Eur J Vasc Endovasc Surg (2019) 57, 382—391

REVIEW

# Editor's Choice — Infrainguinal Bypass Following Failed Endovascular Intervention Compared With Primary Bypass: A Systematic Review and Meta-Analysis☆

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**WHAT THIS PAPER ADDS**

This is the first systematic review of primary infrainguinal bypass after previous failed endovascular interventions for infrainguinal peripheral arterial disease. Pooled data of 11,886 patients shows improved one year amputation free survival in the patients who had primary bypass (OR 1.61; 95% CI 1.14—2.29) compared with patients who had bypass after failed endovascular therapy. There was also a trend towards higher rates of graft occlusion and worse one year primary patency for patients with prior failed endovascular intervention.

**Objectives:** Patients with infrainguinal peripheral arterial disease often undergo multiple revascularisation procedures. Although many centres have adopted an endovascular first approach, some are reluctant to do so for fear of compromising the outcomes of any subsequent bypasses. All studies that compared the outcomes of primary infrainguinal bypass with bypass after failed endovascular intervention were analysed.
**Methods:** A systematic review was conducted of MEDLINE, EMBASE, and CENTRAL databases for studies comparing outcomes of primary infrainguinal bypass with bypass after failed endovascular intervention for peripheral arterial disease. Abstracts and full text studies were screened independently by two reviewers with data abstraction done in duplicate. Dichotomous outcome measures were reported using the OR and 95% CI, and pooled using random effects models.
**Results:** Abstracts were screened (2,528), with 50 selected for full text review. Of these, 15 studies involving 11,886 patients met the inclusion criteria. Pooling the results of studies comparing primary bypass with bypass after failed endovascular intervention showed no significant difference in 30 day mortality (OR 1.00; 95% CI 0.65—1.54), or 30 day amputation rates (OR 1.26; 95% CI 0.95—1.65). Interestingly, one year amputation free survival was higher in the patients who had primary bypass (OR 1.30; 95% CI 1.10—1.52) compared with patients who had bypass after failed endovascular therapy. There was also worse one year primary patency (OR 1.65; 95% CI 1.04—2.62) for patients with prior failed endovascular intervention. The review demonstrated a trend towards higher rates of early graft occlusion (OR 4.54; 95% CI 0.97—21.28).
**Conclusions:** Meta-analysis of the existing literature comparing primary bypass with bypass following failed endovascular intervention shows worse one year amputation free survival and worse primary patency in those patients who undergo bypass after failed endovascular intervention. There is also a trend towards higher rates of early graft occlusion, although these results were not statistically significant. These conclusions are limited by observational study design, inconsistent patient selection, and significant heterogeneity between studies.

**Keywords:** Amputation, Angioplasty and stent, Critical limb ischaemia, Endovascular intervention, Graft occlusion, Peripheral arterial disease
Article history: Received 5 March 2018, Accepted 20 September 2018, Available online 2 November 2018


☆ Presented as a podium presentation at the Canadian Society of Vascular Surgery annual meeting in Banff, Alberta, September 16, 2017.
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https://doi.org/10.1016/j.ejvs.2018.09.025

## INTRODUCTION

Both surgical bypass and endovascular intervention have become well recognised modalities for the treatment of peripheral arterial disease (PAD).[1] Endovascular therapy offers a minimally invasive alternative to patients and can often be performed under local anaesthesia. With ongoing advances in endovascular technology, many surgeons and interventionalists have adopted an endovascular first strategy.[2] Others have remained cautious for fear of damaging outflow vessels and potentially compromising the outcome of any subsequent surgical bypass.[3] Endovascular failure may also complicate or even preclude a previously feasible open bypass opportunity, leaving the patient with fewer treatment options.[4–6] Existing studies are contradictory as some centres have reported equivalent outcomes following an endovascular first approach, whereas others found worse outcomes when bypass after failed endovascular intervention is compared with primary bypass.[3,7]

This is a systematic review and meta-analysis of all studies that compared primary infrainguinal bypass with bypass after failed endovascular intervention for PAD to determine whether bypass after failed endovascular intervention leads to inferior outcomes.

## METHODS

The protocol for this study was registered with the Prospective Register of Systematic Reviews (PROSPERO registration number CRD42017058030). This systemic review and meta-analysis was performed as per the Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[8,9]

### *Study selection*

Randomised control trials (RCTs) and observational studies reporting comparative outcomes of primary bypass and bypass after failed endovascular revascularisation of the lower extremity were considered for inclusion. For studies to be included they had to report on outcomes after both primary bypass and bypass after failed endovascular intervention. Excluded studies included patients who underwent intervention for reasons other than PAD and studies with less than one year follow up.

### *Literature search*

The electronic literature search was performed in consultation with a professional clinical librarian experienced in systematic reviews. A systematic literature search was conducted in the following electronic bibliographic databases: United States National Library of Medicine's database (MEDLINE via Ovid), Excerpta Medica database (EMBASE), and the Cochrane Central Register of Controlled Trials (CENTRAL). A combination of search terms (keywords and subject headings), such as vascular grafting, revascularisation, endovascular surgery, endovascular procedures, peripheral occlusive artery disease, critical limb ischaemia, leg artery, and lower limb were used to identify eligible studies. A detailed description of the MEDLINE search strategy can be found in Appendix I, with the final search occurring on September 6, 2018. No language restrictions were applied. The grey literature including conference abstracts and conference publications was reviewed for relevance through EMBASE. Dissertations relating to the topic were also searched using the Open Access Theses and Dissertations webpage (https://oatd.org/). Bibliographies of selected articles were searched manually for any additional relevant studies.

Two investigators (SH, DL) screened all titles and abstracts collected from the search strategy for relevance and full text review. The same reviewers used a standardised form to collect data in duplicate from included articles. Disagreements in data abstraction or study inclusion were resolved by consensus meeting or by input from a third reviewer (LD). Extracted data included study characteristics (year of publication, number of patients, study design, location), patient characteristics (age, gender, vascular risk factors, statin and antiplatelet use), graft characteristics (autogenous saphenous vein or prosthetic), mean length of follow up, and distal target vessel for open bypass. Non-English abstracts were translated before review by the authors.

