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[Intervention Review]

Ultrasound-guided versus anatomic landmark-guided percutaneous femoral artery access

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ABSTRACT

Background

The use of percutaneous arterial access for endovascular procedures has broad applications, from diagnostic angiography in the coronary and peripheral arteries, to thromboembolectomy in people with ischemic stroke and percutaneous coronary intervention in those with acute myocardial infarction. The rise of these procedures worldwide underscores the importance of obtaining precise and timely arterial access while minimizing the risk of adverse events. Traditionally, anatomic landmarks, such as the anterior superior iliac spine and symphysis pubis, have guided percutaneous common femoral artery (CFA) access, along with manual palpation of the pulse and fluoroscopy to confirm bony landmarks. Anatomic landmarks can be deceptive, however, especially in certain subpopulations, such as those with a high femoral artery bifurcation, elevated body mass index (BMI), or non-palpable femoral pulses. Ultrasound has emerged as a promising tool to guide percutaneous CFA access, offering enhanced visualization and providing real-time guidance. Notwithstanding this theoretical advantage, trials have inconsistently demonstrated an advantage to ultrasound guidance over anatomic landmarks, and concerns surrounding added set-up time and training have limited its uptake both clinically and across society guidelines.

Objectives

To assess the efficacy and safety of ultrasound compared to anatomic landmarks to guide percutaneous access of the CFA for the purpose of endovascular arterial imaging or treatment.

Search methods

The Cochrane Vascular Information Specialist searched the Cochrane Vascular Specialised Register, CENTRAL, MEDLINE, Embase, and CINAHL databases and World Health Organization International Clinical Trials Registry Platform and ClinicalTrials.gov trials registers to 25 January 2024.

Selection criteria

We selected randomized controlled trials comparing ultrasound guidance to anatomic landmark guidance (using manual palpation or fluoroscopy, or both) for percutaneous CFA access in people undergoing endovascular therapy for diagnostic or therapeutic purposes.

Data collection and analysis

We used standard Cochrane methods. Primary outcomes included first-pass success, time to successful CFA access, and major bleeding (including hematoma requiring transfusion, hematoma extending length of stay, hematoma ≥ 5 cm, unexplained hemoglobin drop, or major/severe bleeding as defined by each trial). Secondary outcomes included overall cannulation success, venipuncture, pain scores, number of access attempts, major complications (including retroperitoneal hematoma, pseudoaneurysms, dissections, arteriovenous fistulae, or occlusions), adverse events (including minor bleeding, infection, and neuropathy) up to 30 days, quality of life, re-intervention rate up to 30 days, and total number of access sites attempted. We conducted sensitivity analyses to determine whether the effect of ultrasound guidance on time to successful CFA access differed across studies that defined this endpoint differently, and to assess the impact of studies that permitted rescue ultrasound on study endpoints.

Main results

Of 1422 records identified through our search of the databases, nine randomized controlled trials enrolling 4447 participants fulfilled our inclusion criteria. All trials were at high risk of bias in at least one domain, with seven trials at overall high risk of bias and the remaining two at overall unclear risk of bias.

There may be increased first-pass success (odds ratio [OR] 3.35, 95% confidence interval [CI] 2.53 to 4.44; P < 0.001, I^2 = 69%; 7 trials, 4274 participants; low certainty evidence) and reduced time to successful CFA access (mean difference [MD] −17.24 s, 95% CI −27.04 to −7.43 s; P < 0.001, I^2 = 45%; 6 trials, 3570 participants; low certainty evidence) with ultrasound guidance compared to anatomic landmark guidance. Ultrasound guidance may also reduce unintentional venipuncture (OR 0.26, 95% CI 0.18 to 0.38; P < 0.001, I^2 = 33%; 7 trials, 4178 participants; low certainty evidence) and number of access attempts (MD −0.59, 95% CI −0.91 to −0.26; P < 0.001, I^2 = 96%; 5 trials, 3362 participants; very low certainty evidence), although the evidence for the latter outcome is very uncertain. Ultrasound guidance may have little to no effect on major bleeding (OR 0.60, 95% CI 0.32 to 1.13; P = 0.11, I^2 = 38%; 6 trials, 4016 participants; low certainty evidence), overall cannulation success (though the evidence is very uncertain) (OR 1.46, 95% CI 0.93 to 2.30; P = 0.10, I^2 = 59%; 4 trials, 2520 participants; very low certainty evidence), and likely has little to no effect on pain scores (MD 0.00, 95% CI −0.34 to 0.34; P = 1.00, I^2 not applicable; 1 trial, 939 participants; moderate certainty evidence). Ultrasound guidance may also have little to no effect on retroperitoneal hematoma, pseudoaneurysm formation, arterial dissection, arteriovenous fistulae, target vessel occlusion, minor bleeding, or infection compared to anatomic landmark guidance (P > 0.05 for all). Lack of data precluded an assessment of re-intervention rates, neuropathy, quality of life, or number of access sites.

Sensitivity analysis revealed that ultrasound guidance may reduce time to successful CFA access in studies that defined this outcome as time from administration of local anesthetic to successful sheath insertion (MD −23.65 s, 95% CI −34.28 to −13.01 s; 3 trials, 1517 participants), but not in studies that defined it as time from the first movement of the fluoroscopy table/application of the ultrasound probe to successful sheath insertion (MD −14.85 s, 95% CI −33.45 to 3.75 s; 2 trials, 1941 participants) or time from skin penetration by the access needle to sheath insertion (MD 11.00 s, 95% CI −43.06 to 65.06 s; 1 trial, 112 participants).

Sensitivity analysis excluding studies that permitted rescue ultrasound resulted in no change in the overall effect of ultrasound versus anatomic landmark guidance on any of the observed outcomes.

Authors' conclusions

Ultrasound guidance may confer clinical benefit over anatomic landmark guidance for percutaneous CFA access regarding first-pass success, time to successful CFA access, and unintentional venipuncture, without increasing the risk of adverse events. Evidence for other outcomes including major bleeding, overall cannulation success, number of access attempts, retroperitoneal hematoma, minor bleeding, pseudoaneurysms, arterial dissection, arteriovenous fistulae, arterial occlusion, infection, or pain scores demonstrates no benefit to ultrasound guidance over anatomic landmark guidance. Data on higher-risk subgroups, including people with elevated BMI, extensive atherosclerosis or calcification, and high femoral artery bifurcation, are lacking. Generalizability was also limited by the high risk of bias across most studies and the exclusion of important subgroups (e.g. people with non-palpable pulses).

PLAIN LANGUAGE SUMMARY

What are the effects of ultrasound versus anatomic landmark guidance for percutaneous common femoral artery access?

Key messages

• Ultrasound guidance may lead to a higher first-attempt success rate and improved time to successful common femoral artery (CFA) access, while reducing the venipuncture rate (unintentionally accessing the vein instead of the targeted artery) and number of access attempts, compared to anatomic landmark guidance.

• Further research is needed to increase our confidence in the evidence.

What is the condition, and how is it treated?

Percutaneous (through the skin) common femoral artery (CFA) access is an essential step for various endovascular procedures (minimally invasive procedures that address issues within the arteries and/or veins), from diagnostic arterial angiograms (a type of picture taken to assess the inside of an artery and its potential disease) to therapeutic interventions (those used to treat conditions of the arteries), including, but not limited to, stenting (placement of a small device to maintain the openness of an artery), embolization (intentionally causing a clot to form to block off an unwanted portion of a blood vessel), and thromboembolectomy (removal of an unwanted clot from a blood vessel). These procedures make it possible to diagnose and treat occlusive arterial disease (blockages of the arteries) as well as aneurysms (bulge in the wall of an artery), dissections (tears in the wall of an artery), and arteriovenous fistulae (an abnormal connection between an artery and a vein). Traditionally, landmarks in the anatomy (anatomic landmarks) have been used to guide CFA access. More recently, ultrasound guidance has emerged as a possibly lower-risk and more effective option, although results of studies comparing ultrasound versus anatomic landmarks for guiding percutaneous CFA access have differed.

What did we want to find out?

We aimed to find out whether ultrasound guidance improves the rate and speed of successful CFA access, reduces the complication rate associated with percutaneous CFA access, and/or improves the patient's experience compared to anatomic landmark guidance for percutaneous CFA access.

What did we do?

We searched for studies comparing ultrasound guidance to anatomic landmark guidance using palpation (pressing the surface of the body with the fingers or hands) or fluoroscopy (X-ray guidance), or both, for obtaining percutaneous CFA access in people undergoing diagnostic or therapeutic endovascular procedures. We compared and summarized the results of the studies and rated our confidence in the evidence based on factors such as study methods and sizes.

What did we find?

We found nine studies enrolling 4447 participants. The studies suggest that ultrasound guidance may lead to a higher first-attempt success rate and improved time to successful CFA access, while reducing the venipuncture rate (unintentionally accessing the vein instead of the targeted artery) and number of access attempts, compared to anatomic landmark guidance.

What are the limitations of the evidence?

We have moderate to little confidence in the evidence because it is possible that people in the studies knew which treatment they were getting; some important outcomes could not be addressed due to limited evidence; and the studies failed to look at certain important patient populations, like those at high risk.

How up-to-date is this evidence?

The evidence is current to January 2024.

SUMMARY OF FINDINGS

Summary of findings 1. Ultrasound guidance compared to anatomic landmark guidance for percuatenous common femoral artery (CFA) access

Ultrasound guidance compared to anatomic landmark guidance for percutaneous common femoral artery (CFA) access

Patient or population: people undergoing endovascular imaging or interventions involving sheath insertion via percutaneous CFA access

Setting: endovascular treatment facility

Intervention: ultrasound guidance

Comparison: anatomic landmark guidance

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)
	Risk with anatomic landmark guidance	Risk with ultrasound guidance			
First-pass success (follow-up)	583 per 1000	824 per 1000 (779 to 861)	**OR 3.35** (2.53 to 4.44)	4274 (7 studies)	⊕⊕⊖⊖ Low[1]
Time to successful CFA access (seconds)	The mean time to successful CFA access ranged from 41.3 to 213 across control groups.	The mean time to successful CFA access in the intervention group was **17.24 lower** (27.04 to 7.43 lower).	**MD −17.24** (−27.04 to −7.43)	3570 (6 studies)	⊕⊕⊖⊖ Low[2]
Major bleeding	23 per 1000	14 per 1000 (8 to 26)	**OR 0.60** (0.32 to 1.13)	4016 (6 studies)	⊕⊕⊖⊖ Low[3]
Overall cannulation success (follow-up)	901 per 1000	930 per 1000 (894 to 954)	**OR 1.46** (0.93 to 2.30)	2520 (4 studies)	⊕⊖⊖⊖ Very low[4]
Venipuncture (follow-up)	116 per 1000	33 per 1000 (23 to 47)	**OR 0.26** (0.18 to 0.38)	4178 (7 studies)	⊕⊕⊖⊖ Low[5]
VAS pain score	The mean VAS pain score in the control group was 3.27.	The VAS pain score in the intervention group was **not different** (0.34 lower to 0.34 higher).	**MD 0** (−0.34 to 0.34)	939 (1 study)	⊕⊕⊕⊖ Moderate[6]

Number of attempts	The number of attempts ranged from 1.32 to 2.16 across control groups.	The number of attempts in the intervention group was **0.59 lower** (0.91 to 0.26 lower).	**MD −0.59** (−0.91 to −0.26)	3362 (5 studies)	⊕⊖⊖⊖ Very low[7]

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CFA: common femoral artery; **CI:** confidence interval; **MD:** mean difference; **OR:** odds ratio; **VAS**: visual analogue scale

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1]We downgraded the certainty of evidence by two levels, as all seven studies were at high risk of bias for lack of blinding; one study was at high risk of bias for selective reporting; and substantial heterogeneity was detected ($Tau^2 = 0.09$; $I^2 = 69\%$). We note that the direction of effect for all studies favored ultrasound; however, not all CIs overlapped, and there was only a small number of studies. All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access, and the 95% CI included only an appreciable effect (2.53 to 4.44).
[2]We downgraded the certainty of evidence by two levels, one level because all six studies were at high risk of bias due to lack of blinding, and one study was at high risk of bias for selective reporting; and a further level as there was moderate to substantial heterogeneity ($Tau^2 = 58.90$; $I^2 = 45\%$), and the 95% CI was somewhat wide (−27.04 to −7.43). All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.
[3]We downgraded the certainty of evidence by two levels, as all six studies were at high risk of bias due to lack of blinding; one study was at high risk of bias for selective reporting; and the 95% CI included both an appreciable and no effect (0.32 to 1.13). We did not detect meaningful heterogeneity ($Tau^2 = 0.21$; $I^2 = 38\%$), and all study CIs overlapped. All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.
[4]We downgraded the certainty of evidence by three levels, as all four studies were at high risk of bias due to lack of blinding, and the 95% CI included both no effect and an appreciable benefit (0.93 to 2.30). In addition, moderate to substantial heterogeneity was detected ($Tau^2 = 0.11$; $I^2 = 59\%$). All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.
[5]We downgraded the certainty of evidence by two levels, as all seven studies were at high risk of bias due to lack of blinding, and one study was at high risk of bias for selective reporting. There was also moderate heterogeneity ($Tau^2 = 0.08$; $I^2 = 33\%$). We note that the direction of effect for all studies favored ultrasound; however, there was only a small number of studies. All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access. The 95% CI included only an appreciable effect (0.18 to 0.38).
[6]We downgraded the certainty of evidence by one level, as the included study was at high risk of bias due to lack of blinding and selective reporting. The study directly studied ultrasound guidance in comparison to anatomic landmark guidance for VAS pain scores. The 95% CI demonstrated no effect (−0.34 to 0.34). Heterogeneity was not applicable as there was only one study contributing to this outcome.
[7]We downgraded the certainty of evidence by three levels, as all five studies were at high risk of bias due to lack of blinding; one study was at high risk of bias for selective reporting; considerable heterogeneity was detected ($Tau^2 = 0.12$; $I^2 = 96\%$); and the 95% CI included both an appreciable and minimally appreciable effect (−0.91 to −0.26). All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.

BACKGROUND

Description of the condition

Endovascular procedures are performed in large volumes worldwide, especially percutaneous coronary, lower and upper extremity peripheral, and cerebrovascular interventions. From 2017 to 2018, percutaneous coronary interventions (PCIs) alone totaled over 50,000 in Canada (CIHI 2019), and over 100,000 in the UK (Ludman 2019). In the USA, approximately 480,000 PCIs, and over one million diagnostic inpatient cardiac catheterizations, were recorded in 2014 (Virani 2020). The use of endovascular thrombectomy for acute ischemic stroke, as well as endovascular interventions for peripheral arterial disease (PAD), has steadily increased in recent years (Curran 2013; Smith 2017). Percutaneous access is fundamental to all endovascular procedures that involve sheath insertion into the arterial system without surgically exposing the blood vessels. While the common femoral artery (CFA) is a common site for arterial access, the risk of major vascular complications associated with CFA access, including arterial occlusion, pseudoaneurysms, severe bleeding, arteriovenous fistulae, and arterial dissection, has been shown in recent studies to range widely (from 0.54% to 38%) (AL-Momani 2019; Bhatty 2011; Dencker 2016; Sherev 2005; Téblick 2018). The use of anatomic landmarks, such as the anterior superior iliac spine, symphysis pubis, and the femoral head, has traditionally been used to facilitate successful identification and cannulation of the CFA (Sandoval 2017). However, access based on anatomical landmarks can be inaccurate, and inadvertent high or low arterial punctures are associated with higher rates of vascular access complications (Sherev 2005). Additional individual patient and procedural factors, such as obesity, older age, high femoral bifurcation, large sheath size, and peri-procedural anticoagulation, may also increase the risk of vascular access complications (Kim 2018; Naddaf 2020; Sherev 2005). It is important to identify the best method for obtaining arterial access that will optimize cannulation accuracy and reduce access-related complications across a diverse population and range of indications.

Description of the intervention

Ultrasound has emerged as a promising adjunct for CFA access. By allowing direct visualization of the needle as it crosses the arterial wall, ultrasound can minimize the number of access attempts and shorten the time to successful sheath insertion (Gedikoglu 2013; Tuna Katircibaşi 2018). Ultrasound has also been shown to reduce access-related complications, such as bleeding, including hematoma, and pseudoaneurysm formation (Seto 2010; Slattery 2015; Sorenson 2019).

How the intervention might work

Ultrasound guidance assists in identifying and localizing the CFA, and allows direct visualization of the vascular access needle as it enters the target vessel. This is particularly useful when the femoral artery cannot be palpated at the traditional anatomic landmarks, such as in people with severe atherosclerosis or narrow arteries; those who lack a palpable CFA pulse; and those who are obese. Ultrasound guidance is expected to shorten the time to successful cannulation and reduce the risk of procedural complications by avoiding inadvertent cannulation or puncture of smaller vessels, such as the superficial femoral artery, or those that cannot be easily compressed, such as the external iliac artery. Furthermore, ultrasound guidance limits the likelihood of injuring adjacent structures, such as the femoral vein or nerve.

Why it is important to do this review

Clinical equipoise surrounding the utility of ultrasound-guided percutaneous CFA access persists for a variety of reasons. By enabling clear visualization of the CFA bifurcation, ultrasound was expected to improve the accuracy of CFA cannulation, reduce the number of access attempts, and decrease major vascular complications. However, evidence to support this theoretical advantage has been mixed. While some studies have demonstrated reduced rates of procedural complications (Seto 2010), venipuncture (Marquis-Gravel 2018; Seto 2010), time to vascular access (Gedikoglu 2013; Seto 2010; Slattery 2015), and total number of attempts with ultrasound guidance, compared to use the of anatomic landmarks (Gedikoglu 2013; Seto 2010), others have shown similar rates of successful CFA cannulation (Dudeck 2004; Gedikoglu 2013; Seto 2010), procedure-related complications (Dudeck 2004; Gedikoglu 2013), and total number of access attempts (Dudeck 2004). Some studies only demonstrated a benefit for ultrasound over anatomic landmarks for guiding femoral access in certain populations, such as people who were obese, or those with a weak arterial pulse (Dudeck 2004; Marquis-Gravel 2018). In addition, widespread uptake has been limited by concerns about speed, increased costs associated with procurement of ultrasound machines, and reluctance to change practice, even in the face of compelling evidence (Irani 2009; Rashid 2019; Soverow 2016). The lack of consensus is reflected in professional society practice guidelines, which to date do not preferentially recommend either ultrasound or anatomic landmarks to guide CFA access (Marquis-Gravel 2018).

