U.PORTO

FMUP FACULDADE DE MEDICINA UNIVERSIDADE DO PORTO

MESTRADO INTEGRADO EM MEDICINA

2020/2021

Inês Costa Peneda Ferreira

Completion Imaging after lower limb bypass surgery for peripheral artery disease: a systematic review

ABRIL, 2021

U.PORTO

FMUP FACULDADE DE MEDICINA
UNIVERSIDADE DO PORTO

Inês Costa Peneda Ferreira

Completion imaging after lower limb bypass surgery for peripheral artery disease: a systematic review

Mestrado Integrado em Medicina

Área: Cirurgia Vascular

Tipologia: Revisão Sistemática

Trabalho efetuado sob a Orientação de:

Doutora Marina Felicidade Dias Neto

E sob a Coorientação de:

Dr. João Manuel Palmeira da Rocha Neves

Trabalho organizado de acordo com as normas da revista:

Vascular SAGE Journals

ABRIL, 2021

Title:

Completion imaging after lower limb bypass surgery for peripheral artery disease: a systematic review.

Abbreviated title:

Completion imaging after lower limb bypass.

Type of manuscript:

Systematic review.

Authors:

Inês Ferreira[1], João Rocha-Neves[2,3], Marina Dias-Neto[2,4]

Filiation:

1 Faculty of Medicine University of Porto

2 Department of Angiology and Vascular Surgery, São João University Hospital Center, Porto

3 Biomedicine Department – Unit of Anatomy, Faculty of Medicine, University of Porto, Portugal

4 Surgery and Physiology - Cardiovascular R&D Centre (UNIC), Faculty of Medicine, University of Porto, Portugal

Author information:

Inês Costa Peneda Ferreira

Address: Rua Professor Mota Pinto, 124, 12º Esquerdo; 4100-354 Porto, Portugal

Phone: +351 919519680

E-mail: ines_cp_ferreira@hotmail.com ; up201505992@up.pt

Marina Felicidade Dias Neto

Address: Av. de Abelha n.º 616; 4780-132 Burgães, Santo Tirso, Portugal

Phone: +351 916750433

E-mail: marina_f_neto@hotmail.com; m04166@med.up.pt.

João Manuel Palmeira da Rocha Neves

Phone: +351 910486230

E-mail: joaorochaneves@hotmail.com

Table of Contents

Abbreviations

LEB – lower extremity bypass

PAD – peripheral artery disease

CIM – completion imaging

DUS – duplex ultrasound

PTFE – polytetrafluoroethylene

Abstract

Objectives:

Lower extremity bypass (LEB) remains a suitable choice in symptomatic peripheral artery disease patients with a suitable conduit and acceptable surgical risk. The main reason for short-term failure are defects associated with technique or with the graft itself. Completion imaging (CIM) techniques are used to detect and correct errors occurred during the procedure. The aim of this systematic review is to assess available evidence on the role of CIM in detecting errors and improving patency of LEB.

Methods:

This systematic review was conducted according to PRISMA Guidelines. MEDLINE and Web of Science were systematically searched from 1990 to December 2020. Studies were included if they presented results about the use of CIM (angiography, angioscopy or DUS) during LEB due to peripheral artery disease. The primary outcomes were: identification of bypass defects, need for reintervention based on intraoperative findings and graft patency. Secondary outcomes were: time, cost, sensibility and specificity. The data was extracted by two investigators following a predefined protocol. A qualitative analysis was then undertaken.

Results:

The search yielded 571 articles, from which, 17 articles were included in this review: 3 RCTs, 9 prospective and 5 retrospective studies. From the included articles, 4 studied the role of angiography in LEB (Group A), 2 compared the use of CIM (including angiography, DUS or both) with a control group (Group B), 2 compared angiography with DUS (Group C), 8 compared angiography with angioscopy (Group D) and 1 compared angiography, angioscopy and DUS.

Conclusions:

Evidence suggests that all techniques are useful for the intraoperative detection and correction of technical errors, improving graft patency rates. Even while faced with a lack of quantitative analysis, the available results seem to favor angioscopy and its

integration with the other techniques, namely angiography, for better results in terms of overall operative success and graft patency.

Keywords:

peripheral artery disease; lower limb bypass surgery; completion imaging; angiography; Doppler ultrasound; angioscopy.

Introduction

Peripheral arterial disease (PAD), which includes the lower extremities, is one of the most common atherosclerotic morbidities affecting elderly population groups.[1] This disease remains a concerning health problem, affecting 10.7% of the American population every year.[2]

Although in recent years there has been an increase in the use of an endovascular approach to treat PAD, the lower extremity bypass (LEB) is still a suitable alternative in patients who present with symptomatic PAD and a suitable conduit, as long as the surgical risk is acceptable, maintaining its place as the gold standard technique for limb revascularization when complex anatomical changes are present.[2-4]

It is important to monitor and optimize the procedure, in order to improve its technical quality and the success rate in terms of graft patency. The main reason for short-term failure are defects associated with technique or with the graft itself and compromised runoff and if these irregularities are not detected during surgery, there will be a need for posterior reexploration.[5, 6] In fact, technical shortcomings are responsible for the majority of bypass graft failure in the first year of follow-up, which highlights the need for an adequate evaluation of the procedure as close to real time as possible. [3, 7] Identifying and correcting these errors intraoperatively improves future graft patency, increasing the success rate of the surgical procedure.[7]

In order to intraoperatively assess the technical success of the intervention, surgeons started to employ methods of completion imaging (CIM), such as angiography, Doppler ultrasound (DUS), angioscopy and others. These techniques have a positive effect on graft patency and morbidity and better in-patient stay.[3, 8] In the late nineteen-sixties, it was suggested that completion angiography could be potentially beneficial for the timely detection of technical issues during bypass surgery. [2] At the moment, angiography is considered the gold standard for intraoperative assessment of bypass quality, relying on its ability to detect graft or anastomosis defects. [9, 10] However, this method is not without shortcomings. Aside from being an invasive and time-consuming process, some authors defend that its results are not always clinically relevant when it comes to long-term outcomes.[3, 9] More recently, there has been a shift in focus towards less invasive techniques and research has been made in order to obtain

overlapping results with those of intraoperative completion angiography. These techniques include intraoperative monitoring with DUS and with angioscopy.

The aim of this systematic review is to assess available evidence on the role of CIM in detecting technical errors and defects during LEB, in patients with peripheral artery disease, and improving graft patency in the future.

Methods

The databases MEDLINE and Web of Science were searched from 1990 to December 2020, in order to collect articles that focused on the role of CIM in LEB. The detailed search query is available in Appendix I. The terms used included but were not limited to “intraoperative”, “completion”, “angiography”, “bypass”, “reconstruction”, “open surgery”, “revascularization”, “graft”, “lower extremity”, and “infrainguinal”.

Titles and abstracts were screened independently by two authors (I.F. and M.N.) and differences were settled by careful analysis and joint open discussion. The selected articles were further evaluated based on consultation of the full-text papers, according to the settled inclusion and exclusion criteria. All included articles were approved of by both authors.

Articles were included in the systematic analysis if they presented data about patients with peripheral artery disease undergoing open revascularization bypass surgery and results about the use of at least one completion imaging technique: angiography, doppler ultrasound or angioscopy. The main outcomes were identification of defects, need for reintervention based on intraoperative findings and graft patency. Secondary outcomes included: cost and time, sensibility and sensitivity. This encompasses randomized clinical trials (RCTs), prospective and retrospective observational studies and case series.

Papers designed as literature reviews, case reports, animal studies and studies with small series (<10 bypasses) were therefore excluded. Other exclusion criteria included a main focus on treatment and not the assessment of bypass quality, on preoperative or postoperative evaluation, on graft mapping or on the realization of intraoperative monitoring only in exceptional cases (with no discriminated results) or only to confirm the quality of the anastomosis. Articles covering other clinical scenarios other than PAD or studying other techniques such as an endovascular approach, endarterectomy, thromboembolectomy, angioplasty, venous arterialization or amputation were excluded as well. We also excluded papers with no intraoperative data, pharmacological studies and articles published before 1990.

We refined the exclusion criteria for screened full-text articles, excluding papers that reported on inappropriate outcomes, that employed a technique other than angiography, DUS or angioscopy, articles that focused on the identification of graft

permeability prognosis factors but not a method of completion imaging (CIM), studies that compared preoperative and intraoperative angiography and articles available only in German.