### *Outcome definition*

Primary patency was defined as patency without any need for re-intervention. Secondary patency was achieving patency of a graft that had previously been occluded. Major amputation was defined as any above ankle amputation. Critical limb isch-aemia was defined as rest pain, non-healing ulcers, or gangrene across all studies. If a study reported outcomes by the Kaplan–Meier curve only, the numerical results were extrapolated as previously described.[10]

### *Quality assessment*

Two authors (SH, DL) independently assessed the quality of each included study. Discrepancies were resolved by discussion and a consensus decision. Observational studies were evaluated using the Newcastle-Ottawa Scale to assess the risk of bias.[11] For RCTs, the Cochrane risk of bias tools were used. The Newcastle-Ottawa Scale uses a star system ranging from 0 to 9 stars, which covers three categories: the selection of cohorts, the comparability of groups, and the adequacy of outcome assessment and reporting. A study was considered high quality if the NOS score was $\geq$ 7. Moreover, the system developed by the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) working group was used to categorise the quality of evidence as high, moderate, low, or very low, based on within study directness of evidence, consistency of results, risk of bias, precision of effect estimates, and heterogeneity.[12]

### *Statistical analysis*

The results from each study were pooled using random effects model to generate summary OR and 95% CI for each outcome using Revman 5.3 (The Cochrane Collaboration, Copenhagen, 2014). Heterogeneity was assessed using the $I^2$ statistic which indicates the proportion of in between study variability that is not a result of chance. Anything with an $I^2 > 50\%$ was considered to represent significant heterogeneity.[13] Results of the Cochrane Q test for heterogeneity were also reported, although this test is often under powered when only a small number of studies are included. Publication bias was assessed by looking for asymmetry on a funnel plot generated for one year primary patency, as this was the most commonly reported outcome measure across the included studies.

## RESULTS

### *Study selection*

A total of 3693 articles were found through the literature review, with no other studies identified through additional sources. After removal of duplicate citations, 2528 studies were identified for screening by title and abstraction. From this review, 50 studies were included for full text review. Thirty-five articles were excluded, including nine abstracts, three commentary articles, a review article, and a single study protocol. Eleven studies did not report the primary outcomes of interest, three studies did not have a comparator group, and six studies did not include the relevant patient population. One study contained duplicate analysis of data from another included study. A bibliography of excluded full text studies can be found in Appendix II. The study by Gavrilenko et al. was translated from the Russian language.[14] Fig. 1 summarises the results of the literature search.

One RCT and fourteen retrospective observational studies reporting on the comparison between primary lower extremity bypass and bypass following prior failed endovascular therapy were included.[14–28] Agreement between raters for study inclusion was excellent ($\kappa = 0.9$). The study population consisted of 11,886 limbs of which 9410 limbs underwent infrainguinal bypass and 2476 limbs underwent bypass after prior failed endovascular intervention (Table 1). The studies were published between 2005 and 2018. Critical limb ischaemia was the indication for infrainguinal bypass in 10 studies, while the other four included a mix of claudication and critical limb ischaemia patients.

Table 2 presents demographic data according to treatment group. Jones et al. grouped demographic data for patients who had secondary bypass after both failed endovascular and open procedures.[27] The outcomes data were obtained specifically for patients with bypass after prior failed endovascular intervention. Two retrospective studies did not indicate the proportion who received autologous vein conduits or prosthetic bypass[16,20] (Table 3). Prosthetic grafts with vein cuff, vein patch, and all other composite grafts that were not exclusively great saphenous vein were listed as prosthetic bypass for clarity in Table 3. The trials varied in terms of use of distal pedal targets; and Santo et al. presented data that included patients undergoing failed iliac artery endovascular interventions in addition to failed infrainguinal interventions.[21] Authors of included studies were contacted to provide clarification and additional data, when required. Jones et al. were contacted regarding the Kaplan–Meier curves plotting MALE free

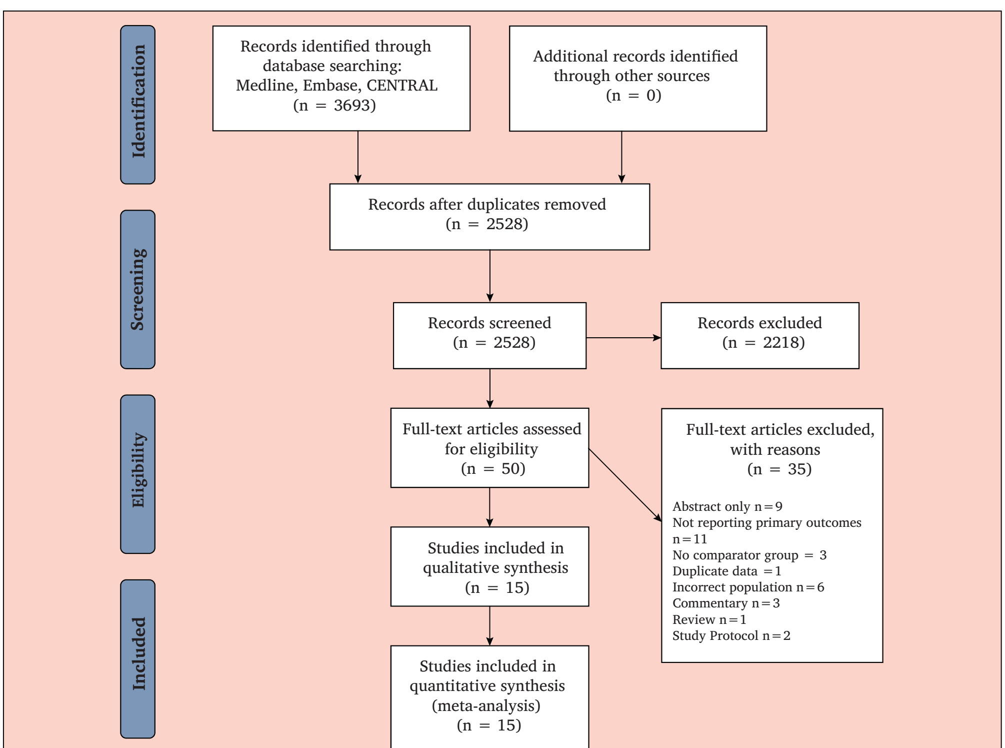


**Figure 1.** PRISMA flow diagram of study selection. CENTRAL = Cochrane central register of controlled trials.

**Table 1. Characteristics of studies comparing primary infrainguinal bypass with secondary infrainguinal bypass following failed endovascular therapy**