OBJECTIVES

To assess the efficacy and safety of ultrasound compared to anatomic landmarks to guide percutaneous access of the CFA for the purpose of endovascular arterial imaging or treatment.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) that compared the use of ultrasound guidance with anatomic landmark guidance for percutaneous CFA access for endovascular imaging or treatments that involve sheath insertion. We included studies that examined both femoral and radial artery access; however, we only extracted and analyzed data from the femoral access group.

We excluded studies examining CFA access for arterial line placement (routinely performed in the intensive care unit [ICU], emergency department, and operating room), as arterial line placement is not subject to the same risk of access complications as procedures involving sheath insertion. We excluded non-randomized studies, such as cross-sectional, cohort, and case-control studies, quasi-randomized trials, case reports, and case series.

Types of participants

We included participants undergoing percutaneous vascular access of the CFA for any endovascular diagnostic or therapeutic

procedure involving sheath insertion. For studies with only a subset of eligible participants (e.g. studies including participants undergoing both femoral and radial artery access), we included outcomes only from the subset including the population of interest (i.e. from the femoral artery access group). If the study did not separately report outcomes from each subset (i.e. if the outcomes were reported only for the entire cohort and not just for the CFA subset), then the study was excluded.

We excluded participants undergoing CFA access for arterial line placement for blood pressure monitoring.

Types of interventions

We included studies in which ultrasound guidance was compared with anatomic landmark guidance (via palpation or fluoroscopy, or both) for percutaneous access of the CFA for endovascular imaging or interventions. We included studies evaluating both antegrade access, in which the vascular access sheath was advanced toward the foot, and retrograde access, in which the vascular access sheath was advanced toward the heart.

Types of outcome measures

Primary outcomes

- First-pass success: defined as successful placement of a sheath within the CFA, following the first attempt at CFA access
- Time to successful CFA access (measured in seconds)
- Major bleeding (including hematoma requiring transfusion, hematoma extending length of stay, hematoma ≥ 5 cm, unexplained hemoglobin drop, or major/severe bleeding as defined by each trial)

Secondary outcomes

- Overall cannulation success: defined as number of procedures in which cannulation was successful
- Venipuncture (unintentional), evaluated at the time of the procedure
- Pain score (applicable to procedures done under local anesthetic): measured by a validated questionnaire, such as the visual analogue scale (VAS) (Karcioglu 2018)
- Number of attempts (at successful CFA cannulation)
- Major complications: retroperitoneal hematoma/hemorrhage, pseudoaneurysm formation, or flow-limiting injuries (e.g. dissection, arteriovenous fistula, occlusion), up to 30 days post-procedure
- Adverse events: including minor bleeding, infection, and neuropathy, up to 30 days post-procedure
- Quality of life: measured by a validated questionnaire, such as the EQ-5D (Rabin 2001)
- Re-intervention: required for access site bleeding or pseudoaneurysm, including return to the operating room/angiography suite, percutaneous thrombin injection, ultrasound-guided compression, or endovascular repair (e.g. covered stent), up to 30 days post-procedure
- Total number of access sites attempted, with each site defined as a discrete anatomic location

Search methods for identification of studies

Electronic searches

The Cochrane Vascular Information Specialist conducted systematic searches of the following databases for RCTs and controlled clinical trials without language, publication year, or publication status restrictions. An Information Specialist from Cochrane Central Executive updated the searches on 25 January 2024.

- Cochrane Vascular Specialised Register via the Cochrane Register of Studies (CRS-Web) to 25 January 2024
- Cochrane Central Register of Controlled Trials (CENTRAL; 2024, Issue 1) via the Cochrane Register of Studies Online (CRSO)
- MEDLINE (Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE) (1946 to 25 January 2024)
- Embase Ovid (1980 to 2024, week 3)
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) (1937 to 25 January 2024)

We developed search strategies for other databases based on the search strategy designed for MEDLINE. Where appropriate, these strategies were combined with adaptations of the Highly Sensitive Search Strategy designed by Cochrane for identifying RCTs and controlled clinical trials, as described in Chapter 4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2024). Search strategies for major databases are provided in Appendix 1.

We searched the following trial registries.

- World Health Organization International Clinical Trials Registry Platform (trialsearch.who.int/)
- ClinicalTrials.gov (clinicaltrials.gov)

The most recent searches were carried out on 25 January 2024 (Appendix 1; Appendix 2).

Searching other resources

We examined the bibliographies of the studies identified in our search to identify other relevant articles.

Data collection and analysis

Selection of studies

Two review authors (SS and CS) independently selected trials for inclusion in the review from the studies identified by the search. A third review author (AK) assessed these trials to determine their suitability, and adjudicated any disagreements between the first two review authors. The inclusion criteria used to determine suitability are outlined in Criteria for considering studies for this review.

Data extraction and management

Two review authors (SS and CS) independently extracted relevant data from the included studies using a standardized data extraction form. A third review author (AK) cross-checked the data. We collected the following information.

- Methods (study design, number of participants, exclusions post-randomization, losses to follow-up, intention-to-treat (ITT) analysis, duration of study)
- Participant characteristics (e.g. country, setting, inclusion and exclusion criteria, age, gender, comorbidities such as PAD, hypertension, smoking, diabetes, chronic liver disease, chronic kidney disease, and coagulopathy), peri-procedural antithrombotic therapy (defined as antiplatelet or anticoagulant therapy within seven days pre- or post-procedure), anatomical data (high femoral artery bifurcation, CFA calcification, obesity, previous ipsilateral punctures or open surgery in the access groin), procedural data (elective or emergency, diagnostic or therapeutic, setting, type of procedure)
- Interventions (ultrasound or anatomic landmark guidance for CFA access), access data (antegrade or retrograde, capabilities of ultrasound machine [e.g. simple imaging device or adaptive scanner, curvilinear or linear probe, use of short axis out-of-plane or long axis in-plane], use of palpation or fluoroscopy [or both] in conjunction with anatomic landmarks, sheath size, use of an arterial closure device or manual compression, compression time, where applicable), operator experience with ultrasound guidance and intervention
- Outcomes reported by study, and as specified in Criteria for considering studies for this review. We dichotomized complications and re-intervention rates when evaluating the overall effect of the intervention on the primary outcome to allow for more flexibility in pooling the outcomes from different trials; however, we also collected data on the type and severity of each complication and re-intervention, to allow for a more detailed comparison.
- Study funding source and declarations of interest by the study authors

We defined femoral artery bifurcation as high if it was located superior to the inferior border of the femoral head, as identified by angiography (Gupta 2014). We defined obesity as body mass index (BMI) > 30 kg/m^2, or waist circumference ≥ 102 centimeters (40 inches) for men or ≥ 88 centimeters (35 inches) for women, or both (Jensen 2014; Lean 1995). We entered data into Review Manager 5 (Review Manager 2020) and/or RevMan (RevMan 2025).

Assessment of risk of bias in included studies

Two review authors (SS and CS) independently assessed risk of bias in the included studies using Cochrane's RoB 1 tool (Higgins 2011), which includes the following domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias. Each domain receives a score of low, high, or unclear risk of bias, depending on the review author's judgment. Any disagreements were adjudicated by a third review author (AK). In addition, we assessed particular biases related to the nature of the intervention, and limitations in outcome measurements. Specifically, we recorded how and when outcomes were measured, and determined whether these methods contributed to low, high, or unclear risk of bias. For example, we considered studies that routinely screened for access-related complications, such as those that used routine post-procedure surveillance ultrasounds, to be at low risk of bias, whereas studies that did not routinely follow up participants with an objective assessment of adverse outcomes (i.e. by routinely conducting physical exams or imaging) were assessed as at high risk of bias. We also considered who was reporting the intra-procedural details. We considered subjective reporting from the operator alone as indicative of high risk of bias, whereas we considered objective monitoring by a third party present in the room at the time of the procedure as indicative of low risk of bias.

Measures of treatment effect

We calculated and reported continuous outcome measures, such as time to access the CFA, using the mean difference (MD). We also calculated the associated 95% confidence interval (CI) between the two study groups. We excluded studies that reported continuous outcome measures using the median difference from pooled analyses, since they were derived from non-normally distributed data and thus did not lend themselves well to conversion to MD or standardized MD. We calculated and reported dichotomous (binary) outcome measures, such as overall cannulation success and venipuncture, using an odds ratio (OR) or risk difference (RD), with the associated 95% CI, depending on the reported data. We dichotomized complications, such as major bleeding, when evaluating the overall effect of the intervention on the primary outcomes, to allow for more flexibility in pooling the outcomes from different trials. We based our calculations on an ITT approach. Statistical analysis complied with the standard methods of Cochrane Vascular. We used Review Manager 5 or RevMan to perform all statistical analyses and to generate figures (Review Manager 2020; RevMan 2025).

Unit of analysis issues

We used the procedure as the unit of analysis for all outcomes except pain outcomes, for which we used the participant as the unit of analysis. No cross-over RCTs were included in the review. For multi-arm studies (e.g. those with an ultrasound-guidance arm, a palpation-based arm, and a fluoroscopy arm), we dichotomized the arms into those using ultrasound guidance and those not using ultrasound guidance (i.e. using anatomic landmarks via palpation or fluoroscopy). For cluster-RCTs, such as those that examined ultrasound versus anatomic landmark guidance for radial arterial access and femoral arterial access, we included only the common femoral arterial access groups.

Dealing with missing data

We contacted study authors to enquire about missing or incomplete data. When provided, the missing data were incorporated into the analysis. When we were unable to obtain missing data, we either included the outcomes that were available or, if no outcomes of interest were provided, excluded the study. In the case of incomplete data, we explicitly stated what portion of the data was missing and outlined how this gap might have impacted the results.

Assessment of heterogeneity

We assessed inter-study heterogeneity by visually inspecting the forest plots (Higgins 2021). We also calculated I^2 and Chi^2 tests to measure the amount of heterogeneity (Higgins 2003). We interpreted the I^2 values as follows:

- < 50%: low heterogeneity;
- 50% to 75%: moderate heterogeneity;

- > 75%: substantial heterogeneity (Higgins 2021).

We planned to address clinical and methodology heterogeneity through sensitivity and subgroup analyses in the case of sufficient data.

Assessment of reporting biases

We did not construct funnel plots to assess publication bias, as fewer than 10 studies were included in the analysis (Higgins 2021).

Data synthesis

We used a random-effects model to calculate the pooled treatment effect, anticipating that a substantial degree of inter-study and clinical heterogeneity likely existed. We calculated 95% CIs for continuous and dichotomous outcome variables as detailed above. We created a forest plot for each treatment effect as per Cochrane guidelines.

Subgroup analysis and investigation of heterogeneity

A lack of available data precluded subgroup analyses to assess the impact of atherosclerotic disease, CFA calcification, high femoral artery bifurcation, previous ipsilateral punctures, peri-procedural antithrombotic therapy, obesity, method of closure (e.g. use of arterial closure device, manual compression, compression time), urgency of the procedure (elective versus urgent), type of procedure (diagnostic versus therapeutic), procedural setting (cardiac catheterization lab versus interventional radiology catheterization lab versus operating room), and/or operator experience with ultrasonography on the outcomes of interest.

Sensitivity analysis

We planned to conduct sensitivity analyses to assess the impact of studies at high or unclear risk of bias by excluding these from the pooled analysis. We defined studies as being at high risk of bias if two or more domains were determined to be at high risk using Cochrane's RoB 1 tool. We defined studies as being at unclear risk of bias if they provided insufficient information to determine the level of risk for two or more domains. If we assessed that a study had two or more domains at unclear risk of bias *and* two or more domains at high risk of bias, we deemed the study at high risk of bias overall (Higgins 2011b).

We also planned to conduct a sensitivity analysis to assess the impact of 'rescue' ultrasound. This was defined as an instance in which ultrasound was used in the case of failed access attempts using anatomic landmark guidance.

We planned to assess the impact of studies that used palpation alone (i.e. no fluoroscopy) in the anatomic landmark arm by conducting a sensitivity analysis excluding those studies and only including studies that used fluoroscopy in conjunction with anatomic landmarks to guide access in the comparison arm.

Finally, we planned to conduct a sensitivity analysis for the primary outcome of mean time to successful sheath insertion, measured in seconds, to assess the impact of studies that defined time-to-access as time from administration of local anesthetic until successful sheath insertion compared to time from first movement of the table for fluoroscopy or first application of the ultrasound probe or first application of the local anesthetic until successful sheath insertion.

Summary of findings and assessment of the certainty of the evidence

We prepared a summary of findings table using GRADEpro GDT software to present the main findings of the review for the time point at which the most relevant data were available (Atkins 2004; GRADEpro GDT). The population consisted of participants undergoing endovascular imaging or interventions involving sheath insertion via percutaneous CFA access, and we compared ultrasound-guided and anatomic landmark-guided arterial access. Of the outcomes listed in Types of outcome measures, we included the following seven outcomes that we considered to be essential for decision-making in the summary of findings table.

- First-pass success
- Time to successful CFA access (mean)
- Major bleeding
- Overall cannulation success
- Venipuncture
- Pain score
- Number of attempts

We evaluated the certainty of the evidence using the GRADE approach (Atkins 2004). We assigned one of four levels of certainty: high, moderate, low, or very low, based on overall risk of bias, directness of the evidence, inconsistency of results, precision of the estimates, and risk of publication bias, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021). We included our rationale behind these judgments in the footnotes section of the summary of findings table. We used these judgments to aid in our interpretation of the results and to draw our conclusions.

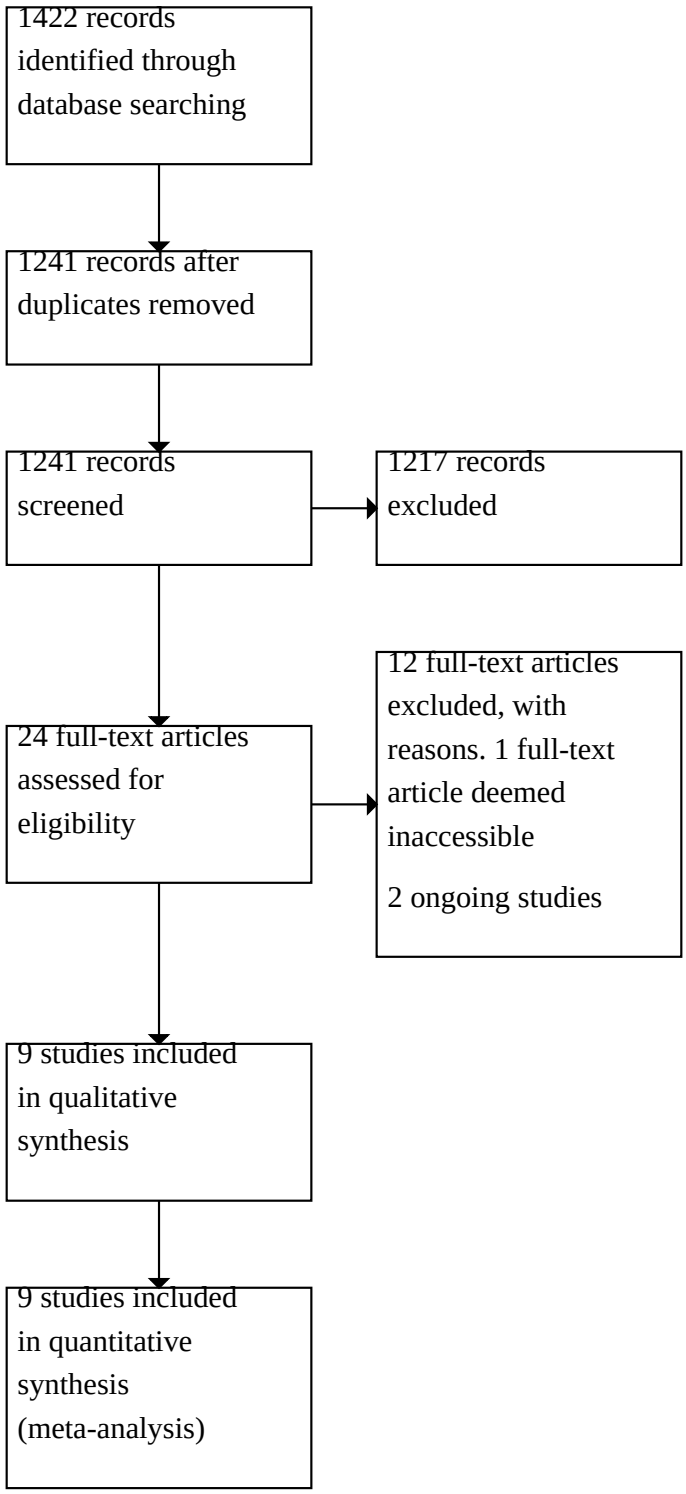
RESULTS

Description of studies

Results of the search

Please see Figure 1 for search results.

Figure 1. PRISMA flow diagram.



Included studies

This review included nine RCTs that compared the use of ultrasound versus anatomic landmarks (palpation or fluoroscopy, or both) for guiding percutaneous common femoral arterial access in people undergoing endovascular arterial imaging or treatment (Dudeck 2004; Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Slattery 2015; Stone 2020). Details of the included studies are provided in the Characteristics of included studies tables.