Data was extracted from the articles and organized into a Microsoft Excel spreadsheet and a qualitative analysis was performed. Papers were divided into four categories according to the main technique studied in each: “angiography”, “completion imaging versus no completion imaging”, “angiography versus DUS” and “angiography versus angioscopy”. From every study, data was extracted regarding the details of publication (title, study authors, country of origin, journal of publication, year of publication, study design, sample size), details of the bypass procedure (type of bypass, bypass orientation, site of anastomosis and degree of ischaemia), and reports on the proposed outcomes (graft patency, need for reintervention based on intraoperative findings, identification of defects, cost and time, sensibility and sensitivity).

Results

After removal of duplicates, our search yielded 569 citations, which were further analyzed by two authors (I.F. and M.N.). The application of the defined inclusion and exclusion criteria resulted in the elimination of 536 articles. A consensus after the independent analysis of the full texts by the two authors, after refinement of the exclusion criteria, resulted in the exclusion of an additional 16 articles. The selection process amounted to a total of 17 original publications included in this review. The flowchart detailing the selection process can be accessed in Figure 1.

Out of the total of 17 articles included in this review, 3 were RCTs, 9 prospective and 5 retrospective studies. Twelve articles established a comparison between at least one intervention and one control group. The total number of bypasses included was 23232. The years of publication ranged from 1990 to 2020. Thirteen studies were published from 1990 to 2000, 2 from 2000 to 2010 and 2 from 2010 to 2015.

Twelve (70.6%) of the studies originated from the United States of America, and the remaining five (29.4%) from the European Union.

From the studies that detailed the type of bypass, 2 focused solely on *in situ* saphenous vein bypass grafts[6, 11], and the remaining either focused solely on reversed vein bypass[12] or a combination of the latter with non-reversed vein grafts, polytetrafluorethylene (PTFE) grafts, spliced veins and/or in situ vein grafts[2, 7, 10, 13-17].

From the included articles, 4 studied the role of intraoperative angiography in LEB (Group A)[7, 11, 12, 16], 2 compared the use of completion imaging (angiography, DUS or both) with a control group (Group B)[2, 3], 2 compared angiography with DUS (Group C)[10, 18] and 8 compared angiography with angioscopy (Group D)[6, 13-15, 17, 19-21]. Finally, Gilbertson *et al*'s article established a comparison between angiography, angioscopy and DUS.[22] Each of these groups will be presented separately. In terms of outcomes, 8 articles reported and described the morphological defects identified by the different techniques[10-17, 22], 9 reported the number of bypasses that required surgical revision after intraoperative error detection[6, 10-12, 14-17, 21] and 11 presented results in terms of graft patency using several follow-up periods, ranging from the first 30 days post-surgery to the following 4 years.[2, 3, 6, 7, 11, 12, 14-17, 19-21]

Group A: Angiography

The first group, pertaining to papers that aimed to study angiography and its role in intraoperative monitoring of LEB, yielded 4 articles, 2 prospective and 2 retrospective studies, analyzed in Table I. Both prospective studies and one retrospective study were dedicated to reversed saphenous vein bypass, while the remaining retrospective study focused on *in situ* bypass. The majority of patients presented with stage III-IV ischaemia, requiring lower limb bypass for limb salvage. Three articles describe the morphological defects detected by intraoperative angiography and expand on the need for reintervention and graft patency rates during their respective follow-up periods. Dividing the errors detected by this technique into three classes according to severity, Grade III defects varied from 8% to 19%.[12] Class I and II defects do not require major surgical reintervention and maintain good patency rates during the follow-up period.

Class III defects such as intraluminal thrombi and anastomotic torsional abnormalities often required prompt revision and correction. In the follow up, bypasses that presented class III defects identified by the angiography and corrected intraoperatively showed similar 30-day primary patency rates. At longer follow up times, there were no differences in patency in two studies, but worse results in the bypasses that had group III defects, possibly due to the angiography's inability to describe the full extent of the lesions or to the shortcomings of the surgical correction.[7, 11, 12]

Independently of the type of bypass (in situ or reversed), evidence seems to point to the fact that angiography has a role in the detection of class III defects, which are in turn the ones responsible for the necessity of surgical reintervention. The possibility of early intervention on a jeopardized bypass might justify its use.

The sensitivity and specificity of the angiography in predicting 30-day graft patency was 90% and 98%, respectively, in the study of Mills *et al*, 1992. This might come with a cost of $700 and an additional 15 minutes of operative time associated with the realization of angiography. [7]

Group B: Completion Imaging (CIM) versus *no completion imaging*

Two prospective studies discussed the role of CIM in LEB, focusing on graft patency during the follow-up period.

While Karen et al defined CIM as completion angiography, completion DUS or both, Tan et al defined it as completion angiography or DUS and compared a group of patients that underwent routine CIM with a group that performed selective CIM. Both detailed the degree of ischaemia of all patients, ranging from claudication to tissue loss.

Both studies reported primary patency at discharge and at 1 year as their outcomes, but none of them found statistically significant differences between the groups they compared. The values of patency rates for each group can be found in Table II. In Tan *et al*'s study, CIM use was associated with dialysis, elective LEB, great saphenous vein conduit and tibial or pedal target artery.

Group C: Angiography versus DUS.

From the 2 articles comparing Angiography to DUS, there was 1 prospective and 1 retrospective study. Details pertaining to these articles can be found in Table III.

One study reported on the identification of errors with both techniques in the intraoperative period, noting that DUS identified defects that angiography missed on 9 of the 28 patients who underwent both DUS and angiography. The grafts that did not show abnormalities in DUS evaluation did not require revision, while 7 of the 22 bypasses that fill the same criteria for the arteriography group required late revision. Therefore, Papanicolaou *et al* concluded that DUS might be superior to arteriography for intraoperative monitoring in terms of the need for further graft revision.[10]

Despite the differences in cost ($650 for Arteriography and $350 for DUS) and additional operative time (22 minutes for Arteriography and 10.4 minutes for DUS), the second study verified a complete overlap between the two techniques in terms of results, the advantage of DUS relying on its lower cost, study time and mechanical graft trauma.[18]

Group D: Angiography versus Angioscopy.

As can be assessed in Table IV, 8 articles, 4 European and 4 American, aimed to establish a comparison between intraoperative angiography and intraoperative angioscopy, in a total of 839 bypasses. Out of the 8 articles, 2 were randomized control trials (RCTs), 4 prospective studies and 2 retrospective observational studies. All but one were published before the year of 2000.

Seven of the 8 studies (87.5%) included a control group. Four studies reported on the identification of graft defects with Angioscopy and Angiography, highlighting abnormalities such as intraluminal webs, bands and vein stenosis, valvulotome injuries in the case of *in situ* bypasses, mural thrombi and conduit calcification. Woelfle *et al* found that angioscopy was able to identify errors in 7 bypass grafts that appeared normal on completion angiography, as well as reveal 1 angiogram as a false positive result. [13]

Five studies reported on the need for reintervention, and Stonebridge *et al* observed that 74% of the bypasses of the Angioscopy group required correction following the identification of intraluminal defects on the arm veins, while no bypasses in the control group needed revision. Regarding patency, the same authors reported a graft patency of 100% in the Angioscopy group *versus* 82% in the control group. [15] 87.5% of the studies analyzed graft patency which, although not always statistically significant, was always tendentially superior in the groups of patients that underwent angiography.

One study focused on *in situ* saphenous vein bypass in patients with stage III-IV ischaemia and while it did not find significant differences between the intervention and control groups in terms of number of reoperations, postoperative complications and hospital stay, it established a statistically significant difference in graft patency at 1 year of follow-up (69% in the Angioscopy group and 42% in the Angiography control group). [6]

Two studies reported on the sensitivity and specificity of arteriography when compared to angioscopy. One study presented data on the volume of irrigation fluid used when both angioscopy and arteriography were performed.

Angiography versus Duplex Scanning versus Angioscopy.

Gilbertson *et al* published a randomized controlled trial in which they compared the use of intraoperative Angiography, DUS and Angioscopy in a group of 20 patients. They employed these techniques and compared their findings with direct inspection in order to validate their results, allowing for the determination of the sensitivity of each method in the identification of abnormalities that require revision and correction.