| Author | Year | Country | Study design | Included patients (n) | Disease status | Bypass after failed EVT[a] (n) | Primary bypass[a] (n) | CLI vs. IC (%) |
|---|---|---|---|---|---|---|---|---|
| Mohapatra[28] | 2018 | USA | OR | 122 | CLI | 27 | 95 | 100 vs. 0 |
| Meecham[17] | 2018 | UK | PCS[b] | 239 | CLI | 49 | 190 | 100 vs. 0 |
| Morisaki[23] | 2017 | Japan | OR | 99 | CLI | 24 | 82 | 100 vs. 0 |
| Bodewes[18] | 2017 | USA | OR | 5766 | CLI, IC | 1226 | 4540 | 69 vs. 31 |
| Martins[25] | 2016 | Brazil | OR | 136 | CLI | 34 | 102 | 100 vs. 0 |
| Gavrilenko[14] | 2016 | Russia | OR | 47 | CLI | 22 | 25 | 100 vs. 0 |
| Spinelli[16] | 2015 | Italy | OR | 213 | CLI | 75 | 138 | 100 vs. 0 |
| Tsuji[19] | 2015 | Japan | OR | 80 | CLI | 43 | 37 | 100 vs. 0 |
| Uhl[24] | 2014 | Germany | OR | 75 | CLI | 36 | 39 | 100 vs. 0 |
| Santo[21] | 2014 | USA | OR | 314 | CLI | 61 | 253 | 100 vs. 0 |
| Jones[7] | 2013 | USA | OR | 2902 | CLI, IC | 552 | 2350 | 70 vs. 30 |
| Nolan[26] | 2011 | USA | OR | 1411 | CLI | 134 | 1277 | 100 vs. 0 |
| Spinelli[20] | 2011 | Italy | OR | 273 | CLI | 114 | 159 | 100 vs. 0 |
| Sandford[22] | 2007 | UK | OR | 126 | CLI, IC | 66 | 60 | 83 vs. 17 |
| Bockler[15] | 2005 | Germany | OR | 83 | CLI | 20 | 63 | 100 vs. 0 |

CLI = critical limb ischaemia; EVT = endovascular therapy; IC = intermittent claudication; OR = observational retrospective study; RCT = randomised controlled trial; PCS = Prospective cohort study.
[a] Number of treated limbs.
[b] Intention to treat analysis of the BASIL trial subjects randomized to primary bypass compared to those who were initially randomized to balloon angioplasty and underwent subsequent bypass following failure of EVT.

survival comparing patients with previous endovascular intervention and patients with lower extremity bypass and they provided the tables used to plot them. Ten studies were considered high quality as per the Newcastle Ottawa Scale for cohort studies (Table 4).

### *Short-term outcomes*

Data on 30 day mortality was present in eight studies. One study reported no deaths in either group during the first month,[14] thus it was excluded from the analysis. There was no significant difference between the groups (OR 1.00; 95% CI 0.65—1.54, $p = .99$) (Fig. 2), with no significant heterogeneity ($I^2 = 0\%$, $p = .87$). The GRADE quality of evidence was low. Pooling the results of six studies showed that 30 day amputation rates were not significantly different between the two groups (OR 1.26; 95% CI 0.95—1.65, $p = .10$) (Fig. 3) with no significant heterogeneity ($I^2 = 0\%$, $p = .61$). The GRADE quality of evidence was low. Four studies reported on early graft occlusion and pooling demonstrated a trend towards higher rates of early graft occlusion in patients undergoing bypass after failed previous endovascular intervention (OR 4.54; 95% CI 0.97—21.28, $p = .05$) (Fig. 4). This finding was of borderline

**Table 2. Patient demographics of included study populations**

| Author | Year | Mean age | Men (%) | Diabetes (%) | CAD (%) | ESRD (%) | CKD (%) | Active smoker (%) | HTN (%) | COPD (%) | Statin (%) | Antiplatelet agent (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mohapatra | 2018 | 72 vs. 70 | 82 vs. 76 | 82 vs. 83 | 70 vs. 66 | 15 vs. 23 | 30 vs. 39 | 52 vs. 47 | 78 vs. 87 | 19 vs. 7 | 41 vs. 51 | 74 vs. 42 |
| Meecham | 2018 | 73 vs. 72 | 57 vs. 66 | 53 vs. 40 | 16 vs. 14 | NR | NR | 49 vs. 39 | 61 vs. 59 | NR | 37 vs. 35 | 65 vs. 73 |
| Morisaki | 2017 | 76 vs. 71 | 67 vs. 75 | 79 vs. 72 | 50 vs. 57 | 46 vs. 48 | NR | NR | 100 vs. 88 | NR | NR | NR |
| Bodewes | 2017 | 67 vs. 68 | 62 vs. 65 | 51 vs. 45 | NR | 6 vs. 7 | 22 vs. 23 | 42 vs. 41 | 85 vs. 82 | 12 vs. 13 | 74 vs. 67 | 88 vs. 77 |
| Martins | 2016 | 69 vs. 70 | 56 vs. 55 | 74 vs. 72 | 24 vs. 18 | NR | 18 vs. 24 | NR | 79 vs. 80 | NR | NR | NR |
| Gavrilenko | 2016 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| Spinelli | 2015 | 71 vs. 75 | 53 vs. 86 | 69 vs. 68 | 75 vs. 62 | 37 vs. 35 | 53 vs. 49 | 5 vs. 13 | 72 vs. 70 | 11 vs. 17 | NR | NR |
| Tsuji | 2015 | 66 vs. 70 | 81 vs. 65 | 81 vs. 70 | 44 vs. 40 | 67 vs. 35 | NR | NR | 67 vs. 76 | NR | NR | 100 vs. 100 |
| Uhl | 2014 | 72 vs. 72 | 77 vs. 72 | 78 vs. 77 | 42 vs. 44 | NR | 47 vs. 47 | NR | 92 vs. 95 | NR | 74 vs. 74 | NR |
| Santo | 2014 | 67 vs. 67 | 56 vs. 64 | 54 vs. 51 | 44 vs. 43 | 12 vs. 11 | 18 vs. 24 | 31 vs. 39 | 66 vs. 82 | 7 vs. 13 | 49 vs. 46 | 74 vs. 64 |
| Jones[a] | 2013 | 68 vs. 68 | 50 vs. 52 | 6 vs. 8 | 38 vs. 36 | 7 vs. 9 | 83 vs. 84 | 88 vs. 86 | 26 vs. 27 | 78 vs. 76 | NR | 78 vs. 77 |
| Nolan | 2011 | 68 vs. 70 | 59 vs. 68 | 58 vs. 56 | 42 vs. 47 | 10 vs. 10 | 13 vs. 20 | 82 vs. 80 | 90 vs. 86 | 34 vs. 31 | 71 vs. 54 | 68 vs. 73 |
| Spinelli | 2011 | NR | NR | 72 vs. 61 | 54 vs. 47 | NR | 14 vs. 21 | 70 vs. 62 | 68 vs. 74 | 57 vs. 59 | NR | NR |
| Sanford | 2007 | 78 vs. 75 | 45 vs. 63 | 33 vs. 18 | 27 vs. 27 | NR | NR | NR | 58 vs. 38 | NR | NR | NR |
| Bockler | 2005 | 65 vs. 72 | 64 vs. 71 | NR | NR | NR | NR | NR | NR | NR | NR | 45 vs. 0 |

Data presented as bypass after failed endovascular intervention vs. primary bypass unless otherwise stated. CAD = coronary artery disease; CKD = chronic kidney disease; CLI = critical limb ischaemia; COPD = chronic obstructive pulmonary disease; ESRD = end stage renal disease; HTN = hypertension; IC = intermittent claudication; NR = not reported.
[a] Data for secondary bypass recipients not further delineated into previous bypass vs. previous endovascular intervention.