Two studies were conducted in the USA (Seto 2010; Stone 2020), two in Canada (Jolly 2022; Marquis-Gravel 2018), one in Ireland (Slattery 2015), and one in Germany (Dudeck 2004). Three studies did not clearly state where the study was conducted; however, the study authors were based in Turkey (Gedikoglu 2013; Katircibasi 2018) and Australia (Nguyen 2020). The majority of included studies were single-center trials (Dudeck 2004; Marquis-Gravel 2018; Slattery 2015; Stone 2020); two studies were multicenter across four sites (Seto 2010) and two sites (Jolly 2022); and the remaining three studies did not specify whether they were single- or multicenter trials (Gedikoglu 2013; Katircibasi 2018; Nguyen 2020).

The majority of participants were male in all studies, with the proportions of male participants ranging between 51% to 75%. Select comorbidities were reported in seven trials (Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Stone 2020). The most commonly reported and most prevalent comorbidity was hypertension (Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Stone 2020), ranging from 57% to 87% prevalence (Jolly 2022; Katircibasi 2018). Additional commonly reported risk factors included diabetes mellitus, smoking history, dyslipidemia, elevated BMI, renal insufficiency, and history of atherosclerotic vascular disease (coronary, cerebrovascular, or PAD). Four of the nine trials reported on the use of pre- or peri-procedural antithrombotic therapy: participants in Seto 2010 were most commonly on clopidogrel (49%) and heparin (41%); participants in Katircibasi 2018 were most commonly on aspirin (24.6%) and heparin (21%); participants in the femoral arm of Nguyen 2020 were most commonly on aspirin (88%) and clopidogrel (44%); and participants in Jolly 2022 were most commonly on aspirin at baseline (84%) and unfractionated heparin during the procedure (53%). Three studies excluded individuals with non-palpable pulses (Gedikoglu 2013; Jolly 2022; Seto 2010).

All studies were exclusive to femoral artery access, except for one that assessed both femoral and radial artery access but separately reported the outcomes of each (with only the femoral group being reported herein) (Nguyen 2020). Three studies were exclusive to coronary procedures (Jolly 2022; Marquis-Gravel 2018; Nguyen 2020); one study involved a vast majority (91%) of coronary procedures (Seto 2010); one study was exclusive to infrainguinal procedures for PAD (Slattery 2015); one study was exclusive to peripheral procedures for PAD, mesenteric stenosis, or carotid disease (Stone 2020); and three studies either involved a combination of peripheral and coronary procedures or did not clearly specify whether coronary or peripheral procedures were included (Dudeck 2004; Gedikoglu 2013; Katircibasi 2018). Eight trials reported sheath size, which ranged from 5 to 7 French (Fr) for most trials (Gedikoglu 2013; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Stone 2020), as low as 4 to 5 Fr for one trial (Dudeck 2004), and as high as 5 to 8 Fr for one trial (Jolly 2022). Six trials either reported or, in the case of trials that assessed only coronary interventions, were *presumed* to have used exclusive retrograde access (Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010); one trial used antegrade access (Slattery 2015); and the remaining two trials did not report the direction of access. For closure of the access site, three trials used exclusive manual compression (+/− weight placement) in all cases (Dudeck 2004; Gedikoglu 2013; Katircibasi 2018). The remaining six trials allowed for use of a closure device at the physician's discretion: Seto 2010 used a closure device in 66% of the ultrasound group and 57% of the control group; Slattery 2015 used an angioseal closure device in 85% of cases; Marquis-Gravel 2018 did not report the proportion of participants who received a closure device; Nguyen 2020 used a closure device in 40% of the ultrasound group and 36% of the control group; Stone 2020 used a closure device in 41% of the ultrasound group and 42% of the control group; and Jolly 2022 used a closure device in 54% of the ultrasound group and 50% of the control group.

For the anatomic landmark-guided control groups, seven trials used a combination of manual palpation and fluoroscopy (Dudeck 2004; Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Seto 2010; Slattery 2015; Stone 2020); one trial used "standard palpation" technique +/− fluoroscopy at the discretion of the operator (Nguyen 2020); and one trial used manual palpation and reserved fluoroscopy as a bail-out method (Marquis-Gravel 2018). For the ultrasound-guided intervention groups, all nine studies used linear transducers. Operator experience with ultrasound varied across studies, from studies not reporting operator experience whatsoever (Slattery 2015), to studies requiring as few as three proctored ultrasound-guided procedures prior to participation as primary operator (Seto 2010), to studies exclusively involving staff interventional radiologists with extensive sonographic experience (Dudeck 2004).

Excluded studies

We excluded 12 studies from our review (Daggubati 2011; Enany 2013; Jayanti 2019; Jayanti 2021; Law 2014; Lazaar 2021; Nguyen 2019; Nguyen 2019 subgroup; Salik 2021; Seto 2008; Siddik-Sayyid 2016; Surmacz 2015). We excluded studies for the following reasons:

- participants were undergoing arterial access for hemodynamic monitoring (rather than arterial imaging/treatment) and/or sheath size was insufficient or not reported (Law 2014; Lazaar 2021; Salik 2021; Siddik-Sayyid 2016);
- focus of the study was a subgroup of a previously included study (Jayanti 2019; Nguyen 2019 subgroup);
- study was a trial registration record of a previously included study (Seto 2008);
- study design was ineligible (Jayanti 2021);
- study was an abstract with inadequately defined outcomes and no corresponding manuscript (Daggubati 2011);
- study did not differentiate between outcomes from radial versus common femoral arterial access or arterial versus venous access, respectively (Enany 2013; Nguyen 2019).

Reasons for exclusion are listed in the Characteristics of excluded studies tables.

Risk of bias in included studies

Please refer to the risk of bias tables in the Characteristics of included studies tables and summary results in Figure 2 and Figure 3.

Figure 2. All studies were at high risk of performance bias due to the inability to blind the operators to the form of arterial access guidance used.

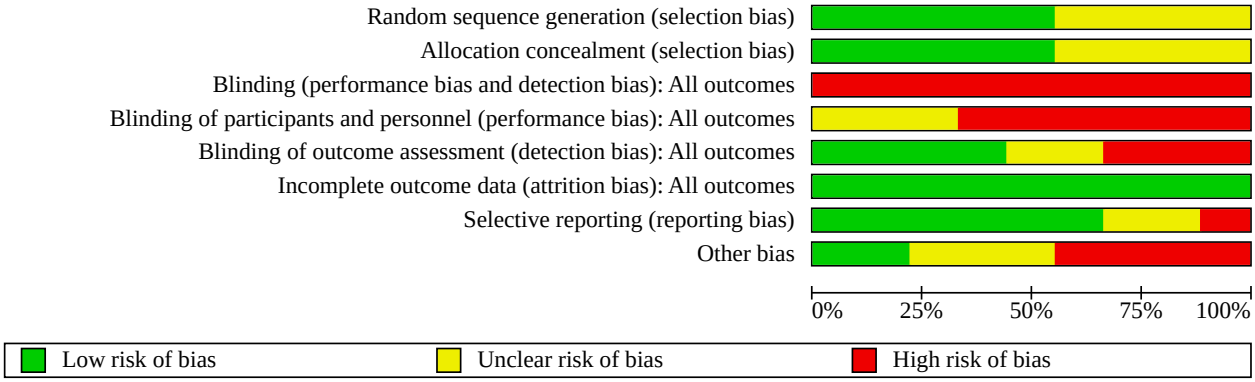
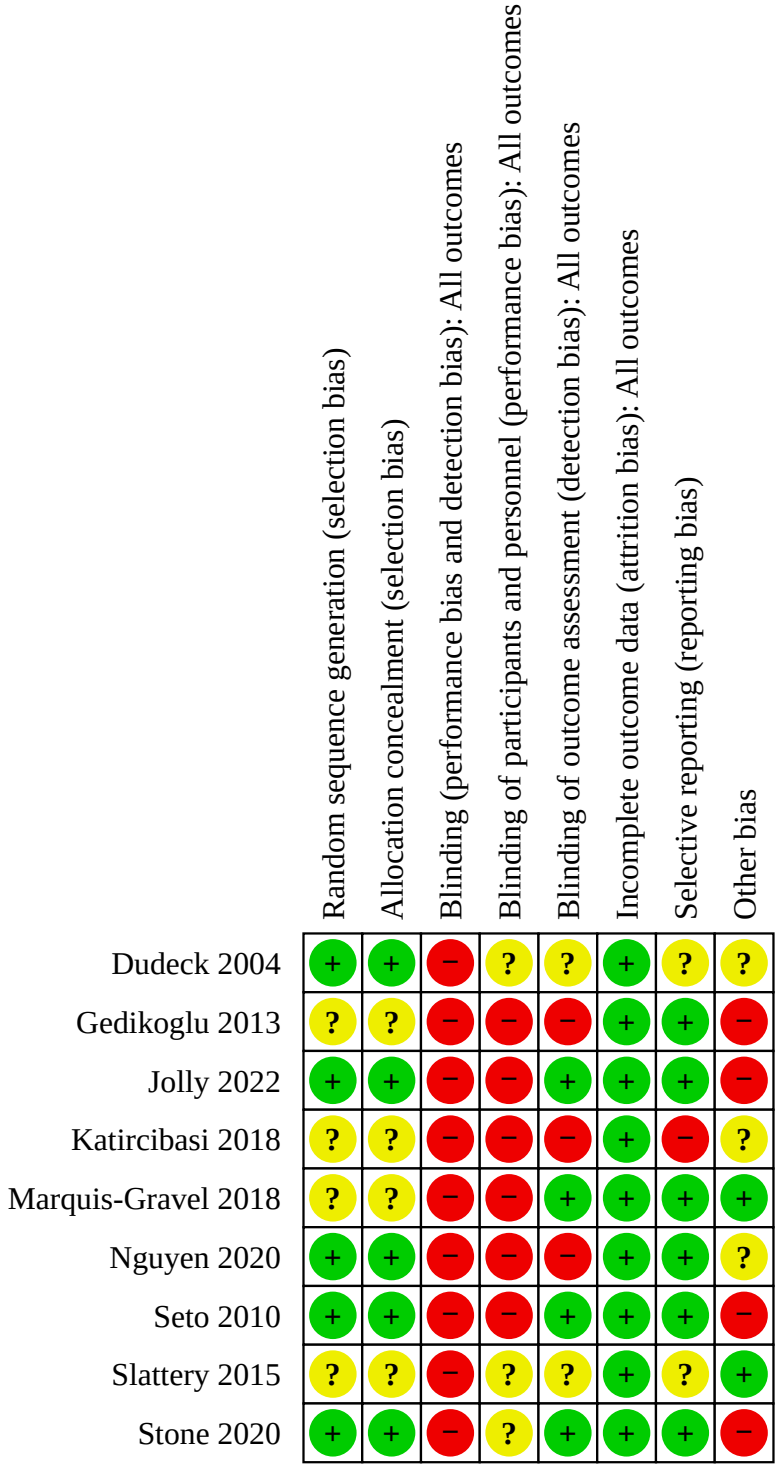


Figure 3. All studies were at high risk of bias for at least one domain, and all studies posed a high and/or unclear risk of bias across multiple domains.



Allocation

All nine studies were randomized; however, four studies were deemed to be at unclear risk of selection bias for random sequence generation as they did not adequately elaborate on the method of randomization used (Gedikoglu 2013; Katircibasi 2018; Marquis-Gravel 2018; Slattery 2015). Likewise, these same four studies were deemed to be at unclear risk of selection bias for allocation concealment, as they either did not report whether allocation concealment was used, or the method employed was unclear (Gedikoglu 2013; Katircibasi 2018; Marquis-Gravel 2018; Slattery 2015). We assessed the remaining five studies to be at low risk of selection bias for random sequence generation and allocation concealment. Four of these studies used sealed envelopes to conceal allocation (Dudeck 2004; Nguyen 2020; Seto 2010; Stone 2020); Nguyen 2020 and Seto 2010 additionally randomized 1:1 in balanced blocks of 50 or 80, and Stone 2020 employed an institutional biostatistician to create a randomization schedule. The fifth trial used a central randomization system to both randomize and allocate treatments (Jolly 2022).

Blinding

All included studies were at high risk of performance bias for operators due to inability to blind the operators to the procedures that they were performing. Likewise, most studies were at high risk of bias with respect to blinding of participants and personnel (Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010). The remaining three studies were at unclear risk, as they did not clearly state whether participants were blinded to their assigned treatment (Dudeck 2004; Slattery 2015; Stone 2020).

We assessed four studies to be at low risk of detection bias (Jolly 2022; Marquis-Gravel 2018; Seto 2010; Stone 2020), as the outcomes adjudicators for post-procedural complications (for all four studies) and proper placement of the introducer within the CFA (Jolly 2022; Marquis-Gravel 2018; Seto 2010) were blinded to the assigned treatment. In Seto 2010, a second observer and lab timer were also employed to reduce the risk of bias in assessing the number of attempts, time to access, or venipuncture; however, none of these three studies could completely eliminate bias in the assessment of number of attempts or time to access. Three studies had the primary (non-blinded) operator assessing all trial outcomes and were thus deemed at high risk for detection bias (Gedikoglu 2013; Katircibasi 2018; Nguyen 2020). The remaining two studies were at unclear risk of bias (Dudeck 2004; Slattery 2015), as they did not report whether the outcomes assessor was blinded to the assigned treatment.

Incomplete outcome data

All the included studies were at low risk of attrition bias, as they had complete or near-complete outcomes data for all randomized participants (Dudeck 2004; Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Slattery 2015; Stone 2020).

Selective reporting

We assessed the majority of studies as at low risk for reporting bias, as they reported the results of all the prespecified outcomes listed in their methods or published protocols, or both (Gedikoglu 2013; Jolly 2022; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Stone 2020).

We assessed one study to be at high risk of reporting bias (Katircibasi 2018), as retroperitoneal hemorrhage rate was prespecified as an outcome in the methods section but not reported in the results, and first-pass success rate was reported in the results but not prespecified as an outcome in the methods section.

We assessed the remaining two studies to have an unclear risk of reporting bias (Dudeck 2004; Slattery 2015). Dudeck 2004 prespecified "post-intervention complications" as an outcome in the methods section but did not clearly define this outcome in the methods or results section, so it is unclear whether they added or dropped specific post-intervention complications as outcomes over the duration of the trial. Similarly, Slattery 2015 listed "immediate post-operative complications" as an outcome in the methods section but failed to elaborate on the specific outcomes of interest as well as how/when they were assessed.

Other potential sources of bias

We considered four studies to be at high risk for other sources of bias (Gedikoglu 2013; Jolly 2022; Seto 2010; Stone 2020). In Gedikoglu 2013, Jolly 2022, and Seto 2010, participants were excluded if they did not have a palpable pulse, which inevitably favored the control group. As the authors of Gedikoglu 2013 suggest, "inclusion of these patients into the study would have increased the technical success of the US-guided group considerably." In addition, inter-operator variability (with respect to use of a needle guide and closure device) and sponsorship (providing research materials) introduced further sources of bias in Seto 2010.

The Stone 2020 study raised several sources of potential bias. Firstly, Doppler needles, which are attachments that can be added to a Doppler probe to help delineate the course of the CFA, were used in the fluoroscopic-guided procedures when the CFA pulse was non-palpable, which likely increased the control group's success rate. Furthermore, the study excluded a number of participants after randomization due to operators' concerns about anatomy, and then proceeded with a per-protocol analysis despite stating in the data analysis section that data would be analyzed on an ITT basis.

We assessed three studies as at unclear risk of other bias (Dudeck 2004; Katircibasi 2018; Nguyen 2020). In Dudeck 2004, the authors outlined the extensive preparation required for their single-operator ultrasound technique, but then measured time to access from the initial puncture attempt to sheath insertion. Since total operative time is an important consideration for many operators, it is unclear whether eliminating all the preparatory work involved from the time measurements would significantly impact this important metric.

Katircibasi 2018 did not mention exclusion criteria, therefore it is unclear whether unreported exclusion criteria may have impacted the results, as seen with the exclusion of participants with non-palpable pulses in other studies, for example.

Nguyen 2020 lacked details specific to the femoral subgroup, since only an abstract for this subgroup analysis has been published to date, and the main trial pooled the results of the femoral and radial

arterial access populations. In addition, the authors of the main trial reported that they were "grateful for the loan of the ultrasound machine during the early trial period by Fujifilm SonoSite and Western Sydney University." It is unclear whether, and how, these factors may have influenced the results of this trial and subgroup analysis and/or introduced additional sources of bias.

Dudeck 2004 and Stone 2020 did not report the direction of access (i.e. antegrade versus retrograde), therefore it was not possible to assess whether a difference between the two intervention groups (with respect to direction of access) may have impacted the outcomes.

We identified no overt additional sources of bias in the remaining two studies (Marquis-Gravel 2018; Slattery 2015), and thus deemed them to be at low risk.

Effects of interventions

See: **Summary of findings 1** Ultrasound guidance compared to anatomic landmark guidance for percuatenous common femoral artery (CFA) access

See Summary of findings 1.

Primary outcomes

First-pass success

First-pass success was defined as successful CFA access at the first puncture. Ultrasound guidance may increase the odds of first-pass success compared to anatomic landmark with or without fluoroscopy guidance (OR 3.35, 95% CI 2.53 to 4.44; P < 0.001, I^2= 69%; 7 studies, 4274 participants; low certainty of evidence; Analysis 1.1).