The authors studied a total of 20 femoral-infrainguinal *in situ* saphenous vein bypasses performed in 10 patients with stage III and 10 with stage IV ischaemia. Patent vein side branches, residual valve cusps and anastomotic stenoses larger than 30% were identified as the abnormalities requiring surgical intervention. The authors report the detection of 14 residual valve cusps, 49 patent vein branches and 6 anastomotic stenoses by at least one technique. Direct inspection confirmed the presence of 9 residual valve cusps and 32 patent vein branches, but no anastomotic stenoses. The study also analyzed operative time with angiography, DUS and angioscopy, reporting an increase of 17, 20 and 19 minutes, respectively. However, they found these differences to be non-statistically significant. The other secondary outcome was the sensitivity and specificity of the three methods. For the detection of patent side branches, they report a sensitivity of 44% for angiography, 12% for DUS and 66% for angioscopy. For the identification of unligated side branches, angiography and angioscopy were significantly superior to DUS ($p<0.01$). For the detection of residual valve cusps, angioscopy showed to be significantly more sensitive than the remaining methods, with a sensitivity of 100% against 22% for angiography and 11% for DUS. Angioscopy also showed a 0% false positive rate, given that all its findings were supported and confirmed by direct inspection. In contrast, angiography obtained a 20% rate DUS a rate of 10%.

These results show that Angioscopy is tendentially more sensitive than Angiography and Duplex Scanning for the detection of errors during the intraoperative period. They also found that Angioscopy yielded a false-positive rate of 0%, given that all its findings were supported and confirmed by direct inspection.

Discussion

It is crucial to apply measures that allow surgeons to identify anomalies that arise during the LEB, allowing for their immediate correction. This early intervention minimizes the risk of postoperative complications and loss of graft viability. Angiography, DUS and angioscopy were all found to be described in the literature in order to facilitate this intraoperative monitoring, and to increase the chances of bypass success.

Angiography is especially useful in grade I and II defects.[12] It was shown to results in significantly lower patency rates for grade III defects because of its difficulty in identifying the latter to their full extent, but it is still valuable in error detection and allows early correction of bypasses at risk.[11, 12] Its risks are acceptable and it remains a viable technique for intraoperative monitoring in this particular type of surgery.

DUS has shown to be a useful technique in postoperative identification of vein graft defects and flow abnormalities.[10] Its role in intraoperative monitoring is still being studied, but evidence suggests that it can detect minor anomalies that standard completion arteriography cannot identify and that could have the potential to evolve into graft failure later on. Therefore, DUS presents itself as a useful technique in the early detection of abnormalities that could affect graft patency in the postoperative period and their timely correction.[10] This technique has logistic benefits as well, given that it is less expensive and less invasive than angiography while remaining equally accurate.[23] In this regard, DUS may be superior to angiography, its results reliable and its logistical characteristics favorable (short study time, less expensive than arteriography and less associated mechanical trauma).[10, 18]

It must be pointed that studies comparing the use of angiography/DUS or both with a control group that used no CIM, showed no significant benefit of using CIM when it comes to graft patency at discharge or at 1 year, and there is no difference between performing CIM routinely or using a surgeon-specific selective approach.[2, 3] These results might indicate that, despite identifying defects in LEB, the full correction of these problems might not be always possible to achieve or that that they miss important defect which therefore were not corrected.

Intraoperative angioscopy facilitates the identification of intraluminal anomalies, such as webs and bands, that are not detected by doppler or arteriography alone, thus

allowing their correction and subsequent improvement on graft patency.[15] This technique must be used with attentiveness to its potential, albeit not frequent, risks. There have been a few reports of volume overload, potentially generating excessive pressures within the graft [28], intimal discoloration and subintimal haemorrhage.[13, 20] The former can be minimized by using an irrigation pump to administer an average of half a liter of fluid.[20] Evidence shows that the employment of angioscopic techniques has a positive impact on primary graft patency based on its accurate intraoperative identification of defects and swift correction.[6] It is safe and effective, allowing the detection and correction of technical abnormalities.[14] However, despite its superiority against angiography in the detection of conduit defects, it is less reliable for the detection of distal artery anatomy.[13, 21] Albeit the absence of statistically significant results, angioscopy tends to show better patency rates when compared with angiography.[19] Therefore, it is beneficial to think of angioscopy and angiography as procedures that complement each other instead of choosing solely one.[14] While angioscopy is crucial for direct observation of specific segments of the graft, arteriography provides a broader vision of limb vascularization.[14]

Overall, evidence suggests that all techniques have stronger and weaker points. Even while faced with a lack of statistically significant pool of results, the available results seem to favor angioscopy and its integration with the other techniques, namely angiography, for better results in terms of overall graft patency and operative success.[14, 22]

This systematic review is conditioned by several limitations. The studies included were very heterogenous in terms of study design (3 RCTs, 9 prospective and 3 retrospective studies were included), methodology (only part of the articles had a formal control group) and outcomes. For those reasons, a formal risk of bias assessment using a single quality assessment tool was not performed. Our search was restricted to two databases, MEDLINE and Web of Science, which decreases the overall quantity of pertinent information currently existing in literature included in our study. Adding a language barrier and a period restriction (exclude articles which full-text was written solely in German and all articles published before 1990, respectively) narrowed our results. The time restriction was added because studies from over 30 years ago would not reflect current practice guidelines and it would skew our conclusions towards a potentially outdated approach to lower limb bypass surgery. Finally, these results may

be hampered by lack of external validation, if the center has no experience with the use of intra-operative angiography, DUS or angioscopy.

Figures:

Tables:

Appendixes:

Declarations

Declaration of Conflicting Interests:

The Authors declare that there is no conflict of interest.

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Word Count:

Main text of 3472 words.

References

1. Fowkes FG, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet* 2013; 382: 1329-1340. 2013/08/07. DOI: 10.1016/S0140-6736(13)61249-0.
2. Woo K, Palmer OP, Weaver FA, et al. Outcomes of completion imaging for lower extremity bypass in the Vascular Quality Initiative. *J Vasc Surg* 2015; 62: 412-416. 2015/05/09. DOI: 10.1016/j.jvs.2015.03.037.
3. Tan TW, Rybin D, Kalish JA, et al. Routine use of completion imaging after infrainguinal bypass is not associated with higher bypass graft patency. *J Vasc Surg* 2014; 60: 678-685 e672. 2014/04/12. DOI: 10.1016/j.jvs.2014.03.004.
4. Rybicka A, Rynio P, Samad R, et al. The Impact of a Simplified Hydrostatic Bypass Flow Technique on Error Detection during Surgical Limb Revascularization. *J Clin Med* 2020; 9 2020/04/16. DOI: 10.3390/jcm9041079.
5. Courbier R, Jausseran JM and Reggi M. Detecting complications of direct arterial surgery: the role of intraoperative arteriography. *Arch Surg* 1977; 112: 1115-1118. 1977/09/01. DOI: 10.1001/archsurg.1977.01370090097021.
6. Thorne J, Danielsson G, Danielsson P, et al. Intraoperative angioscopy may improve the outcome of in situ saphenous vein bypass grafting: a prospective study. *J Vasc Surg* 2002; 35: 759-765. 2002/04/05. DOI: 10.1067/mva.2002.119240.
7. Dalman RL, Harris EJ and Zarins CK. Is completion arteriography mandatory after reversed-vein bypass grafting? *J Vasc Surg* 1996; 23: 637-644. 1996/04/01. DOI: 10.1016/s0741-5214(96)80044-9.
8. Jagadesham VP, Snowdon S, Weston MJ, et al. Intra-operative Doppler flow measurement do not predict 'at-risk' status of infrainguinal bypass grafts. *Eur J Vasc Endovasc Surg* 2005; 30: 597-603. 2005/08/02. DOI: 10.1016/j.ejvs.2005.04.048.
9. Bosma J, Minnee RC, Erdogan D, et al. Transit-time volume flow measurements in autogenous femorodistal bypass surgery for intraoperative quality control. *Vascular* 2010; 18: 344-349. 2010/10/29. DOI: 10.2310/6670.2010.00058.
10. Papanicolaou G, Aziz I, Yellin AE, et al. Intraoperative color duplex scanning for infrainguinal vein grafts. *Ann Vasc Surg* 1996; 10: 347-355. 1996/07/01. DOI: 10.1007/BF02286778.
11. Chalmers RT, Synn AY, Hoballah JJ, et al. Is the use of intraoperative post-reconstruction angiography following in situ saphenous vein bypass redundant? *Am J Surg* 1993; 166: 141-145. 1993/08/01. DOI: 10.1016/s0002-9610(05)81045-1.
12. Marin ML, Veith FJ, Panetta TF, et al. A new look at intraoperative completion arteriography: classification and management strategies for intraluminal defects. *Am J Surg* 1993; 166: 136-139; discussion 139-140. 1993/08/01. DOI: 10.1016/s0002-9610(05)81044-x.
13. Woelfle KD, Kugelmann U, Bruijnen H, et al. Intraoperative imaging techniques in infrainguinal arterial bypass grafting: completion angiography versus vascular endoscopy. *Eur J Vasc Surg* 1994; 8: 556-561. 1994/09/01. DOI: 10.1016/s0950-821x(05)80590-0.
14. Trubel W, Magometschnigg H, al-Hachich Y, et al. Intraoperative control following femorodistal revascularization: angioscopy is superior to angiography. *Thorac Cardiovasc Surg* 1994; 42: 199-207. 1994/08/01. DOI: 10.1055/s-2007-1016488.
15. Stonebridge PA, Miller A, Tsoukas A, et al. Angioscopy of arm vein infrainguinal bypass grafts. *Ann Vasc Surg* 1991; 5: 170-175. 1991/03/01. DOI: 10.1007/BF02016751.
16. Mills JL, Fujitani RM and Taylor SM. Contribution of routine intraoperative completion arteriography to early infrainguinal bypass patency. *Am J Surg* 1992; 164: 506-510; discussion 510-501. 1992/11/01. DOI: 10.1016/s0002-9610(05)81190-0.
17. Miller A, Marcaccio EJ, Tannenbaum GA, et al. Comparison of angioscopy and angiography for monitoring infrainguinal bypass vein grafts: results of a prospective randomized trial. *J Vasc Surg* 1993; 17: 382-396; discussion 396-388. 1993/02/01. DOI: 10.1067/mva.1993.42067.

