revascularisation n=5 | 5 |
| Ting 1997 | 33 | 34 | 34 | 8 | Ligation and debridement n=34 | 6 |
| Welch 1990 | 6 | 6 | 6 | 1 | Excision and revascularisation n=6 | 5 |
| Wu 2010 | 21 | 21 | - | 14 | Excision and revascularisation n=21 | 4 |
| Yegane 2006 | 65 | 41 | 15 | 7 | Ligation and debridement n=34, excision and revascularisation n=9 | 4 |
| Zainal 1998 | 56 | 51 | - | - | Ligation and debridement n=51 | 4 |

**Table 2**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intervention | Total cases | Primary outcomes | | Secondary outcomes | | |
| **Amputation** | **Death** | **Rebleeding** | **Reintervention** | **CLTI** |
| Ligation and debridement | 993 | 66 (6.6%) | 8 (0.8%) | 17 (1.7%) | 120 (12.1%) | 177 (17.8%) |
| Excision and revascularisation | 224 | 14 (6.3%) | 3 (1.3%) | 17 (7.6%) | 47 (21.0%) | 17 (7.6%) |
| Total | 1217 | 80 | 11 | 34 | 147 | 194 |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Supplementary Table 1 | | | | | | | | | |
|  | | **Selection** | | | | **Comparability** | **Outcome of interest** | | |
| Study | | Is the case definition adequate? | Representativeness of the cases | Selection of controls | Definition of controls | Comparability of cohorts | Outcome assessment | Same methods of ascertainment for case and controls | Non-response rate |
| Al Shakari | 2019 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Anderson | 1974 | \* | 0 | \* | \* | 0 | \* | 6 | 0 |
| Arora | 2001 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Behera | 2003 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Benjamin | 1999 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Cheng | 1992 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Elahwal | 2019 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Gan | 2000 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Georgiadis | 2007 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Hu | 2010 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Jaiswal | 2019 | \* | 0 | \* | \* | 0 | 0 | 0 | 0 |
| Klonaris | 2007 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Kozelj | 2006 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Lasikarizedeh | 2011 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Levi | 1997 | \* | 0 | \* | \* | 0 | 0 | 0 | 0 |
| Li | 2014 | \* | 0 | \* | \* | 0 | \* | 0 | \* |
| Mcllroy | 1989 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Mohammedzade | 2007 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Moini | 2008 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Mousavi | 2010 | \* | 0 | \* | \* | 0 | \* | \* | 0 |
| Naqi | 2005 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Naqi | 2009 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Padberg | 1992 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Patel | 1988 | \* | 0 | \* | \* | 0 | \* | \* | 0 |
| Peirce | 2009 | \* | 0 | \* | \* | 0 | \* | \* | 0 |
| Qiu | 2016 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Quanming | 2009 | \* | 0 | \* | \* | 0 | \* | 0 | \* |
| Rabbani | 2008 | \* | 0 | \* | \* | - | \* | \* | \* |
| Rammell | 2017 | \* | 0 | \* | \* | - | \* | \* | \* |
| Reddy | 1986 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Salimi | 2008 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Samarakoon | 2020 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Stevenson | 2017 | \* | 0 | \* | \* | 0 | \* | \* | 0 |
| Tan | 2009 | \* | 0 | \* | \* | 0 | \* | \* | 0 |
| Ting | 1997 | \* | 0 | \* | \* | 0 | \* | \* | \* |
| Welch | 1990 | \* | 0 | \* | \* | - | \* | \* | 0 |
| Wu | 2010 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Yegane | 2006 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |
| Zainal | 1998 | \* | 0 | \* | \* | 0 | \* | 0 | 0 |

**Supplementary Figure 1**

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**Legends**

Figure 1 – Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram of study selection

Figure 2 – Forest plot of studies reporting amputation following ligation and debridement or excision revascularisation. CI = confidence interval; M-H = Mantel Haenszel odds ratio

Figure 3 - Forest plot of studies reporting reintervention following ligation and debridement or excision revascularisation. CI = confidence interval; M-H = Mantel Haenszel odds ratio

Figure 4 – Forest plot of studies reporting chronic limb threatening ischemia following ligation and debridement or excision revascularisation. CI = confidence interval; M-H = Mantel Haenszel odds ratio

Table 1 – Characteristics of studies included in the systematic review

Table 2 – Summary of outcomes. Data presented as n (%)

Supplementary Table 1 – Newcastle Ottawa scale for risk of bias

Supplementary Figure 1 – Funnel plot of studies reporting amputation. SE(log[OR]) = standard error (log[odds ratio])