Time to successful CFA access

Eight studies reported time to successful CFA access. Seven studies reported mean time (Dudeck 2004; Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Nguyen 2020; Seto 2010; Slattery 2015), while one reported median time (Stone 2020). Among the studies that reported mean time, five published standard deviations (SD) of the mean (Dudeck 2004; Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Seto 2010); one provided SD upon author request (Nguyen 2020); and one did not report SD and was thus excluded from the pooled analysis for this outcome (Slattery 2015). All eight studies that reported this outcome did so in seconds, and they all stopped the timer at the point of sheath insertion. There were slight variations across studies with respect to the initiation of the timer: four studies began timing when local anesthetic was administered (Gedikoglu 2013; Jolly 2022; Nguyen 2020; Slattery 2015); two began timing with the first movement of the table for fluoroscopy or application of the ultrasound probe (Katircibasi 2018; Seto 2010); one began timing from skin penetration of the access needle (Dudeck 2004); and one began timing when the surgeon verbally initiated the start time (Stone 2020).

Mean time to successful CFA access

Among the six studies that reported, or separately provided, mean time to successful CFA access along with SD (Dudeck 2004; Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Nguyen 2020; Seto 2010), ultrasound guidance may reduce time to successful CFA access compared to anatomic landmark guidance, with an MD of −17.24 s (95% CI −27.04 to −7.43 s; P < 0.001, I^2= 45%; 6 studies, 3570 participants; low certainty of evidence; Analysis 2.1).

Median time to successful CFA access

Ultrasound guidance reduced the median time to successful CFA access compared to anatomic landmark guidance by 20 s (median 80 s (interquartile range [IQR] 58 to 119 s) with ultrasound versus 100 s (IQR 66 to 190 s) with anatomic landmarks; P < 0.001, I^2 not applicable (N/A); 1 study, 687 participants).

Major bleeding

Overall, ultrasound guidance may not affect the odds of major bleeding compared to anatomic landmark-guided access (OR 0.60, 95% CI 0.32 to 1.13; P = 0.11, I^2 = 38%; 6 studies, 4016 participants; low certainty of evidence; Analysis 3.1).

For the purpose of this review, studies that reported bleeding outcomes that were discrete from retroperitoneal hematoma and considered more severe than minor bleeding were pooled to constitute the outcome major bleeding. These outcomes included bleeding or hematoma formation requiring transfusion, hematoma ≥ 5 cm in size, fatal bleeding, or a composite 'major bleeding' outcome (as defined by each trial) combining some or all of the above.

For studies that reported multiple separate outcomes consistent with our definition of major bleeding, such as hematoma requiring transfusion, hematoma extending hospital length of stay, and/or hematoma ≥ 5 cm in size (Nguyen 2020; Seto 2010; Stone 2020), we preferentially used the hematoma/bleeding requiring transfusion outcome for the pooled analysis of major bleeding, in accordance with our definition of 'major complications' outlined in the systematic review study protocol.

For the study that reported major bleeding outcomes for two time points at 24 hours post-procedure and up to 90 days post-procedure, we preferentially used the 24-hour outcome for the pooled analysis (Stone 2020). Thus, the following outcomes were pooled from each study to comprise the major bleeding outcome of this systematic review: access bleeding/hematoma requiring transfusion up to 30 days post-procedure and at 24 hours post-procedure, respectively (Seto 2010; Stone 2020); hematoma ≥ 5 cm up to seven days post-discharge (Katircibasi 2018); "significant bleeding," defined as Bleeding Academic Research Consortium (BARC) types 2, 3, or 5 bleeding, up to day one post-procedure (Marquis-Gravel 2018); "major bleed," defined as BARC types 2, 3, or 5 bleeding, up to 30 days post-procedure (Jolly 2022); and major ACUITY (Acute catheterization and Urgent Intervention Triage stategY) bleeding, defined as intracranial bleeding, intraocular bleeding, access site hemorrhage requiring intervention, ≥ 5-centimeter diameter hematoma, reduction in hemoglobin concentration of ≥ 4g/dL without an overt source of bleeding, reduction in hemoglobin concentration of ≥ 3 g/dL with an overt source of bleeding, reoperation for bleeding, or the use of any blood product transfusion, up to 30 days post-procedure (Nguyen 2020).

Secondary outcomes

Overall cannulation success

Ultrasound guidance may not affect the odds of overall cannulation success compared to anatomic landmark guidance, but the

evidence is very uncertain (OR 1.46, 95% CI 0.93 to 2.30; P = 0.10, I^2 = 59%; 4 studies, 2520 participants; very low certainty of evidence; Analysis 4.1).

Venipuncture

Ultrasound-guided access may reduce the odds of venipuncture compared to anatomic landmark-guided access (OR 0.26, 95% CI 0.18 to 0.38; P < 0.001, I^2 = 33%; 7 studies, 4178 participants; low certainty of evidence; Analysis 5.1).

Pain scores

Two studies assessed pain during the procedures (which, notably, were all performed under local anesthetic). However, the methods of measuring this outcome were too heterogeneous to permit pooling of results. One study used a VAS to measure pain scores and found likely no difference between groups (MD 0.00, 95% CI −0.34 to 0.34; P = 1.00, I^2 N/A; 1 study, 939 participants; moderate certainty of evidence; Analysis 6.1) (Katircibasi 2018). In contrast, another study measured "pain anticipated by the patient while obtaining vascular access" by recording the need for additional intravenous sedoanalgesia during the procedure (Gedikoglu 2013). This study also found no differences between participants who underwent ultrasound- versus anatomic landmark-guided access with respect to the odds of requiring additional analgesia (OR 0.79, 95% CI 0.38 to 1.65; P = 0.54, I^2 N/A; 1 study, 208 participants; Analysis 6.2).

Number of attempts

Eight studies reported the number of attempts at successful CFA cannulation. However, four of these studies reported the mean number of attempts with SD (Dudeck 2004; Jolly 2022; Katircibasi 2018; Seto 2010); one reported the mean number of attempts and provided the SD upon author request (Nguyen 2020); and three reported the median number of attempts with IQRs (Gedikoglu 2013; Marquis-Gravel 2018; Stone 2020). Among the three studies that reported median and interquartile ranges, one provided the mean number of attempts and SD upon request (Marquis-Gravel 2018). However, the authors confirmed that their data were not normally distributed for this outcome, therefore we opted not to pool their mean results with the other studies or to pool the three medians together. Among the five studies that reported or provided the mean number of attempts along with SD, ultrasound guidance may reduce the number of attempts relative to anatomic landmark guidance, but the evidence is very uncertain (MD −0.59, 95% CI −0.91 to −0.26; P < 0.001, I^2 = 96%; 5 studies, 3362 participants; very low certainty of evidence; Analysis 7.1).

Major complications

Retroperitoneal hematoma

There was no difference in the risk of retroperitoneal hematoma formation between participants who underwent ultrasound- versus anatomic landmark-guided access (RD −0.00, 95% CI −0.00 to 0.00; P = 0.96, I^2 = 0%; 6 studies, 2680 participants; Analysis 8.1).

Pseudoaneurysm formation

There was no difference in the risk of pseudoaneurysm formation between participants who underwent ultrasound- versus anatomic landmark-guided access (RD 0.00, 95% CI −0.00 to 0.00; P = 0.81, I^2 = 0%; 7 studies, 3648 participants; Analysis 9.1).

Flow-limiting injuries: dissection, arteriovenous fistula, and occlusion

There was no difference in the risk of arterial dissection (RD −0.00, 95% CI −0.01 to 0.01; P = 0.57, I^2 = 0%; 4 studies, 1453 participants; Analysis 10.1), arteriovenous fistulae (RD −0.00, 95% CI −0.01 to 0.00; P = 0.58, I^2 = 55%; 7 studies, 3648 participants; Analysis 11.1), or target vessel occlusion (RD −0.00, 95% CI −0.01 to 0.00; P = 0.33, I^2 = 0%; 3 studies, 1768 participants; Analysis 12.1) between participants who underwent ultrasound- versus anatomic landmark-guided access.

Adverse events

Minor bleeding

There was no difference in the odds of minor hematoma formation between participants who underwent ultrasound- versus anatomic landmark-guided access (OR 0.81, 95% CI 0.14 to 4.55; P = 0.81, I^2 = 41%; 3 studies, 420 participants; Analysis 3.2).

Infection

Only one study reported access site infection as an outcome and did not observe any infections in either the ultrasound- or anatomic landmark-guided access group up to 30 days post-procedure (RD 0.00, 95% CI −0.00 to 0.00; P = 1.00, I^2 N/A; 1 study, 1004 participants; Analysis 13.1) (Seto 2010).

Neuropathy

No studies reported rates of neuropathy.

Quality of life

No studies reported any quality of life measures.

Re-intervention

Re-intervention, as defined in Secondary outcomes, was not reported as a stand-alone outcome in any of the included trials.

Total number of access sites attempted

No studies reported the number of access sites attempted.

Sensitivity analysis

We performed a sensitivity analysis to assess the impact of differences in definitions for mean time to successful CFA access. Among the three studies that defined time to successful CFA access as time of administration of the local anesthetic to time of successful sheath insertion, and reported both mean and SD (Gedikoglu 2013; Jolly 2022; Nguyen 2020), ultrasound guidance reduced the time to successful CFA access compared to anatomic landmark-guided access (MD −23.65 s, 95% CI −34.28 to −13.01 s; P < 0.001, I^2 = 0%; 3 studies, 1517 participants; Analysis 2.2). Among the two studies that defined time to successful CFA access as the time of the first movement of the table for fluoroscopy or the application of the ultrasound probe to the time of successful sheath insertion (Katircibasi 2018; Seto 2010), there was no difference between groups in time to successful CFA access (MD −14.85 s, 95% CI −33.45 to 3.75 s; P = 0.12, I^2 = 63%; 2 studies, 1941 participants; Analysis 2.3). Likewise, for the one study that defined time to successful CFA access as time of skin penetration by the access needle to the time of sheath insertion (Dudeck 2004), there was no difference between ultrasound- and anatomic landmark-guided access for this outcome (MD 11.00 s, 95% CI −43.06 to 65.06 s; P = 0.69, I^2 N/A; 1 study, 112 participants; Analysis 2.4).

We had planned to conduct sensitivity analyses excluding studies deemed to be at overall high or unclear risk of bias. However, we were unable to perform these sensitivity analyses because all nine studies were deemed to be at either high or unclear overall risk of bias (Figure 3).

Likewise, we had planned to conduct a sensitivity analysis to assess the impact of studies using palpation alone in the anatomic landmark-guided access study arm by excluding those studies and only including studies that used fluoroscopy in conjunction with anatomic landmarks in the analysis of each outcome. However, we were unable to perform this sensitivity analysis as all nine studies either routinely used fluoroscopy in the anatomic landmark-guidance arm (Dudeck 2004; Gedikoglu 2013; Jolly 2022; Katircibasi 2018; Seto 2010; Slattery 2015; Stone 2020) or permitted the use of fluoroscopy at the discretion of the operator (Nguyen 2020) or as a bail-out method (Marquis-Gravel 2018) in the anatomic landmark-guided access arm.

We performed a sensitivity analysis excluding studies that allowed the use of rescue ultrasound (Gedikoglu 2013; Jolly 2022; Nguyen 2020; Seto 2010). For the primary outcome of first-pass success, the difference between ultrasound- and anatomic landmark-guided access persisted after the exclusion of these studies, with ultrasound guidance demonstrating greater odds of first-pass success (OR 3.15, 95% CI 2.21 to 4.49; P < 0.001, I^2= 53%; 3 studies, 1755 participants; Analysis 1.2). Similarly, the difference between ultrasound- and anatomic landmark-guided access persisted for the primary outcome of mean time to successful CFA access, with ultrasound guidance demonstrating shorter time to successful CFA access (MD −7.75 s, 95% CI −14.00 to −1.49 s; P = 0.02, I^2 = 0%; 2 studies, 1051 participants; Analysis 2.5). For the primary outcome of major bleeding, there remained no difference between the ultrasound- and anatomic landmark-guided access groups after excluding studies that allowed for rescue ultrasound (OR 0.35, 95% CI 0.12 to 1.00; P = 0.05, I^2 = 21%; 3 studies, 1703 participants; Analysis 3.4).

We performed a sensitivity analysis excluding studies that permitted the use of rescue ultrasound for the secondary outcomes of venipuncture, number of access attempts, retroperitoneal hematoma formation, minor bleeding, pseudoaneurysm formation, arterial dissection, arteriovenous fistula formation, and target vessel occlusion. For the secondary outcome of venipuncture, the odds remained lower in the ultrasound-guided access group compared to the anatomic landmark-guided access group (OR 0.29, 95% CI 0.18 to 0.45; P < 0.001, I^2 = 0%; 4 studies, 1867 participants; Analysis 5.2) after excluding studies that allowed for rescue ultrasound. For the secondary outcome of number of access attempts, the mean number of attempts remained lower in the ultrasound-guided access group compared to the anatomic landmark-guided access group (MD −0.26, 95% CI −0.33 to −0.19; P < 0.001, I^2 = 0%; 2 studies, 1051 participants; Analysis 7.2) after excluding studies that allowed for rescue ultrasound. Among the bleeding outcomes, there remained no difference between the ultrasound- and anatomic landmark-guided access groups with respect to risk of retroperitoneal hematoma formation (RD −0.00, 95% CI −0.03 to 0.02; P = 0.72, I^2= 47%; 3 studies, 847 participants; Analysis 8.2) and odds of minor bleeding (OR 1.26, 95% CI 0.38 to 4.17; P = 0.70, I^2 = 0%; 2 studies, 212 participants; Analysis 3.3) after excluding studies that allowed for rescue ultrasound. Finally, there remained no difference between ultrasound and anatomic landmark guidance after excluding studies that permitted the use of rescue ultrasound for the secondary outcomes of pseudoaneurysm formation (RD −0.00, 95% CI −0.01 to 0.01; P = 0.97, I^2 = 0%; 4 studies, 1815 participants; Analysis 9.2), arterial dissection (RD −0.01, 95% CI −0.04 to 0.02; P = 0.51, I^2 = 16%; 2 studies, 241 participants; Analysis 10.2), arteriovenous fistula formation (RD −0.01, 95% CI −0.02 to 0.01; P = 0.49, I^2 = 74%; 4 studies, 1815 participants; Analysis 11.2), and target vessel occlusion (RD −0.00, 95% CI −0.01 to 0.01; P = 0.49, I^2 = 0%; 2 studies, 764 participants; Analysis 12.2).

We did not perform a sensitivity analysis excluding studies that permitted rescue ultrasound for the secondary outcomes of overall cannulation success, infection, or pain scores, as measured using the VAS pain scale, or the need for additional analgesia because three of the four studies that reported overall cannulation success allowed for rescue ultrasound (Analysis 4.1), and only included one study was included in each analysis for the outcomes of infection, VAS pain scores, and need for additional analgesia, respectively (Analysis 13.1; Analysis 6.1; Analysis 6.2).

DISCUSSION

Summary of main results

The use of ultrasound guidance for percutaneous CFA access for endovascular imaging or therapy may be associated with higher first-pass success rates and less time to successful access compared with anatomic-guided access. It may also be associated with a lower number of required attempts (though the evidence is very uncertain) and lower rate of venipuncture compared to anatomic landmark-guided access. The evidence also suggests that ultrasound-guided access does not result in differences in rates of major bleeding, overall cannulation success (though this evidence is also very uncertain), retroperitoneal hematoma formation, minor bleeding, pseudoaneurysm formation, arterial dissection, arteriovenous fistulae formation, arterial occlusion, infection, periprocedural pain, or the need for additional analgesia. A lack of data precluded assessments of differences in re-intervention rates, post-procedural neuropathy, quality of life outcomes, or the number of access sites attempts.

Sensitivity analyses revealed that excluding studies that permitted rescue ultrasound from the analysis of first-pass success, mean time to successful CFA access, major bleeding, venipuncture, number of access attempts, retroperitoneal hematoma formation, minor bleeding, pseudoaneurysm formation, arterial dissection, arteriovenous fistula formation, and target vessel occlusion resulted in no change in the effect of ultrasound- compared to anatomic landmark-guided access.

Overall completeness and applicability of evidence

We included nine RCTs that were designed to compare ultrasound- versus anatomic landmark-guided access via fluoroscopy or manual palpation, or both, for percutaneous CFA access in people undergoing endovascular imaging or treatment involving sheath insertion. All primary and secondary outcomes evaluated were clinically relevant and patient-centered, and were thus clinically applicable.

All the included trials had significant limitations, with each trial demonstrating at least an unclear risk of bias (Dudeck 2004; Slattery 2015) or a high risk of bias overall (Gedikoglu 2013; Jolly 2022;

Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Stone 2020). The most common limitations were related to the blinding of the operators across all studies, and of the participants and outcomes assessors in some studies, followed by other sources of bias such as the exclusion of patients with non-palpable pulses, inconsistent use of needle guides or Doppler needles, and the potential for clustering that was not clearly accounted for in the analysis (Figure 3).

Several clinically relevant and patient-centered outcomes, including re-intervention rate, neuropathy, quality of life, and number of access sites attempted, were not reported in any of the included studies. Future studies may benefit from including these outcomes to increase the relevance of the study findings to the patient population.

A number of highly clinically relevant outcomes, such as pain scores and major bleeding, were reported in some studies but were inconsistently defined. For example, pain was assessed in one study according to the need for additional analgesia, and in another using the VAS pain scale (Gedikoglu 2013; Katircibasi 2018), while different aspects of 'major bleeding,' such as bleeding requiring transfusion, hematoma ≥ 5 cm, and/or bleeding extending length of stay in hospital, or a combination of the above, were reported across different studies (Jolly 2022; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Stone 2020). The heterogeneity in these definitions limited the possibility of pooling these data and, consequently, the ability to extrapolate the findings to a broader population. While each of these individual outcomes is valuable, future studies could maximize the potential for pooled analyses by adhering to more uniform definitions of major bleeding and perceived pain.