18. Sawaqed RS, Podbielski FJ, Rodriguez HE, et al. Prospective comparison of intraoperative angiography with duplex scanning in evaluating lower-extremity bypass grafts in a community hospital. *Am Surg* 2001; 67: 601-604. 2001/06/21.
19. Woelfle KD, Bruijnen H, Zuegel N, et al. In situ saphenous vein grafts for femorodistal bypass: evaluation of endoscopically monitored valvulotomy on graft patency. *Cardiovasc Surg* 1993; 1: 690-694. 1993/12/01.
20. Kwolek CJ, Miller A, Stonebridge PA, et al. Safety of saline irrigation for angioscopy: results of a prospective randomized trial. *Ann Vasc Surg* 1992; 6: 62-68. 1992/01/11. DOI: 10.1007/BF02000670.
21. Baxter BT, Rizzo RJ, Flinn WR, et al. A comparative study of intraoperative angioscopy and completion arteriography following femorodistal bypass. *Arch Surg* 1990; 125: 997-1002. 1990/08/01. DOI: 10.1001/archsurg.1990.01410200061009.
22. Gilbertson JJ, Walsh DB, Zwolak RM, et al. A blinded comparison of angiography, angioscopy, and duplex scanning in the intraoperative evaluation of in situ saphenous vein bypass grafts. *J Vasc Surg* 1992; 15: 121-127; discussion 127-129. 1992/01/01. DOI: 10.1067/mva.1992.32985.
23. Yu A, Gregory D, Morrison L, et al. The role of intra-operative duplex imaging in arterial reconstructions. *Am J Surg* 1996; 171: 500-501. 1996/05/01. DOI: 10.1016/S0002-9610(96)00013-X.

Tables

Table I. Angiography – Group A.

Angiography (Group A)	**Chalmers *et al*, 1993**	**Marin *et al*, 1993**	**Mills *et al*, 1992**	**Dalman *et al*, 1996**
Study design	Retrospective	Prospective	Prospective	Retrospective
Country	USA	USA	USA	USA
Number of bypasses	298	78	214	93
Intervention (nr.)	298	78	213	Group 1 (25): inspection, continuous-wave doppler insonation and routine completion arteriography
Control (nr.)	0	0	214	Group 2 (68): inspection and insonation alone
Type of bypass	Infrainguinal	Infrapopliteal	Infrainguinal	Infrainguinal
Bypass orientation	In situ saphenous vein bypass	Reversed vein bypass	Reversed vein bypass (209), polytetrafluorethylene grafts (PTFE) (5)	Reversed vein bypass (73), Alternative autogenous vein conduits (19), Polytetrafluoroethylene (PTFE) (1)
Site of anastomosis	Popliteal (58), Infrapopliteal (240)		Above-knee popliteal artery: 45 (21%), below-knee popliteal artery or blind popliteal segment: 85 (40%), tibial or pedal vessel: 84 (39%)	Above-knee popliteal (4), below-knee popliteal (37), posterior or anterior tibial or peroneal (39), inframalleolar-named arteries (13)
Degree of ischaemia				
Stage II (claudication)	0	0	40 (19%) (life-limiting)	12
Stage III (rest pain)	42%	0	161 (75%) (limb salvage)	75 (limb salvage)
Stage IV (ischaemic ulcer/gangrene)	58%	78		
Other	0	0	Popliteal aneurysm: 12 (6%)	Popliteal aneurysm exclusion (6)
Defects identified and respective need for	Class I (9%): minor abnormalities, no requirement of surgical intervention (spasm of the	Grade 0 (50%): no visible abnormality; Grade I (8%): round lucencies, valve leaflets, no revision; Grade II (23%): uniform	8% of grafts requiring revision (due to distal anastomotic stenoses, distal arterial disease requiring sequential	-

intraoperative intervention	bypass or native artery or intraluminal filling defects); Class II (2%) (adventitial or extrinsic band): anastomotic buckle or extrinsic compression due to an adventitial band; Class III (8%): defects requiring major surgical revision (intraluminal thrombus, anastomotic torsional abnormalities)	smooth tapering of the graft or outflow artery, irregular intraluminal filling defect within the distal graft or its adjacent outflow artery, incomplete or faint graft opacification, nonsurgical manipulation (repetition of arteriography with or without papaverine infusion or urokinase instillation); Grade III (19%): total cutoff of graft or outflow artery opacification or irregular intraluminal filling defect in the distal graft or adjacent outflow artery, further surgical intervention (graftotomy, thrombectomy, vein patching, interposition graft or graft extension)	bypass, mid-graft valvular or branch ligature stenoses, distal arterial thrombosis, graft kink or twist)	
Later need for reintervention	3 of the 24 class III bypasses required revision within the first month after surgery vs 14 of the remaining bypasses	On grade III defects		-
Primary patency 30-day	88% in class III vs. 95% in the remaining bypasses (NS)	87% in Grade I, II vs. 87% in Grade III	99% for femoropopliteal grafts and 93% for femorodistal grafts	-
Patency other	30-day and 48-month secondary patency: Class III 100% and 93%, respectively and equivalent to non-class III bypasses	1-year primary patency: 79% in Grade I and II vs. 20% in Grade III (significantly worse patency)		6-months, 1, 2 and 3-year primary patency: 87%, 81%, 76% and 76%, respectively; 14 occlusions after surgery (5 in group 1, 9 in group 2) (NS)
Angiography costs	$700	-	-	-
Increase in operative time	Additional 15 minutes	-	-	-
Sensitivity and Specificity	-	-	Sensitivity 90%, specificity 98% (for 30-day graft patency)	-

PTFE: Polytetrafluoroethylene; Grade 0 defects: no visible abnormality; Grade I: round lucencies, valve leaflets; Grade II: uniform smooth tapering of the graft or outflow artery, irregular intraluminal filling defect within the distal graft or its adjacent outflow artery, incomplete or faint graft opacification; Grade III: total cutoff of graft or outflow artery opacification or irregular intraluminal filling defect in the distal graft or adjacent outflow artery. NS: non statistically significant.

Table II. Completion Imaging *versus* No Completion Imaging – Group B.

Completion Imaging *versus* No Completion Imaging (Group B)	**Karen et al, 2015**	**Tan et al, 2014**
Study design	Prospective	Prospective
Country	USA	USA
Number of bypasses	3147	20132
Intervention (nr.)	1457	1368
Control (nr.)	1690	664
Type of bypass	-	-
Bypass orientation	Reversed (1325); In situ (1064); Nonreversed, transposed (758)	-
Site of anastomosis	Popliteal (58), Infrapopliteal (240)	
Degree of ischaemia		
Stage II (claudication)	0	544: routine CMI 340; selective CIM 204
Stage III (rest pain)	814: CIM 377, No CIM 437	515: routine CIM 336, selective CIM 179
Stage IV (ischaemic ulcer/gangrene)	2333: CIM 1080, No CIM 1253	973: routine CIM 692, selective CIM 281
Primary patency At discharge	CIM: 93.2% (95.1% for completion duplex ultrasound and 92.8% for completion angiography); no CIM, 93.8% (p=0.52, NS)	Routine CIM: 96% Selective CIM: 68% (NS)
1-year	CIM: 63% (60% for duplex ultrasound, 65% for angiography); 68% in the no CIM group (p=0.051, NS)	Routine CIM: 94% Selective CIM: 72% (NS)

CIM: Completion Imaging. NS: non statistically significant.