**Table 3.** Operative characteristics of included study populations

| Author | Year | GSV bypass (%) | Prosthetic bypass[a] (%) | Popliteal target (%) | Tibial target (%) | Pedal target (%) |
|---|---|---|---|---|---|---|
| Mohapatra | 2018 | 89 vs. 75 | 11 vs. 25 | 0 vs. 0 | 0 vs. 0 | 100 vs. 100 |
| Meecham | 2018 | 92 vs. 78 | 8 vs. 22 | 64 vs. 68 | 36 vs. 29.5 | 0 vs. 1.5 |
| Morisaki | 2017 | 100 vs. 97.6 | 0 vs. 1.2 | 0 | 16.7 vs. 52.4 | 83.3 vs. 47.6 |
| Bodewes | 2017 | 63.0 vs. 62.0 | 37.0 vs. 38.0 | 60.0 vs. 64.0 | 40.0 vs. 36.0 | 0 vs. 0 |
| Martins | 2016 | 67.6 vs. 54.9 | 32.4 vs. 45.0 | 35.3 vs. 59.8 | 52.9 vs. 31.4 | 11.8 vs. 8.8 |
| Gavrilenko | 2016 | 56.0 vs. 45.4 | 13.6 vs. 0 | 69.6 vs. 45.4 | 0 vs. 0 | 0 vs. 0 |
| Spinelli | 2015 | NR | NR | 0 vs. 0 | 92.0 vs. 94.2 | 7.99 vs. 5.79 |
| Tsuji | 2015 | 100 vs. 100 | 0 vs. 0 | 0 vs. 0 | 81.4 vs. 97.3 | 18.6 vs. 2.7 |
| Uhl | 2014 | 100 vs. 100 | 0 vs. 0 | 0 vs. 0 | 16.7 vs. 7.7 | 83.3 vs. 92.3 |
| Santo | 2014 | 74.0 vs. 85.0 | 0 vs. 0 | 45.9 vs. 38.8 | 47.5 vs. 56.5 | 6.6 vs. 4.8 |
| Jones[b] | 2013 | 72.0 vs. 73.0 | 30.0 vs. 30.0 | 33.0 vs. 33.0 | 28.0 vs. 28.0 | 10.0 vs. 10.0 |
| Nolan | 2011 | 55.0 vs. 71.0 | 46.0 vs. 24.0 | 47.0 vs. 53.0 | 53.0 vs. 47 | 0 vs. 0 |
| Spinelli[c] | 2011 | 73.4 | 26.2 | 0 vs. 0 | 24.0 vs. 46.0 | 76.0 vs. 54.0 |
| Sanford | 2007 | 79.0 vs. 58.0 | 20.0 vs. 37.0 | 59.0 vs. 72.0 | 41.0 vs. 25.0 | 0 vs. 0 |
| Bockler | 2005 | 80.0 vs. 76.2 | 20.0 vs. 23.8 | 39.0 vs. 0 | 50.0 vs. 100 | 0 vs. 0 |

Data presented as bypass after failed endovascular intervention vs. primary bypass unless otherwise stated. NR = not reported. GSV = great saphenous vein.
[a] Prosthetic bypass includes grafts with vein cuff, vein patch, and all other composite grafts that were not exclusively great saphenous vein.
[b] Data for secondary bypass recipients not further delineated into previous bypass vs. previous endovascular intervention.
[c] These data are for the whole study population, as data for individual groups are not reported.

**Table 4.** Study quality as per the Newcastle Ottawa scale (NOS)

| Author | Selection | Comparability | Outcomes | NOS score |
|---|---|---|---|---|
| Mohapatra | 4 | 2 | 2 | 8 |
| Morisaki | 4 | 0 | 2 | 6 |
| Bodewes | 4 | 2 | 2 | 8 |
| Martins | 4 | 0 | 3 | 7 |
| Gavrilenko | 4 | 0 | 3 | 7 |
| Spinelli | 4 | 0 | 3 | 7 |
| Tsuji | 4 | 0 | 3 | 7 |
| Uhl | 4 | 0 | 3 | 7 |
| Santo | 4 | 0 | 3 | 7 |
| Nolan | 3 | 0 | 3 | 6 |
| Jones | 4 | 2 | 3 | 9 |
| Spinelli | 4 | 0 | 3 | 7 |
| Sanford | 4 | 0 | 3 | 7 |
| Bockler | 3 | 0 | 2 | 5 |

NOS assesses the quality of nonrandomized studies based on the selection of the study groups; the comparability of the groups; and the ascertainment of either the exposure or outcome of interest for case-control or cohort studies respectively. Scores range from 0–9; scores of 7 or greater indicate a high-quality study.

statistical significance, and there was substantial heterogeneity between studies ($I^2$ = 77%, $p$ = .005). The GRADE quality of evidence was low.

### *Long-term outcomes*

The analysis of primary patency at one year included 10 studies. The results of studies comparing primary bypass with bypass after failed endovascular intervention showed improved primary patency in the primary bypass group (OR 1.65; 95% CI 1.04–2.62, $p$ = .03) (Fig. 5). These results were limited by significant heterogeneity between the studies ($I^2$ = 74%, $p$ = .0003). The GRADE quality of evidence was low. Pooling the results of eight studies showed that rates of secondary patency at one year were similar between groups (OR 1.27; 95% CI 0.66–2.43, $p$ = .48) (Fig. 6), with significant heterogeneity ($I^2$ = 63%, $p$ = .008). The GRADE quality of evidence was low. The analysis of one year amputation fr free survival (AFS) included eight studies. The patients undergoing bypass after failed endovascular therapy had worse one year amputation free survival when compared with patients undergoing primary bypass (OR 1.30; 95% CI 1.10–1.52, $p$ = .001) (Fig. 7), with no

| Study or Subgroup | Bypass after failed EVT Events | Total | Primary bypass Events | Total | Weight | Odds Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Bockler 2005 | 0 | 18 | 0 | 63 | | Not estimable | 2005 |
| Spinelli 2011 | 4 | 114 | 4 | 159 | 9.4% | 1.41 [0.34, 5.76] | 2011 |
| Santo 2014 | 1 | 61 | 10 | 258 | 4.3% | 0.41 [0.05, 3.29] | 2014 |
| Uhl 2014 | 1 | 36 | 2 | 39 | 3.1% | 0.53 [0.05, 6.09] | 2014 |
| Martins 2016 | 2 | 34 | 3 | 102 | 5.6% | 2.06 [0.33, 12.90] | 2016 |
| Bodewes 2017 | 20 | 1226 | 76 | 4540 | 75.7% | 0.97 [0.59, 1.60] | 2017 |
| Mohapatra 2018 | 0 | 27 | 1 | 95 | 1.8% | 1.15 [0.05, 28.92] | 2018 |
| **Total (95% CI)** | | **1516** | | **5256** | **100.0%** | **1.00 [0.65, 1.54]** | |
| Total events | 28 | | 96 | | | | |