For outcomes involving continuous variables, such as time to successful CFA access and the number of attempts at CFA access, studies differed with respect to their choice of reported effect measure, with some studies reporting means +/− SD and others reporting medians +/− IQR. Presuming, and in some cases confirmed by the study authors, that the median was selected over the mean due to non-normally distributed data, it is difficult to determine how applicable those findings are to a broader, and presumably normally distributed population. With this in mind, we limited the pooled analyses to mean data where available, assuming that the authors of those studies accurately reported their results from a normally distributed population.

Finally, a number of pre-planned subgroup and sensitivity analyses could not be carried out due to lack of data. While many studies did report important patient and procedural characteristics, such as obesity, high femoral bifurcation, periprocedural antithrombotic therapy, and method of closure, these studies either failed to conduct or report subgroup analyses to assess the impact of these important characteristics on the study outcomes of interest in this review. In addition, though it may have been beneficial to assess the impact of studies at high or unclear risk of bias on the pooled study findings, the ubiquity of either high or unclear risk of bias across all nine studies precluded such an analysis. Similarly, we hoped to perform a sensitivity analysis including studies that strictly used the palpation method for their anatomic landmark-guidance control group without the use of fluoroscopy. However, even trials using palpation guidance or standard anatomic landmarks as their control method also employed radiography to first identify the femoral head to guide the puncture accordingly (Dudeck 2004), or permitted the use of fluoroscopy as a bail-out method (Marquis-Gravel 2018) or at the operator's discretion (Nguyen 2020).

Quality of the evidence

Although we identified and included nine RCTs enrolling 4447 participants in the review, we found all trials to be at high risk of bias for blinding (performance and detection bias) and at either high or unclear risk of bias for blinding of participants and personnel, due to the nature of the interventions being evaluated (Figure 2; Figure 3). We also found four studies to be at high risk of other bias due to exclusion criteria that favored the control group, interoperator variability, industry sponsorship, use of Doppler needles, and lack of adherence to an ITT analysis (as initially outlined in the methods section) (Figure 3).

We assessed the certainty of evidence for the outcome of first-pass success to be low. We downgraded the certainty of evidence by two levels, as all seven studies were at high risk of bias for lack of blinding; one study was at high risk of bias for selective reporting; and substantial heterogeneity was detected (Tau^2 = 0.09; I^2 = 69%). We note that the direction of effect for all studies favored ultrasound; however, not all CIs overlapped, and there was only a small number of studies. All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access, and the 95% CI included only an appreciable effect (2.53 to 4.44).

We assessed the certainty of evidence for the outcome of time to successful CFA access to be low. We downgraded the certainty of evidence by two levels: one level as all six studies were at high risk of bias due to lack of blinding, and one study was at high risk of bias for selective reporting; and another level as there was moderate to substantial heterogeneity (Tau^2 = 58.90; I^2 = 45%) and a somewhat wide 95% CI (−27.04 to −7.43). We are reassured that all studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.

We assessed the certainty of evidence for the outcome of major bleeding to be low. We downgraded the certainty of evidence by two levels, as all six studies were at high risk of bias due to lack of blinding; one study was at high risk of bias for selective reporting; and the 95% CI included both an appreciable and no effect (0.32 to 1.13). We did not detect meaningful heterogeneity (Tau^2 = 0.21; I^2 = 38%), and all study CIs overlapped. All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.

We assessed the certainty of evidence for the outcome of overall cannulation success to be very low. We downgraded the certainty of evidence by three levels, as all four studies were at high risk of bias due to lack of blinding, and the 95% CI included both no effect and an appreciable benefit (0.93 to 2.30). In addition, moderate to substantial heterogeneity was detected (Tau^2 = 0.11; I^2 = 59%). All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.

We assessed the certainty of evidence for the outcome of venipuncture to be low. We downgraded the certainty of evidence by two levels, as all seven studies were at high risk of bias due to lack of blinding, and one study was at high risk of bias for selective reporting. There was also moderate heterogeneity (Tau^2 = 0.08; I^2 = 33%). We note that the direction of effect for all studies favored

ultrasound; however, there was only a small number of studies. All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access. The 95% CI included only an appreciable effect (0.18 to 0.38).

We assessed the certainty of evidence for the outcome of VAS pain score differences to be moderate. We downgraded the certainty of evidence by one level, as the included study was at high risk of bias due to lack of blinding and selective reporting. The study directly studied ultrasound guidance in comparison to anatomic landmark guidance for VAS pain scores. The 95% CI demonstrated no effect (−0.34 to 0.34). Heterogeneity was not applicable, as only one study contributed to this outcome.

We assessed the certainty of evidence for the outcome of number of attempts to be very low. We downgraded the certainty of evidence by three levels, as all five studies were at high risk of bias due to lack of blinding; one study was at high risk of bias for selective reporting; considerable heterogeneity was detected (Tau^2 = 0.12; I^2 = 96%); and the 95% CI included both an appreciable and minimally appreciable effect (−0.91 to −0.26). All studies directly studied ultrasound guidance in comparison to anatomic landmark guidance for percutaneous CFA access.

Potential biases in the review process

We conducted this review according to Cochrane guidelines. We were able to find contact information (email addresses of study authors) for all studies with missing information, and all email inquiries were delivered successfully. Missing data were generously provided by the authors of Marquis-Gravel 2018 and Nguyen 2020. We did not receive a response from the authors of Gedikoglu 2013, Slattery 2015, or Stone 2020 despite multiple attempts at contacting the corresponding authors by email.

Potential biases may have arisen as a result of subjective decisions made by the review authors throughout the review process. For example, when evaluating the risk of attrition bias, there is a certain amount of ambiguity when deciding whether the proportion of participants lost to follow-up in each arm of a study—as well as their reasons for becoming lost to follow up—would merit a rating of high, as opposed to low, risk of attrition bias. These decisions affect the overall risk of bias rating for each study and, in turn, affect the grading of the certainty of evidence for each outcome. We attempted to mitigate this risk by ensuring that there was agreement between review authors with respect to these subjective decisions, and by thoroughly discussing any disagreements and/or reviewing them with the principal investigator before arriving at a final decision.

Agreements and disagreements with other studies or reviews

We identified five meta-analyses that examined the effectiveness of ultrasound guidance for percutaneous femoral artery access (Jolly 2022; Marquis-Gravel 2018; Rashid 2019; Sobolev 2015; Sorrentino 2020). Similar to our review, all of those studies demonstrated an advantage for ultrasound guidance, although the selection of reported outcomes differed across studies, as did the presence or absence of specific sensitivity and subgroup analyses. Furthermore, our review included more recently published studies and/or more patient-centered outcomes, such as perceived pain.

Sobolev and colleagues published the first of these meta-analyses in 2015 (Sobolev 2015), and thus included the four trials that were published up to that point (Dudeck 2004; Gedikoglu 2013; Seto 2010; Slattery 2015). The primary outcome of interest was a composite of "overall complication rate," defined as local hematoma formation, retroperitoneal hematoma formation, venipuncture, superficial femoral artery puncture, pseudoaneurysm formation, arteriovenous fistula formation, and arterial dissection. The secondary outcomes were first-pass success rate, hematoma formation rate, venipuncture rate, number of attempts, and time of procedure. The Jadad criteria, which take into account the randomization of participants, use of blinding, and completeness of follow-up data, were used to evaluate the methodological quality of the included trials, and no sensitivity or subgroup analyses were performed (Sobolev 2015). The authors found that catheterization using real-time 2-dimensional ultrasound guidance reduced the primary outcome of overall complication rate compared to traditional palpation techniques or a combination of palpation and fluoroscopy. Likewise, ultrasound guidance increased the first-pass success rate and reduced the rate of venipuncture as well as the time to access the artery. Hematoma formation and number of attempts were both numerically lower with ultrasound guidance compared to palpation with or without fluoroscopy, albeit neither met statistical significance. The study authors concluded that ultrasound guidance conferred a benefit over palpation with or without fluoroscopy for CFA access by reducing the complication rate and improving the first-pass success rate, while conceding that data were limited and further studies were needed (Sobolev 2015).

The next two meta-analyses by Rashid and colleagues and Marquis-Gravel and colleagues were published within one year of one another (Marquis-Gravel 2018; Rashid 2019). Marquis-Gravel and colleagues reported both the results of their own RCT followed by a meta-analysis of their data pooled with the data available to date. Thus, both Marquis-Gravel and colleagues and Rashid and colleagues included a total of five trials: the four aforementioned trials plus the addition of Marquis-Gravel's study data.

Marquis-Gravel and colleagues did not list specific primary or secondary outcomes for their meta-analysis a priori. Rather, they selected outcomes post hoc based on availability, assessing primary and secondary outcomes for which data were reported from two or more trials. Those included bleeding events, defined heterogeneously according to each trial, multiple access attempts, venipuncture, and CFA cannulation rates. No quality of evidence or risk of bias assessment was performed or reported in either the supplementary methods or results sections. The study authors found that ultrasound guidance reduced the rate of bleeding events, venipuncture, and the need for multiple attempts but did not affect the rate of successful CFA cannulation (Marquis-Gravel 2018). A sensitivity analysis was conducted involving studies that only used the anatomic landmark approach as the comparator group, as opposed to fluoroscopy, which revealed a consistent reduction in the number of procedures requiring more than one puncture attempt and the rate of venipuncture with ultrasound guidance, though it did result in loss of significance between the ultrasound- and anatomic landmark-guided groups for bleeding events. However, it should be noted that the studies included in this sensitivity analysis, despite being classified as using anatomic landmarks only and no fluoroscopy for the control group, all reported either using fluoroscopy or radiography to mark the head

of the femur in the control group (Dudeck 2004; Gedikoglu 2013) or allowing for fluoroscopy as a bail-out method in the control group (Marquis-Gravel 2018). A sensitivity analysis was also conducted using only studies involving coronary procedures (Marquis-Gravel 2018; Slattery 2015), and the benefit to ultrasound guidance with respect to bleeding events, more than one puncture attempt, and venipuncture rates remained consistent with the primary analysis results.

In contrast, Rashid and colleagues identified the primary outcome "vascular-access related complications," which they defined as a composite of access-related major and minor bleeding, including local hematoma formation, dissection, vessel thrombosis, arteriovenous fistula, or pseudoaneurysm formation, as well as secondary outcomes, including major bleeding, minor bleeding, venipuncture, first-pass success rate, number of attempts, access time, and successful CFA cannulation (Rashid 2019). The authors conducted a quality assessment using the Cochrane risk of bias tool, as well as a sensitivity analysis to assess the primary outcome after excluding local hematoma and a subgroup analysis including only studies that involved coronary procedures. The study revealed that ultrasound guidance was associated with a reduction in the rate of vascular access-related complications as well as venipuncture. Ultrasound guidance also resulted in a higher first-pass success rate, lower number of attempts, and shorter access time compared to the control group. There was no difference between groups with respect to the incidence of major or minor bleeding or successful CFA cannulation rates. The subgroup analysis of trials involving coronary procedures (Marquis-Gravel 2018; Seto 2010) was consistent with the primary analysis, while the sensitivity analyses excluding local hematoma formation from the composite primary outcome resulted in a loss of significance between the ultrasound guidance and control groups (Rashid 2019).

The next meta-analysis, by Sorrentino and colleagues, compared ultrasound-guided CFA cannulation to the "standard approach" in people undergoing invasive endovascular procedures (Sorrentino 2020). With the addition of data from two randomized trials published in the same year as this meta-analysis, the authors included a total of seven studies (Dudeck 2004; Gedikoglu 2013; Katircibasi 2018; Marquis-Gravel 2018; Nguyen 2020; Seto 2010; Slattery 2015). Similar to the previous meta-analyses, Sorrentino and colleagues found that ultrasound guidance resulted in higher rates of first-pass success, which was the primary efficacy outcome, and lower rates of vascular complications, which were the primary safety outcomes. Furthermore, among the secondary outcomes, ultrasound guidance resulted in shorter access times, lower number of access attempts, and lower rates of venipuncture and access site hematoma. No differences were observed between groups with respect to rates of major bleeding, pseudoaneurysm formation, or retroperitoneal hematoma formation (Sorrentino 2020).

The final and most recently published study, by Jolly and colleagues, was structured similarly to Marquis-Gravel 2018, in that it reported both the results of their own RCT, as well as a meta-analysis that pooled their data with the studies available to date (Jolly 2022). For their meta-analysis, Jolly and colleagues examined the effect of ultrasound-guided CFA access compared to CFA access with no ultrasound guidance in people undergoing vascular or cardiac interventions. Their primary outcome was a composite of major vascular complications (including femoral artery pseudoaneurysm, arteriovenous fistula, retroperitoneal bleed, large hematoma, and/or ischemic limb) or major bleeding (defined as BARC type 2, 3, or 5). Additional outcomes were listed in the study's PROSPERO registration, including successful placement of introducer sheath in the CFA, venipuncture, mean number of attempts, and total time to obtain femoral artery access; however, none of these additional outcomes were reported in the meta-analysis. The authors included the same nine RCTs that we included in our study, and found that ultrasound guidance resulted in a reduced risk of the composite outcome (major bleeding or major vascular complications), as well as major vascular complications alone (Jolly 2022).

The findings of our study are consistent with those reported by the studies above, demonstrating a benefit to ultrasound guidance in increasing the first-pass success rate and reducing the time to access, number of access attempts, and rates of venipuncture compared with anatomically guided access attempts. Similarly, we found no difference between ultrasound- and anatomic landmark-guided access with respect to rates of successful CFA access, as well as various vascular access-related complications including retroperitoneal hematoma formation, minor bleeding, pseudoaneurysm formation, arterial dissection, arteriovenous fistulae formation, or vessel occlusion.

The only outcome that was inconsistent across the above studies was the incidence of bleeding events, which is likely due to the variability in defining this endpoint across the individual trials. For example, Sobolev 2015 found no difference in the rates of hematoma development with the use of ultrasound guidance, and Rashid 2019 found no difference in the rates of major or minor bleeding. However, Sorrentino 2020 found a reduction in access site hematoma formation but no difference in major bleeding or retroperitoneal hematoma; Marquis-Gravel 2018 found a reduction in pooled bleeding events; and Jolly 2022 found a reduction in the composite outcome of major bleeding or major vascular complications. Without a uniform definition for each of these outcomes, and no severity scale to standardize these findings, it is difficult to translate these results into clinical practice. For example, there is a big difference between a small, local hematoma that does not affect the patient's quality of life or length of stay in hospital, and a hemorrhage that results in a hemoglobin drop, blood transfusion, and the need for surgical exploration and repair. These nuances not only differ in their clinical implications, but they also have different resource impacts that can, in turn, impact hospital policies.

In our study, we utilized a broad definition for major bleeding to maximize the pooling of available data, while still differentiating between major and minor bleeding to permit meaningful conclusions. Nonetheless, it is notable that our study found no difference in both major and minor bleeding event rates with the use of ultrasound guidance.

Our study also builds upon, and complements, the findings of its predecessors by including additional clinically relevant and patient-centered outcomes, such as the incidence of infection rates and pain scores. To our knowledge, this is the only meta-analysis that includes all relevant studies to date (including Jolly 2022 and Stone 2020) and reports on more than two outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

Our study suggests that ultrasound guidance, as compared to anatomic landmark guidance, for percutaneous common femoral artery (CFA) access may increase first-pass success rates, and may reduce time to successful CFA access, number of attempts (though the evidence was very uncertain), and rates of venipuncture. Our analysis showed that there may be little or no difference between groups for major bleeding, overall cannulation success (though the evidence was very uncertain), retroperitoneal hematoma formation, minor bleeding, pseudoaneurysm formation, arterial dissection, arteriovenous fistulae, arterial occlusion, infection, visual analogue scale pain scores, or the need for additional analgesia between the two modalities to a maximum of 30 days post-procedure. These are all clinically relevant and applicable outcomes, which demonstrated a benefit or neutral effect of ultrasound guidance over anatomic landmark guidance for CFA access. Furthermore, the exclusion of important subgroups from certain studies, such as patients with non-palpable groin pulses, may have blunted the beneficial effect of ultrasound over anatomic landmark guidance. However, all the included studies were at either high or unclear risk of bias, which may limit the generalizability of our findings. In addition, our study did not evaluate the impact of operator experience with ultrasound, nor did it address the training time required to become proficient in ultrasound use or the associated costs of procuring an ultrasound machine and its accessories.

Implications for research

To effectively evaluate, and broadly extrapolate, the role of ultrasound guidance in successfully and safely obtaining percutaneous CFA access for endovascular imaging or treatments involving sheath insertion, it is essential to carry out independently funded randomized trials with diverse inclusion criteria, uniform definitions for relevant outcomes (such as major bleeding and time to successful CFA access), and standardized protocols for operator training and ultrasound technique. Future trials can also improve upon the applicability of their findings by including relevant subgroup analyses, such as patients with high body mass index, extensive atherosclerosis or calcification, and high femoral artery bifurcations.

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Editorial and peer-reviewer contributions

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Stavros Kakkos, Department of Vascular Surgery, University of Patras Medical School;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Anupa Shah, Cochrane Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments, and supported the editorial team): Lisa Wydrzynski, Cochrane Central Editorial Service;
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- Peer reviewers (provided comments and recommended an editorial decision): Prof Dr Randon Caren, MD, PhD, Department of Thoracic and Vascular Surgery, Ghent University Hospital, Belgium (clinical/content review), Luisa Ciucci Biagioni, MD, Vascular Surgeon, Vascularline, Brazil (clinical review), Radhehsyam Meher, AIIMS, New Delhi, India (consumer review), Nuala Livingstone, Cochrane Evidence Production and Methods Directorate (methods review), Jo Platt, Central Editorial Information Specialist (search review). One additional peer reviewer provided clinical peer review but chose not to be publicly acknowledged.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Dudeck 2004

Study characteristics	
Methods	RCT
Participants	Patients referred for diagnostic and therapeutic transarterial procedures at a single center.
Interventions	US guided vs. Anatomic landmark guided using palpation
Outcomes	Primary outcome: number of attempts Secondary outcomes: access-related complications

Dudeck 2004 *(Continued)*

Funding	None reported
Declaration of interest	None reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomized in two groups by drawing prepared envelopes"
Allocation concealment (selection bias)	Low risk	Allocation concealed in envelopes
Blinding (performance bias and detection bias) All outcomes	High risk	Operator not blinded
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Method not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Method not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for all patients
Selective reporting (reporting bias)	Unclear risk	Post-intervention complications not defined in methods
Other bias	Unclear risk	Lots of prep required for single-operator US technique (femoral head and bifurcation visualized sonographically, optimal puncture site identified, rule out adjacent atherosclerotic plaques, fix the transducer to the swivel arm, correction of the angle of the swivel arm, etc), but time to access only recorded from initial puncture attempt to sheath insertion. In addition, direction of access (i.e. antegrade vs. retrograde) was not reported.