Table III. Completion Imaging *versus* Doppler Ultrasound – Group C.

Completion imaging *versus* Doppler Ultrasound (Group C)	**Sawaqed *et al*, 2001**	**Papanicolau *et al*, 1996**
Study design	Prospective	Retrospective
Country	USA	USA
Number of bypasses	19	81
Intervention (nr.)	-	Group 1 (28): DUS + angiography Group 2 (21): only DUS
Control (nr.)	-	Group 3 (26): only completion angiography
Type of bypass	Infrainguinal	Infrainguinal
Bypass orientation	-	Reversed vein bypass (66), In situ great saphenous vein bypass (5), Spliced veins (7), Polytetrafluoroethylene (PFTE) graft (2), Arm vein (1)
Site of anastomosis	-	Above-knee popliteal (4 reversed); Below-knee peopliteal (13 reversed, 1 in situ, 1 arm vein); Distal (66 reversed, 5 in situ, 7 spliced veins, 2 PTFE)
Degree of ischaemia		
Stage II (claudication)	-	1 (1%)
Stage III (rest pain)	-	19 (24%)
Stage IV (ischaemic ulcer/gangrene)	-	Gangrene (34), Ischemic ulcers (27) - total of 75% of patients
Identification of defects	-	Group 1: 9 grafts showed defects on color duplex but not on angiography; arteriography showed additional defects in 2 procedures (but no intervention performed); Group 2: abnormality in 8 procedures - 3 immediate repairs and 5 late revisions; Group 3: defects identified in 4 procedures - 3 immediate repairs. 7 of the remaining 22 group 3 procedures required late revision
Need for reintervention	-	Group 1: 6 immediate repairs, 1 early revision and 2 late revisions
Costs	Angiography: $650 Duplex scanning: $350	-
Increase in operative time	Cut-film angiography: 22 +/- 1.8 min. Duplex imaging: 10.4 +/- 1.1 min. Real-time fluoroscopy: 17 +/- 2.5 min.	-

PTFE: Polytetrafluoroethylene. NS: non statistically significant.

Table IV. Completion Imaging versus Angioscopy – Group D.

Angiography *versus* Angioscopy (Group D)	**Thörne *et al*, 2002**	**Woelfle *et al*, 1994**	**Trubel *et al*, 1994**	**Woelfle *et al*, 1993**
Study design	Prospective	Prospective	Prospective	Retrospective
Country	EU (Sweeden)	EU (Germany)	EU (Austria)	United Kingdom
Number of bypasses	101	102	27	135
Intervention (nr.)	32	99	25	96
Control (nr.)	69	99	27	39
Type of bypass	Femorodistal	Infragenicular	Femorodistal	Femorocrural
Bypass orientation	In situ saphenous vein bypass	Reversed long saphenous vein graft (39), Non-reversed long saphenous vein graft (21), In situ long saphenous vein graft (19), Reversed short vein graft (2), PTFE graft (17), Composite vein and PTFE conduit (4)	Above-knee PTFE (6), Reversed autologous saphenous vein grafts (21)	-
Site of anastomosis	-	Below-knee popliteal (24), extended to the crural segment (64), pedal arteries (14)	-	Proximal half of the crural vessels (52), distal half (83)
Degree of ischaemia				
Stage II (claudication)	0	0	-	0
Stage III (rest pain)	95 (30 intervention - 94% + 65 control - 94%)	4	-	0
Stage IV (ischaemic ulcer/gangrene)	73 (23 intervention - 71% + 50 control - 72%)	95	-	135
Other	0	Symptomatic popliteal aneurysm (3)	-	0
Defects identified and respective need for intraoperative intervention	-	7 significant defects found with angioscopy among the 90 patients with normal completion angiogram.	Narrowing of a venovenostomy, residual thrombus close to the distal anastomosis, graft torsion, pseudointima dissection, misplaced suture,	-

			residual thrombus in the distal artery, large residual embolus in the distal artery; the first two were identified by both angiography and angioscopy; the rest only on angioscopy)	
Later need for reintervention	No differences in number of reoperations, postoperative local complications or postoperative hospital stay.	-	Local revision (5), New bypass graft (3)	-
Primary patency 30-day	-	-	No graft failure within the first 30 days of follow-up	Angioscopy 76%, Angiogram 76%.
Patency Other	1-year: 69% in Angioscopy group, 42% in Angiography group (statistically significant).	-	2.5 months: 1 occlusion (appearing incospicuous in angiography and angioscopy)	1 year: 62% vs 44%; 4 years: 43% vs 27%. NS
Feasibility	-	-	In 92.5% of cases	-
Increase in operative time	-	-	Angioscopy: mean duration of 7.5 min	-
Sensitivity and Specificity	-	Angiography: 46% and 98%, respectively (when compared to angioscopy)	-	-

Table IV (cont.). Completion Imaging *versus* Angioscopy – Group D.

	Miller *et al*, 1993	**Kwolek *et al*, 1992**	**Stonebridge *et al*, 1991**	**Baxter *et al*, 1990**
Study design	Randomized Controlled Trial	Randomized Controlled Trial	Retrospective	Prospective
Country	USA	USA	USA	USA
Number of bypasses	250	110	66	49
Intervention (nr.)	128	60	27	-
Control (nr.)	122	50	39 (30 doppler alone, 9 arteriography)	-
Type of bypass	Femoropopliteal (65); femorotibial (74); femoropedal (25); popliteotibial	Femoropopliteal (25); femorodistal	Infrageniculate	Femorodistal

	(26); popliteopedal (49); femoroplantar-popliteoplantar (11)	(57); popliteal-distal (28)		
Bypass orientation	Reversed (71); Non-reversed (81); In situ (90); Composite (8)	Greater saphenous vein graft	Reversed (33 - 50%); Non-reversed (18 - 27%); Both (15 - 23%)	-
Site of anastomosis	-	Infrageniculate arteries (75%)	Popliteal, Tibial or Pedal arteries	-
Degree of ischaemia				
Stage II (claudication)	15 (7 Angioscopy + 8 Angiography)	0	-	-
Stage III (rest pain)	67 (33 Angioscopy + 34 Angiography)	6	-	-
Stage IV (ischaemic ulcer/gangrene)	189 (96 Angioscopyy + 47 Angiography)	104	-	-
Other	Infection (62: 33 Angioscopy + 29 Angiography)	0	-	-
Defects identified and respective need for intraoperative intervention	Narrowed vein segment in the distal vein graft (identified only on angiography); findings on Angioscopy related to the vein conduit (5) and to the anastomosis (8); localized valvulotome injury (3); localized area of nonnobstructing organized mural thrombus and a calcification of the vein conduit (2)	-	Intraluminal abnormalities of the arm veins: webs, bands and localized vein stenosis	-
Later need for reintervention	39 interventions (32 with angioscopy and 7 with angiography)	-	Standard methods group - no significant findings requiring revision or correction; Angioscopy group - intraluminal abnormalities on the arm veins (20; 74%)	5 (10%)
Primary patency 30-day	4 grafts (3.1%) of the Angioscopy group failed and 8 (6.6%) from the Angiography group	95% in the angioscopy group, 88% in the arteriography group	7 occlusions in the Standard methods group - patency rate of 82%; 100% in the Angioscopy group	Early graft failure (<72 hours) in 3 patients

Increase in operative time	Femoropopliteal: 214 vs 202 minutes; Femorotibial: 243 vs 260 minutes; Femoropedal: 305 vs 340 minutes; Popliteotibial: 250 vs 241 minutes; Popliteopedal: 243 vs 208 minutes	-	-	-
Sensitivity and Specificity	-	-	-	Sensitivity of 67% and speceficity of 95% for Arteriography

PTFE: Polytetrafluoroethylene. NS: non statistically significant.

Appendix I. Search query used.