Heterogeneity. Tau² = 0.00; Chi² = 1.81, df = 5 (P= 0.87); I² = 0%
Test for overall effect: Z = 0.01 (P =0.99)

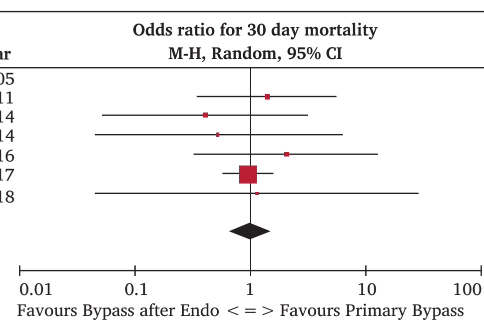


**Figure 2.** Forest plot of pooled studies comparing 30 day mortality between primary bypass and bypass after failed endovascular intervention. EVT = endovascular therapy; M-H = Mantel-Haenszel test; CI = confidence interval; $I^2$ = study heterogeneity; Z = Z-score test statistic.

| Study or Subgroup | Bypass after failed EVT Events | Total | Primary bypass Events | Total | Weight | Odds Ratio M- H, Random, 95% Cl | Year |
|---|---|---|---|---|---|---|---|
| Jones 2013 | 24 | 552 | 82 | 2350 | 35.1% | 1.26 [0.79, 2.00] | 2013 |
| Uhl 2014 | 6 | 36 | 6 | 39 | 5.0% | 1.10 [0.32, 3.78] | 2014 |
| Spinelli 2015 | 4 | 75 | 1 | 138 | 1.6% | 7.72 [0.85, 70.36] | 2015 |
| Gavrilenko 2016 | 0 | 22 | 0 | 25 | | Not estmable | 2016 |
| Bodewes 2017 | 40 | 1226 | 123 | 4540 | 57.7% | 1.21 [0.84, 1.74] | 2017 |
| Mohapatra 2018 | 0 | 27 | 1 | 95 | 0.7% | 1. 15 [0.05, 28.92] | 2018 |
| **Total (95% Cl)** | | **1938** | | **7187** | **100.0%** | **1.26 [0.95, 1.65]** | |
| Total events | 74 | | 213 | | | | |

Heterogeneity. Tau² = 0.00; Chi² = 2.69, df = 4 (P = 0.61); I² = 0%
Test for overall effect: Z = 1.63 (P = 0.10)

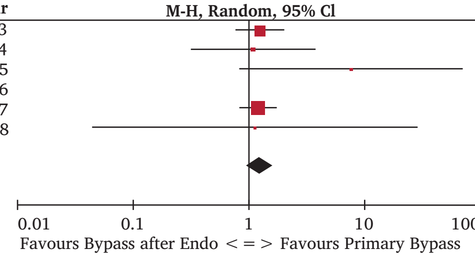


**Figure 3.** Forest plot of pooled studies comparing 30 day amputation rate between primary bypass and bypass after failed endovascular intervention. EVT = endovascular therapy; M-H = Mantel-Haenszel test; CI = confidence interval; $I^2$ = study heterogeneity; Z = Z-score test statistic.

| Study or Subgroup | Bypass after failed EVT Events | Total | Primary bypass Events | Total | Weight | Odds Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Bockler 2005 | 6 | 18 | 1 | 63 | 20.2% | 31.00 [3.42, 281.29] | 2005 |
| Uhl 2014 | 7 | 36 | 7 | 39 | 28.7% | 1.10 [0.35, 3.53] | 2014 |
| Spinelli 2015 | 11 | 75 | 1 | 138 | 21.2% | 23.55 [2.98, 186.33] | 2015 |
| Martins 2016 | 7 | 34 | 15 | 102 | 30.0% | 1.50 [0.56, 4.07] | 2016 |
| **Total (95% CI)** | | **163** | | **342** | **100.0%** | **4.54 [0.97, 21.28]** | |
| Total events | 31 | | 24 | | | | |

Heterogeneity. T au² = 1. 82; Chi² = 12.97, df = 3 (P = 0.005); I² = 77%
Test for overall effect: Z = 1.92 (P = 0.05)

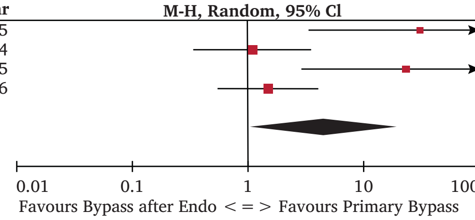


**Figure 4.** Forest plot of pooled studies comparing early graft occlusion (within 30 days) between primary bypass and bypass after failed endovascular intervention. EVT = endovascular therapy; M-H = Mantel-Haenszel test; CI = confidence interval; $I^2$ = study heterogeneity; Z = Z-score test statistic.

| Study or Subgroup | Primary bypass Events | Total | Bypass after failed EVT Events | Total | Weight | Odds Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Bockler 2005 | 55 | 63 | 6 | 18 | 7.4% | 13.75 [4.02, 46.99] | 2005 |
| Sanford 2007 | 30 | 60 | 40 | 66 | 11.3% | 0.65 [0.32, 1.32 ] | 2007 |
| Spinelli 2011 | 137 | 159 | 81 | 114 | 12.2% | 2.54 [1.38, 4.65 ] | 2011 |
| Nolan 20 11 | 1047 | 1277 | 96 | 134 | 13.8% | 1.80 [1.21, 2.69] | 2011 |
| Uhl 2014 | 19 | 39 | 24 | 36 | 9.4% | 0.47 [0.19, 1.21] | 2014 |
| Santo 2014 | 156 | 253 | 36 | 61 | 12.5% | 1.12 [0.63, 1.97] | 2014 |
| Tsuji 2015 | 29 | 37 | 34 | 43 | 8.4% | 0.96 [0.33, 2.81] | 2015 |
| Gavrilenko 2016 | 22 | 25 | 16 | 22 | 5.7% | 2.75 [0.60, 12.68] | 2016 |
| Morisaki 2017 | 59 | 82 | 13 | 24 | 9.4% | 2.17 [0.85, 5.54] | 2017 |
| Mohapatra 2018 | 57 | 95 | 10 | 27 | 9.9% | 2.55 [1. 06, 6.16] | 2018 |
| **Total (95% CI)** | | **2090** | | **545** | **100.0%** | **1.65 [1.04, 2.62]** | |
| Total events | 1611 | | 356 | | | | |