Gedikoglu 2013

Study characteristics	
Methods	RCT
Participants	Patients over 18 years old who required retrograde puncture of the CFA for diagnostic or therapeutic angiography
Interventions	US guidance vs. landmark technique (in conjunction with guidance by palpation and fluoroscopy)

Gedikoglu 2013 *(Continued)*

Outcomes	Procedural outcomes: technical success, first pass success rate, total number of attempts required for access, time to sheath insertion, and pain anticipated by the patient while obtaining the vascular access Safety end point: any access-related complication, defined as hematoma, pseudoaneurysm formation, retroperitoneal hemorrhage, AV fistula, or arterial dissection
Funding	None reported
Declaration of interest	None reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Two hundred and eight patients were randomized in two groups." Method of randomization not reported.
Allocation concealment (selection bias)	Unclear risk	Allocation method not reported
Blinding (performance bias and detection bias) All outcomes	High risk	"Blinding of the operators was possible only for US examination of the CFA before the puncture and not for other measurements."
Blinding of participants and personnel (performance bias) All outcomes	High risk	"We cannot exclude bias in the measurements of number of attempts and time to successful vascular access"
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Post-interventional complications were assessed by physical examination of the groin 6 hr after the procedure by the physician who performed the angiography"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for all patients enrolled
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported except for arterial dissection
Other bias	High risk	"Exclusion of patients who did not have a palpable pulse increased the technical success rate for palpation guidance method. Inclusion of these patients into the study would have increased the technical success of US-guided group considerably"

Jolly 2022

Study characteristics

Methods	RCT
Participants	Patients >18 years old referred for coronary angiography or PCI with planned femoral access.

Jolly 2022 *(Continued)*

Interventions	Ultrasonography guidance vs no ultrasonography guidance for femoral arterial access on a background of fluoroscopic landmarking.
Outcomes	The primary composite outcome is the composite of major bleeding based on the Bleeding Academic Research Consortium 2, 3, or 5 criteria or major vascular complications within 30 days.
Funding	Funding was provided by grants from the Hamilton Health Sciences Foundation and McMaster University, Division of Cardiology. The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.
Declaration of interest	Dr Pinilla-Echeverri reports personal fees from Abbott Vascular, Philips, Novartis, and Amgen outside the submitted work. No other disclosures were reported.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was performed using permuted blocks with stratification according to study center with a 24-hour computerized central system located at the Population Health Research Institute."
Allocation concealment (selection bias)	Low risk	"Allocation will be assigned according to a pre- defined randomization list, with each treatment arm having an allocation probability of a half (0.50). Patients will be considered randomized as soon as the treatment allocation is given."
Blinding (performance bias and detection bias) All outcomes	High risk	Open-label study. "All patients and investigators were aware of study group assignments."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Open-label study. "All patients and investigators were aware of study group assignments."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded assessment of outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Two patients had a procedure cancelled after randomization because of medical decisions, and four patients had radial instead of femoral access after randomization because of physician decision. Overall low risk given exceptionally low number of participants who did not ultimately undergo an attempt at CFA access. Furthermore, no participants were lost to follow up.
Selective reporting (reporting bias)	Low risk	All outcomes listed in protocol and methods section were reported in results.
Other bias	High risk	High risk of bias due to exclusion of patients without palpable femoral pulse (would favor the control group, since US-guidance is likely of particular benefit in this population). Unclear risk of bias due to author-declared conflict of interest (one author reported personal fees from Abbott Vascular, Philips, Novartis, and Amgen outside the submitted work). Unlikely risk of bias due to funding source, since funding provided by grants from the Hamilton Health Sciences

Jolly 2022 *(Continued)*

	Foundation and McMaster University, which had no role in designing or conducting the study.

Katircibasi 2018

Study characteristics	
Methods	RCT
Participants	Patients older than 21 years of age and scheduled to undergo a diagnostic or interventional coronary or peripheral procedure via retrograde femoral arterial with a 6-French sheath
Interventions	US-guided vs. Fluoroscopy
Outcomes	Number of arterial puncture attempts to place the sheath, time to access, and inadvertent venous punctures were recorded. A VAS was used to assess pain level during the procedure. The formation of a pseudoaneurysm, retroperitoneal hemorrhage, arteriovenous fistula, or hematoma > 5 cm were recorded as complications.
Funding	None reported
Declaration of interest	None reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"The present study was designed as a randomized controlled study." Method of randomization not elaborated upon.
Allocation concealment (selection bias)	Unclear risk	Allocation method not reported.
Blinding (performance bias and detection bias) All outcomes	High risk	"Blinding of the operators was only possible for the US examination of the CFA before the puncture and not for other measurements."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Operators not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	"A follow-up visit (7 days after discharge) with the same operator that performed the procedure was scheduled to identify possible complications."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for all enrolled patients
Selective reporting (reporting bias)	High risk	Retroperitoneal hemorrhage rate not reported and listed as outcome; first pass success rate reported but not listed as outcome

Katircibasi 2018 *(Continued)*

Other bias	Unclear risk	No mention of exclusion criteria, unclear whether patients were excluded if pulse was not palpable

Marquis-Gravel 2018

Study characteristics	
Methods	RCT
Participants	Patients older than 18 years of age undergoing elective or urgent coronary angiography via the femoral artery.
Interventions	US guided vs. anatomic landmark guided using palpation
Outcomes	Primary outcomes: (1) Composite of immediate procedural outcomes at day 1 including access failure, ≥ 1 puncture attempts, transfixing arterial puncture, venipuncture, and catheter insertion outside of the CFA boundaries. (2) Composite of immediate access-site outcomes at day 1 including AV fistula, pseudoaneurysms, dissections, thromboses, and significant bleeding. Secondary outcomes: individual components of the composite primary endpoints
Funding	None reported
Declaration of interest	None reported
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Patients underwent 1:1 randomization to either the US-guided approach or the AL approach." Method of randomization not elaborated upon.
Allocation concealment (selection bias)	Unclear risk	Allocation method not reported
Blinding (performance bias and detection bias) All outcomes	High risk	"The patients and the physicians performing the procedures were not blinded to the assignment"
Blinding of participants and personnel (performance bias) All outcomes	High risk	"The patients and the physicians performing the procedures were not blinded to the assignment"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Proper CFA cannulation was assessed by two physicians blinded to the strategy assignment, upon independent review of femoral angiograms" "Access-site outcomes at day one [...] were recorded by an investigator blinded to the approach assignment"
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Immediate procedural outcomes were available for all patients, and access-site complications rate at day one were available for 126 patients (98%)"

Marquis-Gravel 2018 *(Continued)*

Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported
Other bias	Low risk	No other sources of bias identified

Nguyen 2020

Study characteristics		
Methods	RCT	
Participants	Patients undergoing coronary angiography and percutaneous coronary intervention (Note: both femoral and radial artery access patients were enrolled but results were reported separately, and only the femoral access group's data was used for this sytematic review)	
Interventions	US guided vs. "standard" technique	
Outcomes	Primary outcome: Composite of ACUITY (Acute Catheterisation and Urgent Intervention Triage Strategy) major bleeding, MACE (death, stroke, myocardial infarction, or urgent target lesion revascularization) and vascular complications at 30 days Secondary outcomes: access time, number of attempts, venipuncture, difficult accesses, first-pass success	
Funding		
Declaration of interest		
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patients were randomised (1:1) into radial or femoral access, and (1:1) to standard technique or US guidance"
Allocation concealment (selection bias)	Low risk	"Sealed envelopes balanced in blocks of 50 were used for randomisation." *from main trial publication
Blinding (performance bias and detection bias) All outcomes	High risk	"Patients and investigators were not masked to access allocation."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Patients and investigators were not masked to access allocation.
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Patients and investigators were not masked to access allocation." *from main trial publication
Incomplete outcome data (attrition bias)	Low risk	3.8% lost to follow up overall with similar proportions in each group (12/331 in ultrasound group vs. 14/357 in non-ultrasound group)

Nguyen 2020 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	Authors reported all prespecified outcomes
Other bias	Unclear risk	Some details lacking with respect to the femoral subgroup because the main trial did not stratify results according to access site for most outcomes, and the subgroup analysis has only an abstract published to date. Furthermore, the authors report "We are grateful for the loan of the ultrasound machine during the early trial period by Fujifilm SonoSite and Western Sydney University." It is unclear how this donation of equipment may or may not have influenced the reporting or assessment of the results of the trial.

Seto 2010

Study characteristics	
Methods	RCT
Participants	Patients older than 18 years old scheduled to undergo a diagnostic or interventional coronary or peripheral procedure from the retrograde femoral arterial approach
Interventions	US guidance vs. Fluoroscopy
Outcomes	Primary outcome: successful cannulation of the CFA Procedureal outcomes: first pass success rate, total # of attempts required for access, rate of accidental venipunctures, time to sheath insertion Safety end point: any access complication, defined as hematoma ≥ 5 cm, pseudoaneurysm formation, retroperitoneal hemorrhage, arterial dissection, vessel thrombosis, noncoronary artery bypass graft-related access bleeding requiring transfusion, access site infection, or hemoglobin drop of ≥ 3 g/dl with an access source or ≥ 4 g/dl with an unknown source
Funding	"Research materials were supplied by the sponsor, who had no role in the design, analysis, or publication of the trial" "This work was supported by the Memorial Medical Center foundation, the National Institutes of Health, National Center for Research Resources, General Clinical Research Center at University of Oklahoma, and a material research grant from Barc Access, Inc."
Declaration of interest	As above
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patients were randomized in a 1:1 fashion to either US or fluoroscopic guidance with sealed envelopes balanced in groups of either 50 or 80 by each center"
Allocation concealment (selection bias)	Low risk	"Patients were randomized in a 1:1 fashion to either US or fluoroscopic guidance, with sealed envelopes balanced in groups of either 50 or 80 by each center."

Seto 2010 *(Continued)*

Blinding (performance bias and detection bias) All outcomes	High risk	"Blinding of the operator and catheterization lab personnel to the study intervention was not possible. Despite the use of a second observer and lab timer, we cannot completely exclude a bias in the performance or measurement of the number of attempts, venipunctures, or time to access"
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Blinding of the operator and catheterization lab personnel to the study intervention was not possible. Despite the use of a second observer and lab timer, we cannot completely exclude a bias in the performance or measurement of the number of attempts, venipunctures, or time to access"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"All patients were examined by blinded nursing staff before discharge to assess for access site complications" "Two blinded investigators reviewed the femoral angiograms for proper CFA placement[…] Angiograms were also analyzed for the position of the sheath, CFA bifurcation, and origin and most inferior reflection of the inferior epigastric artery relative to the femoral head" "Clinical outcomes were reviewed by an independent blinded clinical events committee who had access to the relevant portions of medical records"
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Successful telephone or clinic follow up was completed in >98% of patients in both groups"
Selective reporting (reporting bias)	Low risk	All prespecified outcomes were reported
Other bias	High risk	Exclusion of patients with non-palpable pulse; variation in type of US machine used and use of a needle guide; "research materials were supplied by the sponsor, who had no role in the design, analysis, or publication of the trial"; use of closure device at discretion of the operator

Slattery 2015

Study characteristics	
Methods	RCT
Participants	Patients with no previous groin surgery undergoing infra-inguinal, unilateral peripheral arterial angioplasty ± stenting at a single center.
Interventions	US guided vs. anatomic landmark guided using palpation and fluoroscopy
Outcomes	Primary outcome: vascular access time Secondary outcomes: immediate postoperative complications
Funding	None reported
Declaration of interest	None reported
Notes	
Risk of bias	

Slattery 2015 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomised, on a case-by-case basis, to undergo either US-guided or fluoroscopic-assisted CFA puncture." Method of randomization not elaborated upon.
Allocation concealment (selection bias)	Unclear risk	Allocation method not reported
Blinding (performance bias and detection bias) All outcomes	High risk	Not possible to blind operator
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Methods not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Methods not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes data reported for all patients
Selective reporting (reporting bias)	Unclear risk	"Immediate post-operative complications" listed as outcome in methods section without elaborating on type of complications that were monitored or how/when they were evaluated
Other bias	Low risk	No alternate sources of bias identified

Stone 2020

Study characteristics	
Methods	RCT
Participants	Patients older than 18 years of age undergoing a noncardiac catheter-based diagnostic or interventional procedure with planned femoral artery cannulation.
Interventions	US guided vs. anatomic landmark guided using palpation and fluoroscopy
Outcomes	Primary outcome: successful CFA cannulation Secondary outcomes: first-pass success rate, total attempts for access, rate of accidental venipunctures, time to sheath insertion, short term (<24 h) and midterm (<90 days postdischarge) access complications
Funding	None reported
Declaration of interest	None reported
Notes	

Stone 2020 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The arterial access technique randomization schedule was created by the institutional biostatistician."
Allocation concealment (selection bias)	Low risk	"Access technique to be used for the procedures were inserted into enveloped based on the randomization schedule. The envelopes were sealed, sequentially numbered, and maintained in the procedure location. A dual trained investigator opened the sealed envelope containing patient randomization immediately before procedure"
Blinding (performance bias and detection bias) All outcomes	High risk	"Blinding of operators to randomized access method was not possible."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"All nursing staff and midlevel providers involved in the postprocedural care of the subjects were blinded to the used arterial access technique." Does not state whether participants were blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study was "single-blinded [to the staff examining for complications]" "Subjects were evaluated again by blinded midlevel providers at the time of their routine scheduled follow-up visit."
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Clinic follow-up (30-90 days postprocedure) was completed in 75.3% of patients in the fluoroscopic guided cohort and 77.7% of patients receiving US-guided femoral access." -->Low risk despite loss to follow up because equal weighting to both groups and no clear reason to suggest why one group would have greater loss to follow up
Selective reporting (reporting bias)	Low risk	All prespecified outcomes listed in protocol and methods section were reported
Other bias	High risk	Data analysis section states that "data were analyzed on an intention-to-treat basis"; however excluding patients after randomization due to anatomy concerns and excluding them from analysis is inconsistent with ITT analysis. "Procedural characteristics and outcomes were analyzed on a per limb basis, whereas patient characteristics and complications were analyzed per patient"--> unclear if they controlled for clustering among the per-limb outcomes. "Doppler needles were used in 74 of 340 (21.7%) of fluoroscopic-guided procedures [due to nonpalpable femoral artery]." In addition, direction of access (i.e. antegrade vs. retrograde) was not reported.

AV: arteriovenous
CFA: common femoral artery
PCI: percutaneous coronary intervention
RCT: randomized controlled trial
US: ultrasound
VAS: visual analogue scale

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

Study	Reason for exclusion
Daggubati 2011	Abstract
Enany 2013	Wrong patient population
Jayanti 2019	Subgroup of included study
Jayanti 2021	Wrong study design
Law 2014	Wrong patient population
Lazaar 2021	Wrong patient population
Nguyen 2019	Wrong patient population
Nguyen 2019 subgroup	Subgroup of already included study
Salik 2021	Wrong patient population
Seto 2008	Trial registration
Siddik-Sayyid 2016	Wrong patient population
Surmacz 2015	Abstract

Characteristics of studies awaiting classification *[ordered by study ID]*

UltraCOLOR Trial

Methods	RCT
Participants	Patients undergoing complex PCI, defined as PCI of CTO, complex bifurcation, heavy calcified lesion or left main, in which the 7-French or 8-French transfemoral access is required
Interventions	Ultrasound-guided femoral puncture compared to fluoroscopy-guided access
Outcomes	Primary outcome is the incidence of the composite end-point of clinically relevant access site related bleeding and/or vascular complications requiring intervention. Access site complications and major adverse cardiovascular events up to 1 month will also be compared between both groups.
Notes	At present, we are unable to obtain a full-text copy of the study (not accessible via multiple hospital/university libraries including via interlibrary loan request).

CTO: chronic total occlusion
PCI: percutaneous coronary intervention
RCT: randomized controlled trial

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

ACCESS-TAVR SIRIO 2022

Study name	ACCESS-TAVR SIRIO
Methods	RCT
Participants	Male or female 18 years and older with severe aortic stenosis evaluated by the Heart Team as candidate to TAVR based on the current cardiology guidelines.
Interventions	Ultrasound-guided femoral puncture and Perclose ProGlide/Prostyle implantation compared to Fluoroscopy-guided puncture and Perclose ProGlide/Prostyle in TAVR
Outcomes	Primary: composite of CV mortality, vascular complications, or access-related bleeding after TAVR at 30 days. Secondary: CV mortality, vascular complications, life-threatening or disabling bleeding, major bleeding (BARC type 3a), major vascular complications, and minor vascular complications at 1 month.
Starting date	2022-07-04
Contact information	Central contact persons: 1) Sergio Berti, MD Telephone: 3488964831, +39 Email: berti@ftgm.it 2) Eliano Navarese, MD Telephone: 3342594725, +39 Email: elianonavarese@gmail.com
Notes	Authors contacted Aug 2024; study is still enrolling participants until Sept 2024, data not yet available.