(intraoperative OR "Monitoring, Intraoperative"[Mesh] OR "Monitoring, Intraoperative"[Text word] OR "Intraoperative Period"[Mesh] OR "Intraoperative Period"[Text word] OR completion [Mesh] OR completion [Text word])

AND

("Angiography"[Mesh] OR "Angiography"[Text word] OR "Computed Tomography Angiography"[Mesh] OR "Computed Tomography Angiography"[Text word] OR "flow measurements" [Mesh] OR "flow measurements" [Text word] OR "Indocyanine Green"[Mesh] OR "Indocyanine Green"[Text word])

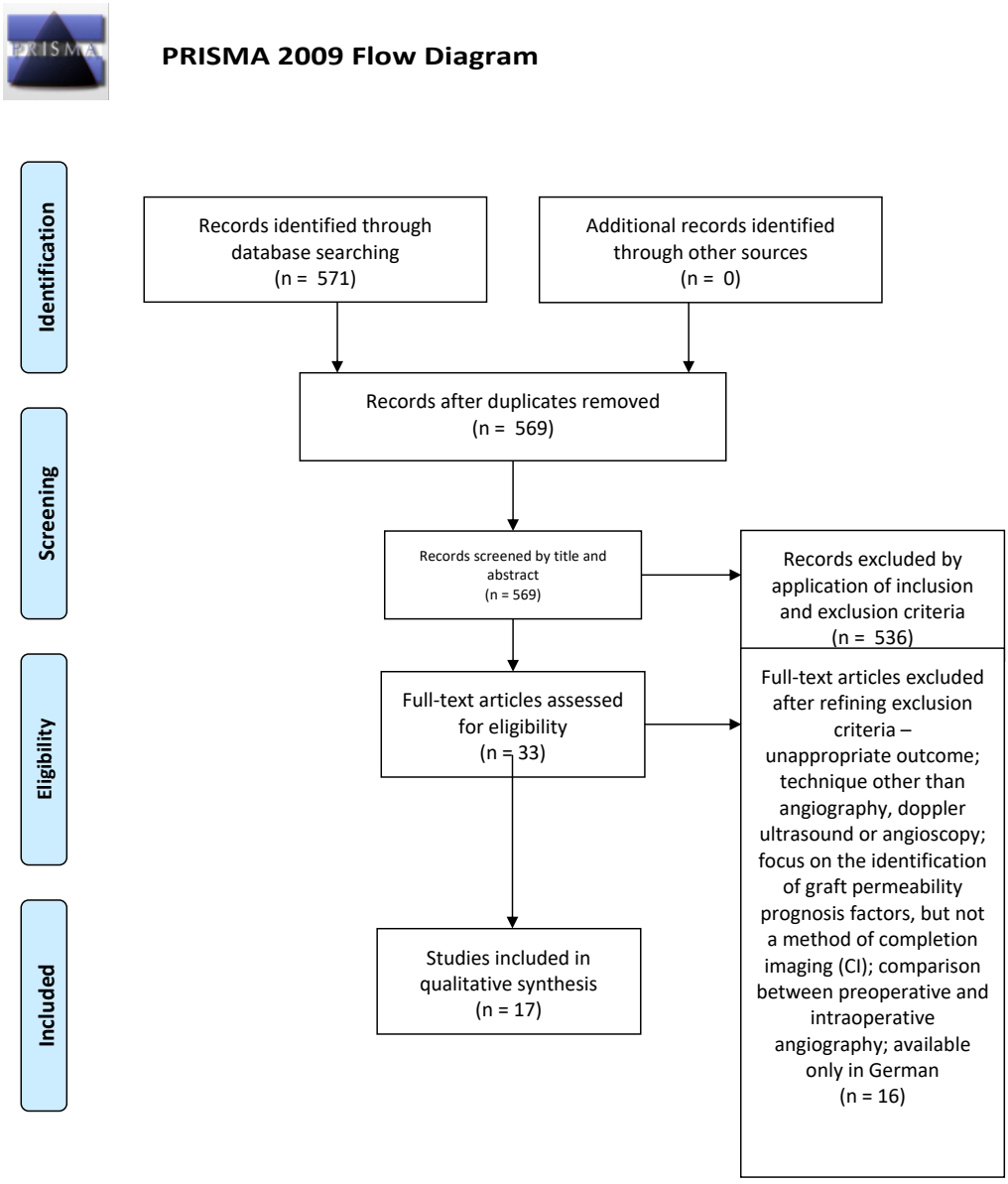
AND

(bypass [Mesh] OR bypass [Text word] OR reconstruction [Mesh] OR reconstruction [Text word] OR “open surgery” OR revascularization OR re-vascularization OR graft OR grafting)

AND

("Lower Extremity"[Mesh] OR "Lower Extremity"[Text word] OR "lower limb" OR leg [Mesh] OR leg [Text word] OR buttock OR gluteal or foot or feet or Hip OR Knee OR Thigh OR femoral OR femoro OR popliteal OR tibial OR peroneal OR infrainguinal OR infra-inguinal)

Figure 1. Detailed selection process



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page and paragraph/ table #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both. **- MANDATÓRIO**	Page 1-3
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. **– SEGUIR RECOMENDAÇÕES DA REVISTA**	Page 7-8
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. **– MANDATÓRIO** ***O rationale corresponde à justificação da importância da revisão sistemática***	Page 9, paragraph 3-4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). **- MANDATÓRIO**	Page 10, paragraph 1
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. **– FACULTATIVO**	NA
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. **– MANDATÓRIO** ***É altamente recomendado, de acordo com as boas práticas da Cochrane, que não sejam aplicados critérios de exclusão baseados na língua e/ou data de publicação dos estudos.***	Page 11, paragraph 2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. **– MANDATÓRIO** ***Em consonância com as boas práticas da Cochrane, é mandatório que se verifique pesquisa em pelo menos duas bases de pesquisa bibliográfica (idealmente, deverão ser pesquisadas duas bases generalistas e uma específica da área). No caso de revisões sistemáticas de estudos experimentais/ensaios clínicos aleatorizados, é altamente recomendado que uma das bases pesquisadas corresponda à CENTRAL ou a bases de ensaios clínicos como a ClinicalTrials.gov.*** ***Estudos de revisão da literatura em que a pesquisa decorra numa única base de dados não serão classificados como revisões sistemáticas.***	Page 11, paragraph 1
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. **– MANDATÓRIO** ***A query de pesquisa deve ser obrigatoriamente disponibilizada. A utilização de filtros de pesquisa da***	Page 33

Figure 2. PRISMA Guidelines.

PRISMA 2009 Checklist

		InterTASC é altamente recomendada (https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/home)	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). **– MANDATÓRIO** ***As fases de selecção dos estudos primários devem ser descritas. Em consonância com as boas práticas da Cochrane, é mandatório que o processo de selecção envolva duas fases (fase de rastreio, em que os registos são seleccionados por título e abstract, e fase de inclusão, na qual se procede à leitura integral dos full texts). Em cada uma destas fases, o processo de selecção deve mandatoriamente envolver dois investigadores actuando de forma independente.***	Page 11, paragraph 3-4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. **– MANDATÓRIO** ***Trata-se de descrever de que forma se procedeu à extracção de dados dos estudos primários. Em consonância com as boas práticas da Cochrane, tal processo deverá envolver dois investigadores de forma independente.***	Page 12, paragraph 1
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. **– MANDATÓRIO** ***Trata-se de descrever as variáveis para as quais foi obtida informação.***	Page 12, paragraph 1
Risk of bias in individual studies / Risk of bias across studies	12/ 15	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. **– MANDATÓRIO** ***Em todas as revisões sistemáticas, deverá existir um processo de avaliação da qualidade dos estudos primários. No caso de revisões sistemáticas de estudos experimentais/ensaios clínicos aleatorizados, a aplicação dos critérios de risco de viés (Risk of Bias) da Cochrane é altamente recomendada. No caso de revisões sistemáticas de estudos observacionais, poderão ser seguidos os critérios ROBINS ou os critérios dos National Institutes of Health (https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools).***	Page 19, paragraph 2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means). **– FACULTATIVO. APENAS NECESSÁRIO SE FOR FEITA META-ANÁLISE**	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis. **– FACULTATIVO. APENAS NECESSÁRIO SE FOR FEITA META-ANÁLISE**	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. **– FACULTATIVO. APLICÁVEL APENAS SE FOR FEITA META-ANÁLISE**	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. **– MANDATÓRIO**	Page 13, paragraph 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. **– MANDATÓRIO**	Page 13, paragraph 2-4

PRISMA 2009 Checklist

Risk of bias within and across studies	19/ 22	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). – **MANDATÓRIO**	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. – **FACULTATIVO. APLICÁVEL APENAS SE FOR FEITA META-ANÁLISE**	NA
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency. – **FACULTATIVO. MANDATÓRIO APENAS SE FOR FEITA META-ANÁLISE**	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). – **FACULTATIVO. APLICÁVEL APENAS SE FOR FEITA META-ANÁLISE**	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). – **MANDATÓRIO**	Page 18, paragraph 1-4
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). – **MANDATÓRIO**	Page 19, paragraph 2
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research. – **MANDATÓRIO**	Page 19, paragraph 1
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. – **SEGUIR RECOMENDAÇÕES DA REVISTA**	Page 22

NA – Não aplicável, visto que esta revisão não se acompanhou de meta-análise.

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Manuscript Submission Guidelines:

Manuscript Submission Guidelines: Vascular

This Journal is a member of the Committee on Publication Ethics.