Heterogeneity. Tau² = 0.36; Chi² = 31. 41, df = 9 (P = 0.0003); I² = 71%
Test for overall effect: Z = 2.13 (P = 0.03)

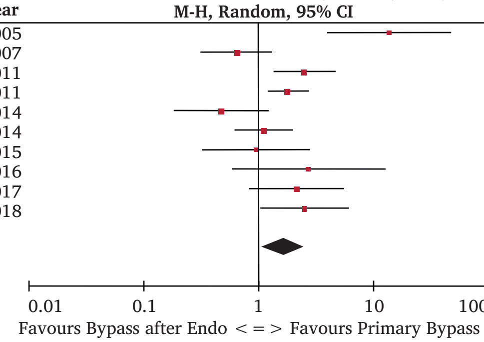


**Figure 5.** Forest plot of pooled studies comparing primary patency at one year between primary bypass and bypass after failed endovascular intervention. EVT = endovascular therapy; M-H = Mantel-Haenszel test; CI = confidence interval; $I^2$ = study heterogeneity; Z = Z-score test statistic.

| Study or Subgroup | Primary bypass Events | Total | Bypass after failed EVT Events | Total | Weight | Odds Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Sanford 2007 | 38 | 46 | 41 | 49 | 13.2% | 0.93 [0.32, 2.72] | 2007 |
| Santo 2014 | 220 | 253 | 55 | 61 | 14.7% | 0.73 [0. 29, 1.82] | 2014 |
| Uhl 2014 | 19 | 39 | 26 | 36 | 14.3% | 0.37 [0. 14, 0.96] | 2014 |
| Tsuji 2015 | 31 | 37 | 34 | 43 | 12.7% | 137 [0 44, 4 28] | 2015 |
| Spinelli 2015 | 137 | 138 | 66 | 75 | 6.6% | 18.68 [2.32, 150.55] | 2015 |
| Manins 2016 | 81 | 102 | 19 | 34 | 15.5% | 3.05 [133, 6.98] | 2016 |
| Morisaki 2017 | 74 | 82 | 22 | 24 | 9.1% | 0.84 [0.17, 4.25] | 2017 |
| Mohapatra 2018 | 76 | 95 | 20 | 27 | 14.0% | 140 [0. 52, 3.79] | 2018 |
| **Total (95% CI)** | | **792** | | 349 | **100.0%** | **1.27 [0.66, 2.43]** | |
| Total events | 676 | | 283 | | | | |

Heterogeneity. Tau² = 0.53; Chi² = 19.12, df = 7 (P = 0.008); I² = 63%
Test for overall effect: Z = 0. 71 (P = 048)

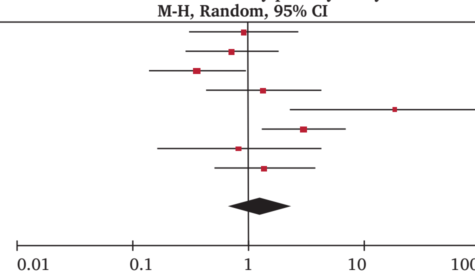


**Figure 6.** Forest plot of pooled studies comparing secondary patency at one year between primary bypass and bypass after failed endovascular intervention. EVT = endovascular therapy; M-H = Mantel-Haenszel test; CI = confidence interval; $I^2$ = study heterogeneity; Z = Z-score test statistic.

| Study or Subgroup | Primary bypass Events | Total | Bypass after failed EVT Events | Total | Weight | Odds Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Spinelli 2 011 | 124 | 159 | 78 | 114 | 8.7% | 1.64 [0.95, 2.82] | 2011 |
| Jones 2013 | 1504 | 2350 | 331 | 552 | 71.3% | 1.19 [0.98, 1.44] | 2013 |
| Santo 2014 | 223 | 253 | 52 | 61 | 4. 0% | 1.29 [0. 58, 2.87] | 2014 |
| Tsuji 2015 | 20 | 30 | 30 | 43 | 2. 6% | 0.87 [0.32, 2.36] | 2015 |
| Martins 2016 | 92 | 102 | 27 | 34 | 2. 3% | 2.39 [0.83, 6.86] | 2016 |
| Morisaki 2017 | 65 | 75 | 17 | 24 | 2.1% | 2.68 [0 89, 8.07] | 2017 |
| Meecham 2018 | 133 | 190 | 27 | 49 | 6. 2% | 1.90 [1.00, 3.62] | 2018 |
| Mohapatra 2018 | 72 | 95 | 19 | 27 | 2. 8% | 1.32 [0.51, 3.41] | 2018 |
| **Total (95% CI)** | | **3254** | | **904** | **100.0%** | **1.30 [1.10, 1.52]** | |
| Total events | 2233 | | 581 | | | | |

Heterogeneity. $Tau^2 = 0.00$; $Chi^2 = 6.45$, df = 7 (P = 0.49); $I^2 = 0\%$
Test for overall effect: Z = 3.18 (P = 0.001)

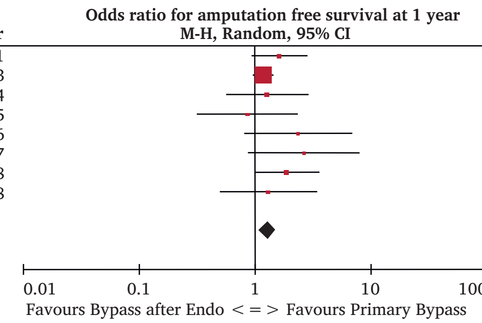


**Figure 7.** Forest plot of pooled studies comparing one year amputation free survival between primary bypass and bypass after failed endovascular intervention. EVT = endovascular therapy; M-H = Mantel-Haenszel test; CI = confidence interval; $I^2$ = study heterogeneity; Z = Z-score test statistic.