PARFEM

Study name	Ultrasound-guided In-plane Puncture of the Femoral Artery (PARFEM)
Methods	RCT
Participants	Patients undergoing transfemoral cardiac catheterization.
Interventions	Vessel puncture guided by ultrasound and fluoroscopy vs. vessel puncture guided by palpation and fluoroscopy only.
Outcomes	Primary endpoint of the study is the rate of primary successful puncture of the femoral common artery above the bifurcation and below the inguinal ligament ("first success rate").
Starting date	
Contact information	
Notes	Study completed as of 30 June 2024. Authors contacted Aug 2024; study is complete but manuscript is being prepared and is not yet published.

CV: cardiovascular
RCT: randomized controlled trial
TAVR: transcatheter aortic valve replacement

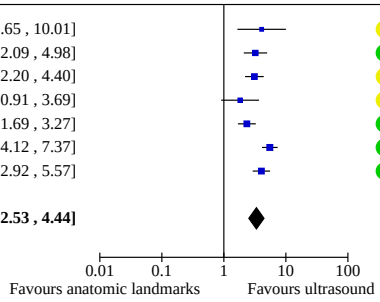
DATA AND ANALYSES

Comparison 1. First-pass success

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 First-pass success	7	4274	Odds Ratio (M-H, Random, 95% CI)	3.35 [2.53, 4.44]
1.2 Sensitivity analysis: first-pass success excluding rescue U/S	3	1755	Odds Ratio (M-H, Random, 95% CI)	3.15 [2.21, 4.49]

Analysis 1.1. Comparison 1: First-pass success, Outcome 1: First-pass success

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Odds Ratio M-H, Random, 95% CI
Gedikoglu 2013	101	108	78	100	6.8%	4.07 [1.65 , 10.01]
Jolly 2022	277	311	222	310	14.6%	3.23 [2.09 , 4.98]
Katircibasi 2018	396	449	346	490	16.7%	3.11 [2.20 , 4.40]
Marquis-Gravel 2018	40	64	31	65	9.3%	1.83 [0.91 , 3.69]
Nguyen 2020	255	331	210	357	17.1%	2.35 [1.69 , 3.27]
Seto 2010	415	502	232	500	18.1%	5.51 [4.12 , 7.37]
Stone 2020	257	347	141	340	17.3%	4.03 [2.92 , 5.57]
Total (Wald[a])		**2112**		**2162**	**100.0%**	**3.35 [2.53 , 4.44]**
Total events:	1741		1260			

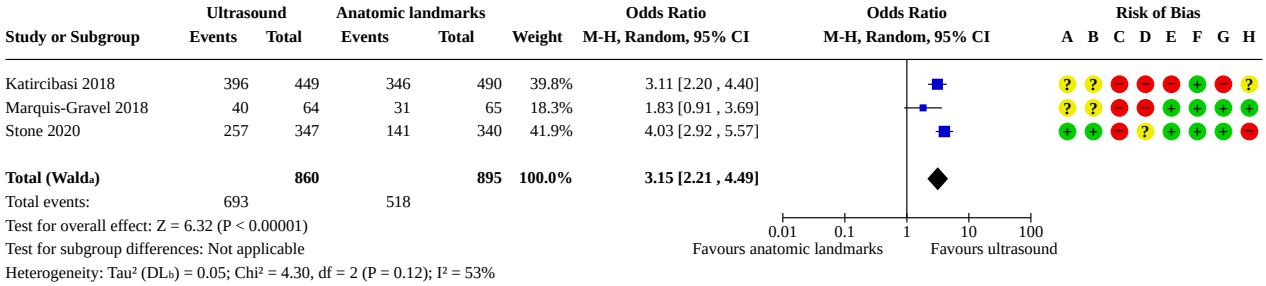


Test for overall effect: Z = 8.43 (P < 0.00001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.09; Chi² = 19.62, df = 6 (P = 0.003); I² = 69%

Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 1.2. Comparison 1: First-pass success, Outcome 2: Sensitivity analysis: first-pass success excluding rescue U/S



Footnotes

[a]CI calculated by Wald-type method.

[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend

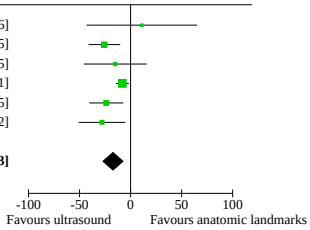
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Comparison 2. Time to successful CFA access

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Time to successful CFA access	6	3570	Mean Difference (IV, Random, 95% CI)	-17.24 [-27.04, -7.43]
2.2 Time to successful CFA access: sensitivity analysis from local anesthetic	3	1517	Mean Difference (IV, Random, 95% CI)	-23.65 [-34.28, -13.01]
2.3 Time to successful CFA access: sensitivity analysis from fluoroscopy table movement or US probe application	2	1941	Mean Difference (IV, Random, 95% CI)	-14.85 [-33.45, 3.75]
2.4 Time to successful CFA access: sensitivity analysis from skin penetration	1	112	Mean Difference (IV, Random, 95% CI)	11.00 [-43.06, 65.06]
2.5 Time to successful CFA access: sensitivity analysis excluding rescue U/S	2	1051	Mean Difference (IV, Random, 95% CI)	-7.75 [-14.00, -1.49]

Analysis 2.1. Comparison 2: Time to successful CFA access, Outcome 1: Time to successful CFA access

Study or Subgroup	Ultrasound Mean [seconds]	Ultrasound SD [seconds]	Ultrasound Total	Anatomic landmarks Mean [seconds]	Anatomic landmarks SD [seconds]	Anatomic landmarks Total	Weight	Mean Difference IV, Random, 95% CI [seconds]
Dudeck 2004[a]	208	124	56	197	165	56	3.1%	11.00 [-43.06 , 65.06]
Gedikoglu 2013[b]	68.6	45.1	108	94.3	66.4	100	20.5%	-25.70 [-41.25 , -10.15]
Jolly 2022[b]	113.8	185.49	311	128.86	205.63	310	8.2%	-15.06 [-45.87 , 15.75]
Katircibasi 2018[c]	33.3	28.2	449	41.3	64.7	490	36.2%	-8.00 [-14.29 , -1.71]
Nguyen 2020[b]	73.12	86.72	331	96.92	131.7	357	19.2%	-23.80 [-40.35 , -7.25]
Seto 2010[c]	185	175	502	213	194	500	12.8%	-28.00 [-50.88 , -5.12]
Total (Wald[d])			**1757**			**1813**	**100.0%**	**-17.24 [-27.04 , -7.43]**

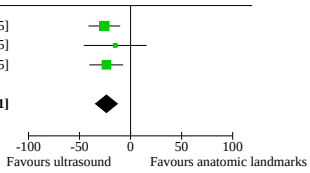


Test for overall effect: Z = 3.45 (P = 0.0006)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[e]) = 58.90; Chi² = 9.03, df = 5 (P = 0.11); I² = 45%

Footnotes
[a]Defined as time that the access needle first penetrated the skin to time of sheath insertion
[b]Defined as time of administration of local anaesthetic to time of sheath insertion
[c]Defined as time of first movement of table for fluoroscopy or application of U/S probe to time of sheath insertion
[d]CI calculated by Wald-type method.
[e]Tau² calculated by DerSimonian and Laird method.

Analysis 2.2. Comparison 2: Time to successful CFA access, Outcome 2: Time to successful CFA access: sensitivity analysis from local anesthetic

Study or Subgroup	Ultrasound Mean [seconds]	Ultrasound SD [seconds]	Ultrasound Total	Anatomic landmarks Mean [seconds]	Anatomic landmarks SD [seconds]	Anatomic landmarks Total	Weight	Mean Difference IV, Random, 95% CI [seconds]
Gedikoglu 2013[a]	68.6	45.1	108	94.3	66.4	100	46.8%	-25.70 [-41.25 , -10.15]
Jolly 2022	113.8	185.49	311	128.86	205.63	310	11.9%	-15.06 [-45.87 , 15.75]
Nguyen 2020[a]	73.12	86.72	331	96.92	131.7	357	41.3%	-23.80 [-40.35 , -7.25]
Total (Wald[b])			**750**			**767**	**100.0%**	**-23.65 [-34.28 , -13.01]**

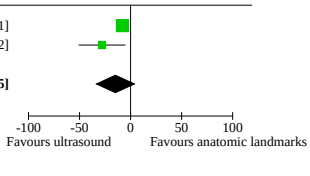


Test for overall effect: Z = 4.36 (P < 0.0001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[c]) = 0.00; Chi² = 0.37, df = 2 (P = 0.83); I² = 0%

Footnotes
[a]Defined as time of administration of local anesthetic to time of sheath insertion
[b]CI calculated by Wald-type method.
[c]Tau² calculated by DerSimonian and Laird method.

Analysis 2.3. Comparison 2: Time to successful CFA access, Outcome 3: Time to successful CFA access: sensitivity analysis from fluoroscopy table movement or US probe application

Study or Subgroup	Ultrasound Mean [seconds]	Ultrasound SD [seconds]	Ultrasound Total	Anatomic landmarks Mean [seconds]	Anatomic landmarks SD [seconds]	Anatomic landmarks Total	Weight	Mean Difference IV, Random, 95% CI [seconds]
Katircibasi 2018[a]	33.3	28.2	449	41.3	64.7	490	65.7%	-8.00 [-14.29 , -1.71]
Seto 2010[a]	185	175	502	213	194	500	34.3%	-28.00 [-50.88 , -5.12]
Total (Wald[b])			**951**			**990**	**100.0%**	**-14.85 [-33.45 , 3.75]**

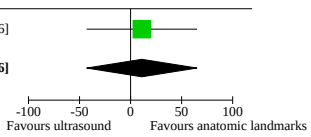


Test for overall effect: Z = 1.56 (P = 0.12)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[c]) = 126.70; Chi² = 2.73, df = 1 (P = 0.10); I² = 63%

Footnotes
[a]Defined as time of the first movement of the table for fluoroscopy or application of the ultrasound probe to time of successful sheath insertion
[b]CI calculated by Wald-type method.
[c]Tau² calculated by DerSimonian and Laird method.

Analysis 2.4. Comparison 2: Time to successful CFA access, Outcome 4: Time to successful CFA access: sensitivity analysis from skin penetration

Study or Subgroup	Ultrasound Mean [seconds]	Ultrasound SD [seconds]	Ultrasound Total	Anatomic landmarks Mean [seconds]	Anatomic landmarks SD [seconds]	Anatomic landmarks Total	Weight	Mean Difference IV, Random, 95% CI [seconds]
Dudeck 2004[a]	208	124	56	197	165	56	100.0%	11.00 [-43.06 , 65.06]
Total			**56**			**56**	**100.0%**	**11.00 [-43.06 , 65.06]**

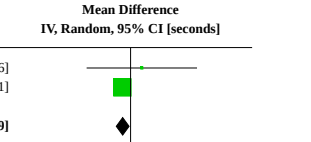


Test for overall effect: Z = 0.40 (P = 0.69)
Test for subgroup differences: Not applicable
Heterogeneity: Not applicable

Footnotes
[a]Defined as time that the access needle first penetrated the skin to time of sheath insertion

Analysis 2.5. Comparison 2: Time to successful CFA access, Outcome 5: Time to successful CFA access: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Mean [seconds]	Ultrasound SD [seconds]	Ultrasound Total	Anatomic landmarks Mean [seconds]	Anatomic landmarks SD [seconds]	Anatomic landmarks Total	Weight	Mean Difference IV, Random, 95% CI [seconds]
Dudeck 2004	208	124	56	197	165	56	1.3%	11.00 [-43.06 , 65.06]
Katircibasi 2018	33.3	28.2	449	41.3	64.7	490	98.7%	-8.00 [-14.29 , -1.71]
Total (Wald[a])			**505**			**546**	**100.0%**	**-7.75 [-14.00 , -1.49]**



Test for overall effect: Z = 2.43 (P = 0.02)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 0.47, df = 1 (P = 0.49); I² = 0%

Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

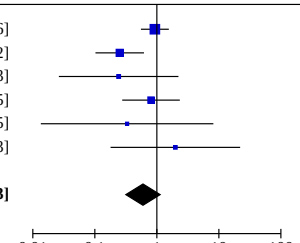
Comparison 3. Major or minor bleeding

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Major bleeding	6	4016	Odds Ratio (M-H, Random, 95% CI)	0.60 [0.32, 1.13]
3.2 Minor bleeding	3	420	Odds Ratio (M-H, Random, 95% CI)	0.81 [0.14, 4.55]
3.3 Minor bleeding: sensitivity analysis excluding rescue U/S	2	212	Odds Ratio (M-H, Random, 95% CI)	1.26 [0.38, 4.17]
3.4 Major bleeding: sensitivity analysis excluding rescue U/S	3	1703	Odds Ratio (M-H, Random, 95% CI)	0.35 [0.12, 1.00]

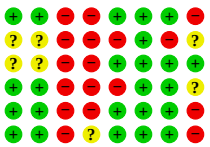
Analysis 3.1. Comparison 3: Major or minor bleeding, Outcome 1: Major bleeding

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Odds Ratio M-H, Random, 95% CI
Jolly 2022[a]	31	311	33	310	37.5%	0.93 [0.55 , 1.56]
Katircibasi 2018[b]	6	449	25	490	25.0%	0.25 [0.10 , 0.62]
Marquis-Gravel 2018[c]	1	64	4	65	7.1%	0.24 [0.03 , 2.23]
Nguyen 2020[d]	6	331	8	357	20.7%	0.81 [0.28 , 2.35]
Seto 2010[e]	0	503	1	501	3.7%	0.33 [0.01 , 8.15]
Stone 2020[f]	2	319	1	316	6.1%	1.99 [0.18 , 22.03]
Total (Wald[g])		**1977**		**2039**	**100.0%**	**0.60 [0.32 , 1.13]**
Total events:	46		72			

Odds Ratio M-H, Random, 95% CI



Risk of Bias: A B C D E F G H



Test for overall effect: Z = 1.58 (P = 0.11)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[h]) = 0.21; Chi² = 8.04, df = 5 (P = 0.15); I² = 38%

Footnotes

[a]Defined as BARC type 2, 3, or 5 bleeding, evaluated immediately after the procedure is finished and prior to discharge from the Heart Investigation Unit, as well as via telephone follow up 3-
[b]Defined as hematoma => 5 cm up to 7 days after discharge
[c]Defined as Bleeding Academic Research Consortium (BARC) types 2, 3, or 5 bleeding at day 1 post-procedure
[d]Defined as ACUITY (Acute catheterization and Urgeny Intervention Triage stategY) major bleeding (hematoma >5 cm, reduction in hemoglobin >40 g/L without bleeding source, reduction in
[e]Defined as access bleeding requiring transfusion up to 30 days post-procedure
[f]Defined as hematoma requiring transfusion up to 24 h post-procedure (note: hematoma extending length of hospital stay and unexplained hemoglobin drop also reported individually)
[g]CI calculated by Wald-type method.
[h]Tau² calculated by DerSimonian and Laird method.

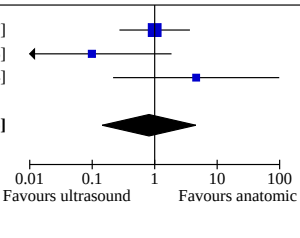
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

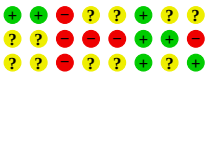
Analysis 3.2. Comparison 3: Major or minor bleeding, Outcome 2: Minor bleeding

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Odds Ratio M-H, Random, 95% CI
Dudeck 2004[a]	5	56	5	56	53.7%	1.00 [0.27 , 3.67]
Gedikoglu 2013[b]	0	108	4	100	23.9%	0.10 [0.01 , 1.86]
Slattery 2015[c]	2	53	0	47	22.5%	4.61 [0.22 , 98.54]
Total (Wald[d])		**217**		**203**	**100.0%**	**0.81 [0.14 , 4.55]**
Total events:	7		9			

Odds Ratio M-H, Random, 95% CI



Risk of Bias: A B C D E F G H



Test for overall effect: Z = 0.24 (P = 0.81)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[e]) = 1.00; Chi² = 3.36, df = 2 (P = 0.19); I² = 41%

Footnotes

[a]Defined as minor loco-regional hematomas not requiring additional treatment
[b]Defined as minor local hematoma not requiring additional treatment
[c]Defined as minor groin hematoma
[d]CI calculated by Wald-type method.
[e]Tau² calculated by DerSimonian and Laird method.