This Journal recommends that authors follow the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals formulated by the International Committee of Medical Journal Editors (ICMJE).

Please read the guidelines below then visit the Journal's submission site http://mc.manuscriptcentral.com/vascular to upload your manuscript. Please note that manuscripts not conforming to these guidelines may be returned.

Only manuscripts of sufficient quality that meet the aims and scope of Vascular will be reviewed.

There are no fees payable to submit or publish in this journal.

As part of the submission process you will be required to warrant that you are submitting your original work, that you have the rights in the work, and that you have obtained and can supply all necessary permissions for the reproduction of any copyright works not owned by you, that you are submitting the work for first publication in the Journal and that it is not being considered for publication elsewhere and has not already been published elsewhere. Please see our guidelines on prior publication and note that *Vascular* may accept submissions of papers that have been posted on pre-print servers; please alert the Editorial Office when submitting (contact details are at the end of these guidelines) and include the DOI for the preprint in the designated field in the manuscript submission system. Authors should not post an updated version of their paper on the preprint server while it is being peer reviewed for possible publication in the journal. If the article is accepted for publication, the author may re-use their work according to the journal's author archiving policy.

1. What do we publish?

1.1 Aims & Scope

Before submitting your manuscript to Vascular, please ensure you have read the Aims & Scope.

1.2 Article Types

Types of manuscript published by the journal include: Original Articles; Review Articles; Technical Articles; Case Reports; and Letters to the Editors/Commentaries.

Word limits:

For main text only, which does not include the references, abstract and keywords:

Original research article: up to 3500 words

Review article: up tp 5000 words

Case reports: up to 1500 words (including a structured abstract of no more than 200 words - see below)

Letters to the Editors/Commentaries: up to 500 words

(N.B. Please metion the word count of your main text file on the file)

Covering letter: Please note that the covering letter is important. To help the Editor in his preliminary evaluation, please indicate why you think the paper suitable for publication. If your paper should be considered for fast-track publication, please explain why.

Title page: The title page should include title of manuscript; type of manuscript (e.g. original paper, case report, book review); name and initials of each author; department and institution to which the work is to be attributed; city and state; acknowledgement of grant support; name, address and telephone number of grant support; a full list of declarations; and name, address, fax and telephone numbers, and e-mail address of the corresponding author.

The title: The title should be concise and informative, accurately indicating the content of the article. An abbreviated title of no more than 40 characters should be included to be used as a running head. The title page should provide complete information (meeting title, city, state, country, and dates) if the paper was presented at a scientific meeting.

Abstract: The second page of the manuscript should provide a structured abstract of no more than 450 words. The abstract should contain the following sub headings: Objectives, Methods, Results and Conclusions. The abstract should also include up to six keywords.

Case Reports: The abstract should contain the following sub headings: Objectives, Methods, Results and Conclusions. This paper type should have a maximum of 3 authors. Case Reports should include no more than 3 figures and 10 references. Tables should not be used.

1.3 Writing your paper

The SAGE Author Gateway has some general advice and on how to get published, plus links to further resources.

1.3.1 Make your article discoverable

When writing up your paper, think about how you can make it discoverable. The title, keywords and abstract are key to ensuring readers find your article through search engines such as Google. For information and guidance on how best to title your article, write your abstract and select your keywords, have a look at this page on the Gateway: How to Help Readers Find Your Article Online.

Back to top

2. Editorial policies

2.1 Peer review policy

Vascular adheres to a single-blind reviewing policy in which the identity of the reviewer is always concealed from the submitting author. Each manuscript is reviewed by at least two referees. All manuscripts are reviewed as rapidly as possible.

As part of the submission process you will be asked to provide the names of peers who could be called upon to review your manuscript. Recommended reviewers should be experts in their fields and should be able to provide an objective assessment of the manuscript. Please be aware of any conflicts of interest when recommending reviewers. Examples of conflicts of interest include (but are not limited to) the below:

-
    - The reviewer should have no prior knowledge of your submission
    - The reviewer should not have recently collaborated with any of the authors
    - Reviewer nominees from the same institution as any of the authors are not permitted

Please note that the Editors are not obliged to invite any recommended/opposed reviewers to assess your manuscript.

2.2 Declarations

The correct order for declarations is:

1. Acknowledgements
2. Declaration of Conflicting Interests
3. Funding
4. Notes
5. References

2.3 Authorship

Papers should only be submitted for consideration once consent is given by all contributing authors. Those submitting papers should carefully check that all those whose work contributed to the paper are acknowledged as contributing authors.

The list of authors should include all those who can legitimately claim authorship. This is all those who:

1.
    1. Made a substantial contribution to the concept or design of the work; or acquisition, analysis or interpretation of data,
    2. Drafted the article or revised it critically for important intellectual content,
    3. Approved the version to be published,
    4. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Authors should meet the conditions of all of the points above. When a large, multicentre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship.

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship, although all contributors who do not meet the criteria for authorship should be listed in the Acknowledgments section. Please refer to the International Committee of Medical Journal Editors (ICMJE) authorship guidelines for more information on authorship.

2.4 Acknowledgements

All contributors who do not meet the criteria for authorship should be listed in an Acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, or a department chair who provided only general support.

Please supply any personal acknowledgements separately to the main text to facilitate anonymous peer review.

2.4.1 Writing assistance

Individuals who provided writing assistance, e.g. from a specialist communications company, do not qualify as authors and so should be included in the Acknowledgements section. Authors must disclose any writing assistance – including the individual's name, company and level of input – and identify the entity that paid for this assistance. It is not necessary to disclose use of language polishing services.

2.5 Funding

Vascular requires all authors to acknowledge their funding in a consistent fashion under a separate heading. Please visit the Funding Acknowledgements page on the SAGE Journal Author Gateway to confirm the format of the acknowledgment text in the event of funding, or state that: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

2.6 Declaration of conflicting interests

It is the policy of Vascular to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please ensure that a 'Declaration of Conflicting Interests' statement is included at the end of your manuscript, after any acknowledgements and prior to the references. If no conflict exists, please state that 'The Author(s) declare(s) that there is no conflict of interest'. For guidance on conflict of interest statements, please see the ICMJE recommendations here.

2.7 Research ethics and patient consent

Medical research involving human subjects must be conducted according to the World Medical Association Declaration of Helsinki.

Submitted manuscripts should conform to the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, and all papers reporting animal and/or human studies must state in the methods section that the relevant Ethics Committee or Institutional Review Board provided (or waived) approval. Please ensure that you have provided the full name and institution of the review committee, in addition to the approval number.

For research articles, authors are also required to state in the methods section whether participants provided informed consent and whether the consent was written or verbal. Information on informed consent to report individual cases or case series should be included in the manuscript text. A statement is required regarding whether written informed consent for patient information and images to be published was provided by the patient(s) or a legally authorized representative. Please do not submit the patient's actual written informed consent with your article, as this in itself breaches the patient's confidentiality. The Journal requests that you confirm to us, in writing, that you have obtained written informed consent but the written consent itself should be held by the

authors/investigators themselves, for example in a patient's hospital record. The confirmatory letter may be uploaded with your submission as a separate file.

Please also refer to the ICMJE Recommendations for the Protection of Research Participants.

All research involving animals submitted for publication must be approved by an ethics committee with oversight of the facility in which the studies were conducted. The journal has adopted the Consensus Author Guidelines on Animal Ethics and Welfare for Veterinary Journals published by the International Association of Veterinary Editors.

2.8 Clinical trials

Vascular conforms to the ICMJE requirement that clinical trials are registered in a WHO-approved public trials registry at or before the time of first patient enrolment as a condition of consideration for publication. The trial registry name and URL, and registration number must be included at the end of the abstract.

2.9 Reporting guidelines

The relevant EQUATOR Network reporting guidelines should be followed depending on the type of study. For example, all randomized controlled trials submitted for publication should include a completed CONSORT flow chart as a cited figure and the completed CONSORT checklist should be uploaded with your submission as a supplementary file. Systematic reviews and meta-analyses should include the completed PRISMA flow chart as a cited figure and the completed PRISMA checklist should be uploaded with your submission as a supplementary file. The EQUATOR wizard can help you identify the appropriate guideline.

Other resources can be found at NLM's Research Reporting Guidelines and Initiatives.

2.10 Research Data

SAGE acknowledges the importance of research data availability as an integral part of the research and verification process for academic journal articles.