| Study or Subgroup | Primary bypass Events | Total | Bypass after failed EVT Events | Total | Weight | Odds Ratio M-H, Random, 95% CI | Year |
|---|---|---|---|---|---|---|---|
| Sanford 2007 | 44 | 60 | 50 | 66 | 7.7% | 0.88 [0.39, 1.96] | 2007 |
| Nolan 2011 | 1124 | 1277 | 117 | 134 | 14.2% | 1.07 [0.62, 1.82] | 2011 |
| Jones 2013 | 1373 | 1658 | 680 | 807 | 32.7% | 0.90 [0.72, 1.13] | 2013 |
| Uhl 2014 | 32 | 39 | 29 | 36 | 4.0% | 1.10 [0.35, 3.53] | 2014 |
| Santo 2014 | 224 | 253 | 54 | 61 | 6.6% | 1.00 [0.42, 2.41] | 2014 |
| Spinelli 2015 | 135 | 159 | 80 | 114 | 12.4% | 2.39 [1.32, 4.32] | 2015 |
| Martins 2016 | 85 | 102 | 27 | 34 | 5.4% | 1.30 [0.49, 3.46] | 2016 |
| Morisaki 2017 | 65 | 75 | 19 | 24 | 3.8% | 1.71 [0.52 , 5.62] | 2017 |
| Meecham 2018 | 152 | 190 | 37 | 49 | 8.7% | 1.30 [0.62, 2.72] | 2018 |
| Mohapalra 2018 | 83 | 95 | 21 | 27 | 4.5% | 1.98 [0.66, 5.88] | 2018 |
| **Total (95% CI)** | | **3908** | | **1352** | **100.0%** | **1.18 [0.92, 1.50]** | |
| Total events | 3317 | | 1114 | | | | |

Heterogeneity. $Tau^2 = 0.03$; $Chi^2 = 11.79$, df = 9 (P = 0.23); $I^2 = 24\%$
Test for overall effect. Z = 1.33 (P= 0.18)

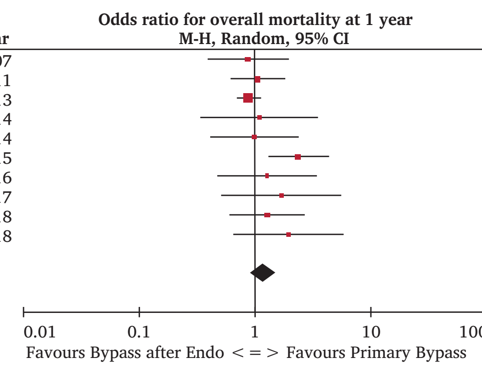


**Figure 8.** Forest plot of pooled studies comparing one year overall survival between primary bypass and bypass after failed endovascular intervention. EVT = endovascular therapy; M-H = Mantel-Haenszel test; CI = confidence interval; $I^2$ = study heterogeneity; Z = Z-score test statistic.

significant heterogeneity between studies ($I^2 = 0\%$, $p = .49$). The GRADE quality of evidence was low. Data on one year overall survival were included in 10 studies (Fig. 8). There were no statistically significant differences between the groups (OR 1.18; 95% CI 0.92—1.50, $p = .18$). Heterogeneity between studies was low ($I^2 = 24\%$; $p = .23$). The GRADE quality of evidence was low.

Publication bias was assessed by visually inspecting the funnel plot for studies reporting one year primary patency with some asymmetry indicating a lack of smaller studies showing more equivalent outcomes between the two groups (Fig. 9).

## DISCUSSION

It is estimated that 25%—30% of patients who undergo bypass do so after failed previous interventions.[21,29] An understanding of the outcomes and potential consequences of performing a bypass after a failed endovascular intervention is critical in guiding both surgeon decision making and patient expectations of treatment. The aim in this systematic review and meta-analysis was to summarise the literature comparing outcomes following infrainguinal bypass after failed endovascular intervention with outcomes following primary bypass. Fifteen studies were identified, reporting on over 11,850 patients that compared the outcomes from these two groups. Unfortunately, these studies represented a mix of patient indications, specific anatomies treated, interventions used, and outcomes reported. Certainly, the level of clinical heterogeneity limits any firm conclusions; however, there were suggestions of better overall results in the primary bypass group. Pooled one year amputation free survival was better among patients who had a primary bypass when compared with bypass after failed endovascular intervention. The difference in one year amputation free survival was probably driven by the higher amputations in the group

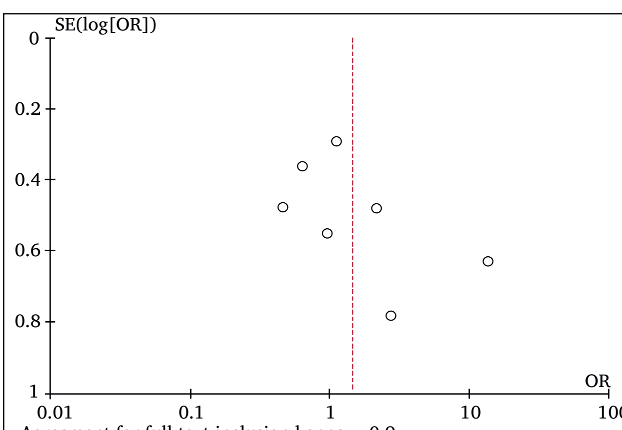


**Figure 9.** Funnel plot of study size and effect size looking for evidence of publication bias for one year primary patency. OR = odds ratio; SE(log[OR]) = standard error for the logarithm of the odds ratio.

undergoing bypass after failed endovascular therapy as pooled one year overall survival was similar between both groups. In addition, there was a worse one year primary patency among patients who underwent bypass after failed endovascular intervention ($p = .03$) and a trend towards higher rates of early graft occlusion ($p = .05$). There were no differences in secondary patency, 30 day amputation rate, and 30 day mortality between the groups. When looking at the results of studies individually, the larger studies tended to support the notion that bypass after failed endovascular intervention is associated with worse post-operative outcomes. Nolan et al., in an analysis of over 1800 patients undergoing lower extremity bypass, found that patients with prior peripheral endovascular interventions had higher one year amputation (31% vs. 20%) and one year graft occlusion rates (28% vs. 18%) when compared with patients without prior intervention, and that this effect was significant even after multivariable adjustement.[26] Similarly, Jones et al. in another large New England study found reduced amputation free survival and higher major adverse limb events (MALE) in patients who underwent bypass after failed endovascular intervention.[27] Meecham et al. recently completed a comprehensive review of the clinical outcomes in all patients from the BASIL trial undergoing primary bypass (PB) vs. secondary bypass (SB) after failed angioplasty. This analysis revealed dramatically improved amputation free survival in the primary bypass group (PB 60% vs. SB 40%; HR 1.58, $p = .04$) and trends towards better limb salvage and overall survival in this cohort (PB 85% vs. SB 73%, $p = .06$; PB 68% vs. 51%, $p = .06$, respectively).[17] This trial was criticised for multiple shortcomings, one of which was the use of plain balloon angioplasty as the sole method of treatment in the endovascular arm.[30,31] This would not be consistent with the modern standard of care and may help explain their dramatic results. Similarly, Bockler et al., in an older study that used infrapopliteal stenting to treat patients, found a deleterious effect on subsequent bypass with a dismal one year patency rate of 33% in this group compared with 88% in their primary bypass group.[15] Certainly, the quality of the initial endovascular procedure and the specific technology used plays a role in the results of subsequent bypass. Unfortunately, the heterogeneity and lack of detailed reporting between studies makes any conclusions about specific endovascular techniques difficult. Most reported on balloon angioplasty and bare metal stenting, while some studies included atherectomy and thrombolysis. Five studies did not have information on the type of endovascular intervention performed, as the patients were often referred from peripheral hospitals without accompanying documentation or represented data obtained from multiple institutions.[16,18,20,26,27]