Vascular requests all authors submitting any primary data used in their research articles alongside their article submissions to be published in the online version of the journal, or provide detailed information in their articles on how the data can be obtained. This information should include links to third-party data repositories or detailed contact information for third-party data sources. Data available only on an author-maintained website will need to be loaded onto either the journal's platform or a third-party platform to ensure continuing accessibility. Examples of data types

include but are not limited to statistical data files, replication code, text files, audio files, images, videos, appendices, and additional charts and graphs necessary to understand the original research. The Editor may consider limited embargoes on proprietary data. The Editor can also grant exceptions for data that cannot legally or ethically be released. All data submitted should comply with Institutional or Ethical Review Board requirements and applicable government regulations.

Back to top

3. Publishing Policies

3.1 Publication ethics

SAGE is committed to upholding the integrity of the academic record. We encourage authors to refer to the Committee on Publication Ethics' International Standards for Authors and view the Publication Ethics page on the SAGE Author Gateway.

3.1.1 Plagiarism

Vascular and SAGE take issues of copyright infringement, plagiarism or other breaches of best practice in publication very seriously. We seek to protect the rights of our authors and we always investigate claims of plagiarism or misuse of published articles. Equally, we seek to protect the reputation of the journal against malpractice. Submitted articles may be checked with duplication-checking software. Where an article, for example, is found to have plagiarised other work or included third-party copyright material without permission or with insufficient acknowledgement, or where the authorship of the article is contested, we reserve the right to take action including, but not limited to: publishing an erratum or corrigendum (correction); retracting the article; taking up the matter with the head of department or dean of the author's institution and/or relevant academic bodies or societies; or taking appropriate legal action.

3.1.2 Prior publication

If material has been previously published it is not generally acceptable for publication in a SAGE journal. However, there are certain circumstances where previously published material can be considered for publication. Please refer to the guidance on the SAGE Author Gateway or if in doubt, contact the Editor at the address given below.

3.2 Contributor's publishing agreement

Before publication, SAGE requires the author as the rights holder to sign a Journal Contributor's Publishing Agreement. SAGE's Journal Contributor's Publishing Agreement is an exclusive licence agreement which means that the author retains

copyright in the work but grants SAGE the sole and exclusive right and licence to publish for the full legal term of copyright. Exceptions may exist where an assignment of copyright is required or preferred by a proprietor other than SAGE. In this case copyright in the work will be assigned from the author to the society. For more information please visit the SAGE Author Gateway.

3.3 Open access and author archiving

Vascular offers optional open access publishing via the SAGE Choice programme. For more information please visit the SAGE Choice website. For information on funding body compliance, and depositing your article in repositories, please visit SAGE Publishing Policies on our Journal Author Gateway.

Back to top

4. Preparing your manuscript for submission

4.1 Formatting

The preferred format for your manuscript is Word. LaTeX files are also accepted. Word and (La)Tex templates are available on the Manuscript Submission Guidelines page of our Author Gateway.

4.2 Artwork, figures and other graphics

For guidance on the preparation of illustrations, pictures and graphs in electronic format, please visit SAGE's Manuscript Submission Guidelines.

Figures supplied in colour will appear in colour online regardless of whether or not these illustrations are reproduced in colour in the printed version.

Tables: Tables must be prepared in MS Word using the Table feature (NOTE: Tables cannot be used if they are in PowerPoint or Excel or if they are supplied as images). Tables should not duplicate information given in the text, should be numbered in the order in which they are mentioned in the text, and should be given a brief title. Tables should be provided at the end of the article, after the references and on separate page.

Figures: All figures should be numbered in the order in which they are mentioned in the text. All figures must be accompanied by a figure legend. If figures are supplied in separate files, the figure legends must all be listed at the end of the main text file.

Line drawings: Line drawings should be produced electronically and clearly labelled using a sans serif font such as Arial. Graphs may be supplied as Excel spreadsheets (one per sheet). Other line drawings should be supplied in a suitable vector graphic file format (e.g., .eps. Bar graphs should be prepared as 3D images. Existing line

drawings should be scanned at 600 dpi at a minimum of 12.5 cm (5 in) in width (2100 pixels) and saved as .eps files (flow charts must not exceed 7 inches [18 cm] in width). *Photographic images:* All photographic images should be submitted in camera-ready form (i.e. with all extraneous areas removed), and where necessary, magnification should be shown using a scale marker. Color photographs should be saved in CMYK as TIF files, preferably at 600 dpi, at 5 inches (12.5 cm) in width (1500 pixels). Black and white photographs should be saved in greyscale as .tif files, preferably at 600 dpi at 5 inches (12.5 cm) in width (1500 pixels). Images supplied at less than 300 dpi are unsuitable for print and will delay publication. The preferred file format is .tif.

4.3 Supplemental material

This journal is able to host additional materials online (e.g. datasets, podcasts, videos, images etc) alongside the full-text of the article. For more information please refer to our guidelines on submitting supplemental files.

4.4 Reference style

Vascular adheres to the SAGE Vancouver reference style. View the SAGE Vancouver guidelines to ensure your manuscript conforms to this reference style.

If you use EndNote to manage references, you can download the SAGE Vancouver EndNote output file.

4.5 English language editing services

Authors seeking assistance with English language editing, translation, or figure and manuscript formatting to fit the journal's specifications should consider using SAGE Language Services. Visit SAGE Language Services on our Journal Author Gateway for further information.

Back to top

5. Submitting your manuscript

Vascular is hosted on SAGE Track, a web based online submission and peer review system powered by ScholarOne™ Manuscripts.

Visit https://mc.manuscriptcentral.com/vascular to login and submit your article online.

IMPORTANT: Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the journal in the past year it is likely that you will have had an account created. For further guidance on submitting your manuscript online please visit ScholarOne Online Help.

5.1 ORCID

As part of our commitment to ensuring an ethical, transparent and fair peer review process SAGE is a supporting member of ORCID, the Open Researcher and Contributor ID. ORCID provides a unique and persistent digital identifier that distinguishes researchers from every other researcher, even those who share the same name, and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between researchers and their professional activities, ensuring that their work is recognized.

The collection of ORCID iDs from corresponding authors is now part of the submission process of this journal. If you already have an ORCID iD you will be asked to associate that to your submission during the online submission process. We also strongly encourage all co-authors to link their ORCID ID to their accounts in our online peer review platforms. It takes seconds to do: click the link when prompted, sign into your ORCID account and our systems are automatically updated. Your ORCID iD will become part of your accepted publication's metadata, making your work attributable to you and only you. Your ORCID iD is published with your article so that fellow researchers reading your work can link to your ORCID profile and from there link to your other publications.

If you do not already have an ORCID iD please follow this link to create one or visit our ORCID homepage to learn more.

5.2 Information required for completing your submission

You will be asked to provide contact details and academic affiliations for all co-authors via the submission system and identify who is to be the corresponding author. These details must match what appears on your manuscript. The affiliation listed in the manuscript should be the institution where the research was conducted. If an author has moved to a new institution since completing the research, the new affiliation can be included in a manuscript note at the end of the paper. At this stage please ensure you have included all the required statements and declarations and uploaded any additional supplementary files (including reporting guidelines where relevant).

5.3 Permissions

Please also ensure that you have obtained any necessary permission from copyright holders for reproducing any illustrations, tables, figures or lengthy quotations previously published elsewhere. For further information including guidance on fair dealing for criticism and review, please see the Copyright and Permissions page on the SAGE Author Gateway.

Back to top

6. On acceptance and publication

6.1 SAGE Production

Your SAGE Production Editor will keep you informed as to your article's progress throughout the production process. Proofs will be made available to the corresponding author via our editing portal SAGE Edit or by email, and corrections should be made directly or notified to us promptly. Authors are reminded to check their proofs carefully to confirm that all author information, including names, affiliations, sequence and contact details are correct, and that Funding and Conflict of Interest statements, if any, are accurate. Please note that if there are any changes to the author list at this stage all authors will be required to complete and sign a form authorising the change.

6.2 Online First publication

Online First allows final articles (completed and approved articles awaiting assignment to a future issue) to be published online prior to their inclusion in a journal issue, which significantly reduces the lead time between submission and publication. Visit the SAGE Journals help page for more details, including how to cite Online First articles.

6.3 Access to your published article

SAGE provides authors with online access to their final article.

6.4 Promoting your article

Publication is not the end of the process! You can help disseminate your paper and ensure it is as widely read and cited as possible. The SAGE Author Gateway has numerous resources to help you promote your work. Visit the Promote Your Article page on the Gateway for tips and advice.

Back to top

7. Further information

Any correspondence, queries or additional requests for information on the manuscript submission process should be sent to the Vascular editorial office as follows:

vascular@sagepub.co.uk

(Guidelines available at https://journals.sagepub.com/author-instructions/VAS)