The reporting of major adverse limb events (MALE) has been recommended by the Society for Vascular Surgery (SVS) Objective Performance Goals (OPG) Working Group specifically for use in critical trials involving patients with CLI and has been endorsed by both the SVS and the Food and Drug Administration.[32,33] MALE, which includes major above ankle amputation, new bypass, jump graft/interposition graft, graft occlusion, or major re-intervention requiring thrombectomy or thrombolysis, was infrequently reported and inconsistently described in the studies. Only three studies reported MALE adequately but differing time points made quantitative pooling impossible. Nolan et al. documented a higher MALE rate in patients undergoing bypass surgery with prior endovascular intervention when compared with primary bypass;[26] while Jones et al. found similar results, with a one year MALE free survival at 67.5% in the primary bypass group compared with 63.6% in the failed endovascular group.[27] Conversely, Mohapatra et al. found freedom from MALE at one year to be comparable between patients undergoing bypass with prior endovascular tibial intervention at 79.6% and patients receiving primary pedal bypass at 77.0%.[28] In general, studies showing equivocal results between the groups tended to be smaller, single centre studies, which may have been underpowered to show a difference.[11,19,21,22,24,25,28]

Multiple factors have been implicated in explaining why patients who have failed an endovascular intervention might have worse outcomes after subsequent bypass. Some authors have argued that this results from loss of potential outflow vessels during the initial endovascular procedure, which may impact the choice and location of distal targets during subsequent bypass.[20,26] Gifford et al. looked at the impact of change in distal target and found that 43% of patients undergoing bypass after failed endovascular therapy had the location of the distal target changed to a more distal location compared with the pre-endovascular intervention angiography.[34] Joels et al., in a small retrospective study, evaluated change in distal bypass site after endovascular intervention of the superficial femoral artery as judged by three operators in a blinded manner.[3] They found that 41% of patients with critical limb ischaemia required a change in distal target site after a failed endovascular intervention. Unfortunately, anatomical details regarding location of endovascular treatment and any potential changes in distal target were often missing from the included studies and could not be assessed systematically.

Others have argued that failure of any intervention may result from systemic effects such as latent hypercoagulability, propensity for neointimal hyperplasia, or aggressive atherosclerosis.[18,26,34,35] However, not all the data support this as Nolan et al. found that prior contralateral revascularisation was not a risk factor for worse outcomes following subsequent bypass, indicating that local factors (conduit, runoff, distal target) are probably more important.[26] The presence of marginal vein quality at the time of the initial revascularisation has also been implicated, as this may lead an interventionalist to favour an initial endovascular procedure but limits the options for subsequent autogenous bypass. Santo et al., in an analysis of autologous vein bypass only, following endovascular procedures, showed no deleterious effect of prior endovascular therapy, suggesting that patients with good veins are not necessarily disadvantaged by having had prior endovascular therapy.[21]

Optimal treatment strategies are also determined by a patient's general health status before revascularisation. Tsai et al. reported in 1858 patients from a community based registry, that those with CLI or claudication treated with endovascular intervention were less likely to die within 30 days when compared with bypass patients (0.2% vs. 3.8%).[36] Patients selected for endovascular intervention may be offered that therapy because of worse baseline comorbidities. In the current meta-analysis, there was no difference in 30 day mortality between patients who underwent primary bypass compared with patients who underwent bypass after prior failed endovascular intervention.

There are several limitations of this systematic review. Most data were derived from observational studies, resulting in a low level of evidence. The patient population represented by the observational studies in this meta-analysis is mostly from single centre reports, with a few exceptions including two studies using the New England Vascular Study Group database, one using NSQIP data, and the multicentre BASIL trial data. These retrospective observational studies were prone to selection bias and confounding. Many of the studies failed to control for differences in baseline characteristics. Outcomes displayed significant statistical heterogeneity and outcome reporting was highly variable, which resulted in numerous analyses with few patients. The heterogeneity seemed to be least when looking at hard outcomes with universally defined time periods, such as 30 day mortality. Ideally, the effect of bypass after failed endovascular intervention would have been analysed separately for patients with claudication and CLI. Unfortunately, four studies tended to mix these patient populations, which made selecting out these subgroups difficult.[18,21,22,27] No cost analyses were performed, and quality of life reporting was also absent. Further studies should consider evaluating quality of life and cost effectiveness as it impacts the value of intervention in peripheral arterial disease.

This review was not designed to answer whether an endovascular first or bypass first strategy is optimal. The GRADE quality of evidence for each outcome was moderate or low. This underlies the importance of further research which is likely or very likely to have an important impact on confidence in the estimate of effect. Current recommendations such as the American College of Cardiology/American Heart Association guidelines are based primarily on the results of the BASIL trial, and recommend that bypass surgery be preferentially performed over endovascular intervention in patients with critical limb ischaemia and a life expectancy of $> 2$ years.[37] The Best Endovascular vs. Best Surgical Therapy in patients with CLI (BEST-CLI) trial is currently under way, which when completed will help answer the question of whether an endovascular or open bypass strategy offers better outcomes.[38] Similarly, the BASIL-2 trial is currently under way looking at whether vein bypass first or best endovascular therapy first is the optimal treatment strategy for patients with severe limb ischaemia caused by infrapopliteal disease.[39] The results of these studies should help to clarify the role of endovascular and open interventions in the treatment of CLI patients.

## CONCLUSION

In conclusion, meta-analysis of the existing literature comparing primary bypass with bypass following failed endovascular intervention shows worse one year amputation free survival and primary patency among those with failed prior endovascular intervention. There is also a trend towards higher rates of graft occlusion, although these results were not statistically significant. The existing literature is limited by observational study design, inconsistent patient selection, and significant heterogeneity, yet suggests that bypass following failed endovascular intervention may result in suboptimal outcomes. Physicians who care for patients with peripheral arterial disease should consider the effect of endovascular treatment failure on future interventions. This study further highlights the need for large and robust prospective trials.

## ACKNOWLEDGMENTS

We would like to thank Drs. Philip P. Goodney, Douglas Jones and Yuanyuan Zhao for providing us with additional data and clarification from their study. We would also like to thank Ms. Alla Iansavitchene for help with the literature search and retrieval.

## FUNDING

There were no external funding sources for this project.

## CONFLICTS OF INTEREST

None.

## APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2018.09.025.

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