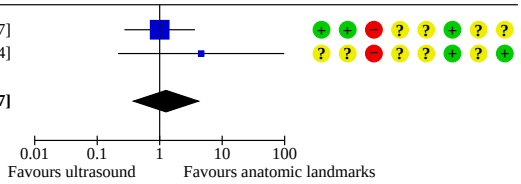
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 3.3. Comparison 3: Major or minor bleeding, Outcome 3: Minor bleeding: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Odds Ratio M-H, Random, 95% CI
Dudeck 2004	5	56	5	56	84.7%	1.00 [0.27 , 3.67]
Slattery 2015	2	53	0	47	15.3%	4.61 [0.22 , 98.54]
Total (Wald[a])		**109**		**103**	**100.0%**	**1.26 [0.38 , 4.17]**
Total events:	7		5			

Test for overall effect: Z = 0.38 (P = 0.70)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 0.83, df = 1 (P = 0.36); I² = 0%



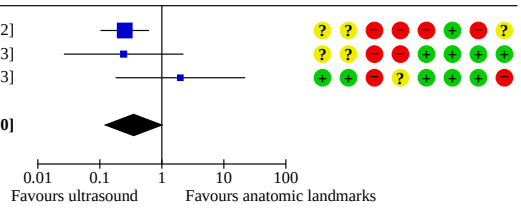
Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

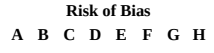
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 3.4. Comparison 3: Major or minor bleeding, Outcome 4: Major bleeding: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Odds Ratio M-H, Random, 95% CI
Katircibasi 2018[a]	6	449	25	490	64.8%	0.25 [0.10 , 0.62]
Marquis-Gravel 2018[b]	1	64	4	65	18.8%	0.24 [0.03 , 2.23]
Stone 2020[c]	2	319	1	316	16.4%	1.99 [0.18 , 22.03]
Total (Wald[d])		**832**		**871**	**100.0%**	**0.35 [0.12 , 1.00]**
Total events:	9		30			

Test for overall effect: Z = 1.96 (P = 0.05)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[e]) = 0.23; Chi² = 2.54, df = 2 (P = 0.28); I² = 21%





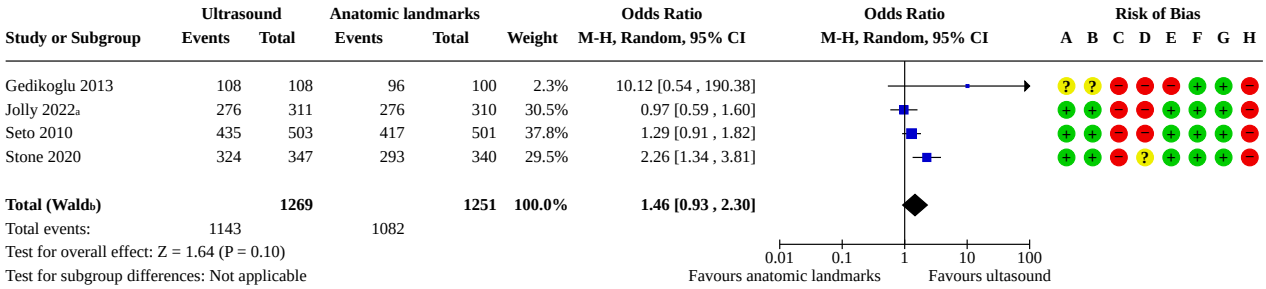
Footnotes
[a]Defined as hematoma => 5 cm up to 7 days after discharge
[b]Defined as Bleeding Academic Research Consortium (BARC) types 2, 3, or 5 bleeding at day 1 post-procedure
[c]Defined as hematoma requiring transfusion up to 24 h post-procedure (note: hematoma extending length of hospital stay and unexplained hemoglobin drop also reported individually but not ir
[d]CI calculated by Wald-type method.
[e]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Comparison 4. Overall cannulation success

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Overall cannulation success	4	2520	Odds Ratio (M-H, Random, 95% CI)	1.46 [0.93, 2.30]

Analysis 4.1. Comparison 4: Overall cannulation success, Outcome 1: Overall cannulation success



Footnotes

[a]Defined as angiographic core laboratory review showing sheath at or above femoral bifurcation and below inferior epigastric artery

[b]CI calculated by Wald-type method.

[c]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

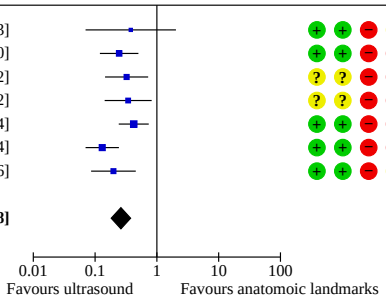
Comparison 5. Venipuncture

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Venipuncture	7	4178	Odds Ratio (M-H, Random, 95% CI)	0.26 [0.18, 0.38]
5.2 Venipuncture: sensitivity analysis excluding rescue U/S	4	1867	Odds Ratio (M-H, Random, 95% CI)	0.29 [0.18, 0.45]

Analysis 5.1. Comparison 5: Venipuncture, Outcome 1: Venipuncture

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic Landmarks Events	Anatomic Landmarks Total	Weight	Odds Ratio M-H, Random, 95% CI
Dudeck 2004	2	56	5	56	4.2%	0.38 [0.07 , 2.03]
Jolly 2022	10	311	37	310	16.1%	0.25 [0.12 , 0.50]
Katircibasi 2018	8	449	26	490	13.8%	0.32 [0.15 , 0.72]
Marquis-Gravel 2018	9	64	21	65	12.2%	0.34 [0.14 , 0.82]
Nguyen 2020	19	331	45	357	21.4%	0.42 [0.24 , 0.74]
Seto 2010	12	502	79	500	19.1%	0.13 [0.07 , 0.24]
Stone 2020	7	347	32	340	13.2%	0.20 [0.09 , 0.46]
Total (Wald[a])		**2060**		**2118**	**100.0%**	**0.26 [0.18 , 0.38]**
Total events:	67		245			

Odds Ratio M-H, Random, 95% CI



Risk of Bias

Test for overall effect: Z = 7.28 (P < 0.00001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.08; Chi² = 9.01, df = 6 (P = 0.17); I² = 33%

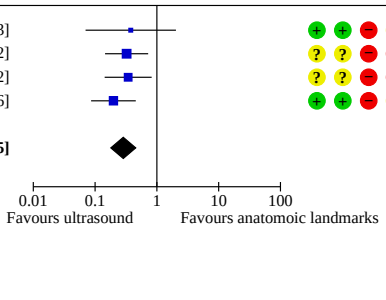
Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

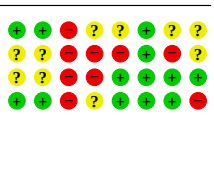
Analysis 5.2. Comparison 5: Venipuncture, Outcome 2: Venipuncture: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic Landmarks Events	Anatomic Landmarks Total	Weight	Odds Ratio M-H, Random, 95% CI
Dudeck 2004	2	56	5	56	7.6%	0.38 [0.07 , 2.03]
Katircibasi 2018	8	449	26	490	33.3%	0.32 [0.15 , 0.72]
Marquis-Gravel 2018	9	64	21	65	28.0%	0.34 [0.14 , 0.82]
Stone 2020	7	347	32	340	31.0%	0.20 [0.09 , 0.46]
Total (Wald[a])		**916**		**951**	**100.0%**	**0.29 [0.18 , 0.45]**
Total events:	26		84			

Odds Ratio M-H, Random, 95% CI



Risk of Bias



Test for overall effect: Z = 5.29 (P < 0.00001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 1.11, df = 3 (P = 0.77); I² = 0%

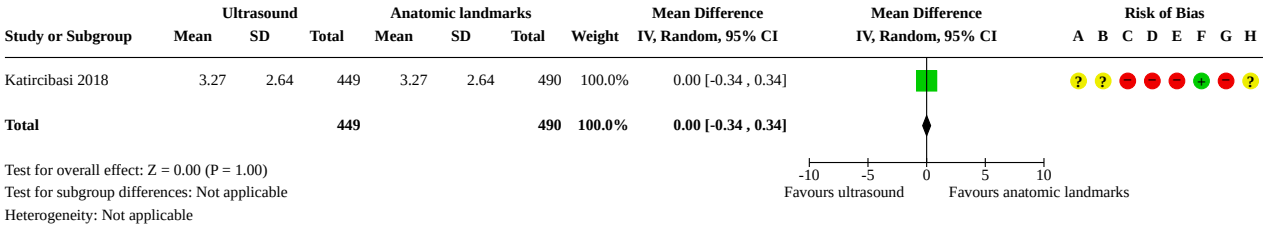
Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Comparison 6. Pain scores

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 VAS pain score	1	939	Mean Difference (IV, Random, 95% CI)	0.00 [-0.34, 0.34]
6.2 Additional analgesia	1	208	Odds Ratio (M-H, Random, 95% CI)	0.79 [0.38, 1.65]

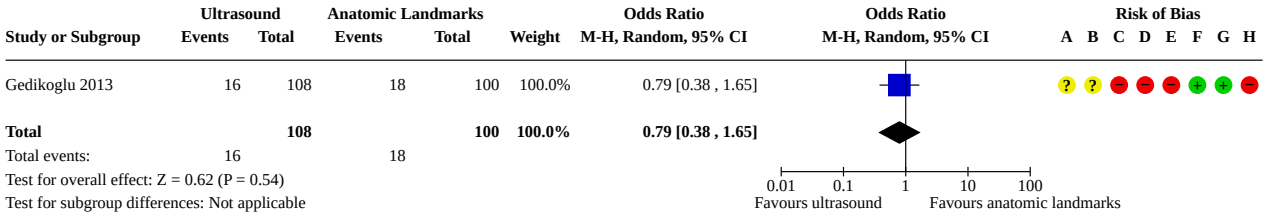
Analysis 6.1. Comparison 6: Pain scores, Outcome 1: VAS pain score



Test for overall effect: Z = 0.00 (P = 1.00)
Test for subgroup differences: Not applicable
Heterogeneity: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 6.2. Comparison 6: Pain scores, Outcome 2: Additional analgesia



Test for overall effect: Z = 0.62 (P = 0.54)
Test for subgroup differences: Not applicable
Heterogeneity: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

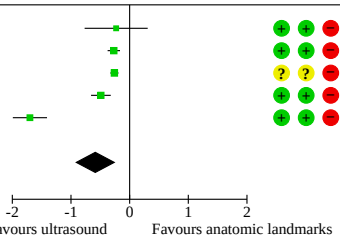
Comparison 7. Number of attempts

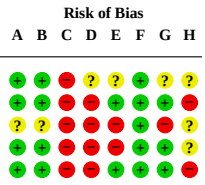
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Number of attempts	5	3362	Mean Difference (IV, Random, 95% CI)	-0.59 [-0.91, -0.26]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.2 Number of attempts: sensitivity analysis excluding rescue U/S	2	1051	Mean Difference (IV, Random, 95% CI)	-0.26 [-0.33, -0.19]

Analysis 7.1. Comparison 7: Number of attempts, Outcome 1: Number of attempts

Study or Subgroup	Ultrasound Mean	SD	Total	Anatomic landmarks Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Dudeck 2004	1.93	1.26	56	2.16	1.62	56	14.0%	-0.23 [-0.77 , 0.31]
Jolly 2022	1.16	0.51	311	1.43	0.8	310	22.4%	-0.27 [-0.38 , -0.16]
Katircibasi 2018	1.06	0.26	449	1.32	0.74	490	22.7%	-0.26 [-0.33 , -0.19]
Nguyen 2020	1.35	0.83	331	1.84	1.37	357	21.6%	-0.49 [-0.66 , -0.32]
Seto 2010	1.3	0.9	502	3	3.2	500	19.3%	-1.70 [-1.99 , -1.41]
Total (Wald[a])			**1649**			**1713**	**100.0%**	**-0.59 [-0.91 , -0.26]**





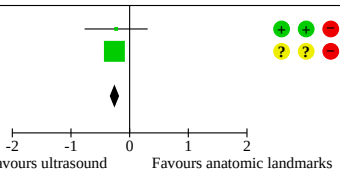
Test for overall effect: Z = 3.55 (P = 0.0004)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.12; Chi² = 93.65, df = 4 (P < 0.00001); I² = 96%

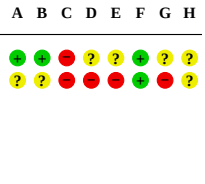
Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 7.2. Comparison 7: Number of attempts, Outcome 2: Number of attempts: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Mean	SD	Total	Anatomic landmarks Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Dudeck 2004	1.93	1.26	56	2.16	1.62	56	1.7%	-0.23 [-0.77 , 0.31]
Katircibasi 2018	1.06	0.26	449	1.32	0.74	490	98.3%	-0.26 [-0.33 , -0.19]
Total (Wald[a])			**505**			**546**	**100.0%**	**-0.26 [-0.33 , -0.19]**





Test for overall effect: Z = 7.35 (P < 0.00001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 0.01, df = 1 (P = 0.91); I² = 0%

Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

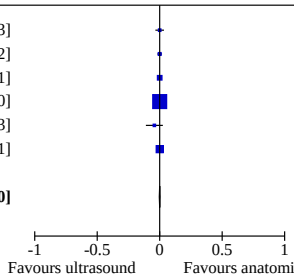
Comparison 8. Retroperitoneal hematoma

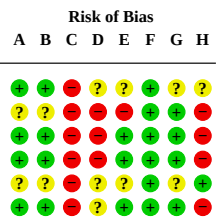
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Retroperitoneal hematoma	6	2680	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.00, 0.00]
8.2 Retroperitoneal hematoma: sensitivity analysis excluding rescue U/S	3	847	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.03, 0.02]

Analysis 8.1. Comparison 8: Retroperitoneal hematoma, Outcome 1: Retroperitoneal hematoma

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	0.8%	0.00 [-0.03 , 0.03]
Gedikoglu 2013	0	108	0	100	2.6%	0.00 [-0.02 , 0.02]
Jolly 2022	1	311	1	310	11.6%	-0.00 [-0.01 , 0.01]
Seto 2010	0	503	0	501	60.5%	0.00 [-0.00 , 0.00]
Slattery 2015	0	53	2	47	0.2%	-0.04 [-0.11 , 0.03]
Stone 2020[a]	0	319	0	316	24.3%	0.00 [-0.01 , 0.01]
Total (Wald[b])		**1350**		**1330**	**100.0%**	**-0.00 [-0.00 , 0.00]**
Total events:	1		3			

Test for overall effect: Z = 0.06 (P = 0.96)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[c]) = 0.00; Chi² = 2.45, df = 5 (P = 0.78); I² = 0%





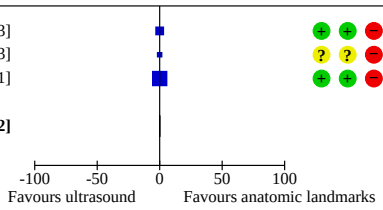
Footnotes
[a]Only short-term data used (<24 hours post op)
[b]CI calculated by Wald-type method.
[c]Tau² calculated by DerSimonian and Laird method.

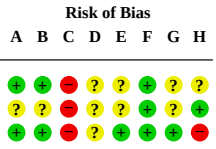
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 8.2. Comparison 8: Retroperitoneal hematoma, Outcome 2: Retroperitoneal hematoma: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	27.6%	0.00 [-0.03 , 0.03]
Slattery 2015	0	53	2	47	10.3%	-0.04 [-0.11 , 0.03]
Stone 2020[a]	0	319	0	316	62.1%	0.00 [-0.01 , 0.01]
Total (Wald[b])		**428**		**419**	**100.0%**	**-0.00 [-0.03 , 0.02]**
Total events:	0		2			

Test for overall effect: Z = 0.36 (P = 0.72)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[c]) = 0.00; Chi² = 3.81, df = 2 (P = 0.15); I² = 47%





Footnotes
[a]Only short-term data used (<24 hours post op)
[b]CI calculated by Wald-type method.
[c]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

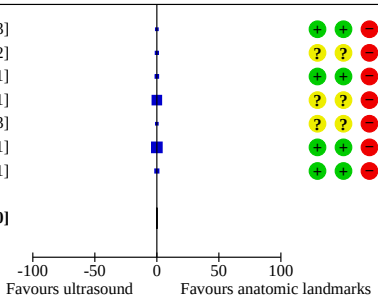
Comparison 9. Pseudoaneurysm formation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Pseudoaneurysm formation	7	3648	Risk Difference (M-H, Random, 95% CI)	0.00 [-0.00, 0.00]
9.2 Pseudoaneurysm formation: sensitivity analysis excluding rescue U/S	4	1815	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.01, 0.01]

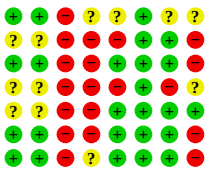
Analysis 9.1. Comparison 9: Pseudoaneurysm formation, Outcome 1: Pseudoaneurysm formation

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	1.1%	0.00 [-0.03 , 0.03]
Gedikoglu 2013	0	108	0	100	3.7%	0.00 [-0.02 , 0.02]
Jolly 2022	2	311	4	310	5.5%	-0.01 [-0.02 , 0.01]
Katircibasi 2018	1	449	1	490	37.2%	0.00 [-0.01 , 0.01]
Marquis-Gravel 2018	0	64	1	65	0.7%	-0.02 [-0.06 , 0.03]
Seto 2010	1	503	0	501	43.1%	0.00 [-0.00 , 0.01]
Stone 2020	2	319	2	316	8.6%	-0.00 [-0.01 , 0.01]
Total (Wald[a])		**1810**		**1838**	**100.0%**	**0.00 [-0.00 , 0.00]**
Total events:	6		8			

Risk Difference M-H, Random, 95% CI



Risk of Bias



Test for overall effect: Z = 0.24 (P = 0.81)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 2.32, df = 6 (P = 0.89); I² = 0%

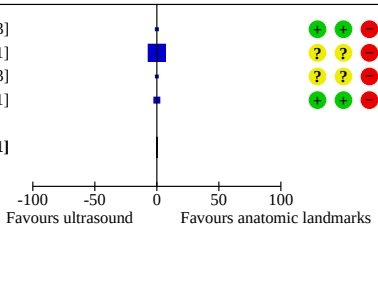
Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

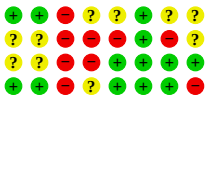
Analysis 9.2. Comparison 9: Pseudoaneurysm formation, Outcome 2: Pseudoaneurysm formation: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	2.3%	0.00 [-0.03 , 0.03]
Katircibasi 2018	1	449	1	490	78.1%	0.00 [-0.01 , 0.01]
Marquis-Gravel 2018	0	64	1	65	1.6%	-0.02 [-0.06 , 0.03]
Stone 2020	2	319	2	316	18.0%	-0.00 [-0.01 , 0.01]
Total (Wald[a])		**888**		**927**	**100.0%**	**-0.00 [-0.01 , 0.01]**
Total events:	3		4			

Risk Difference M-H, Random, 95% CI



Risk of Bias



Test for overall effect: Z = 0.04 (P = 0.97)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 0.64, df = 3 (P = 0.89); I² = 0%

Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

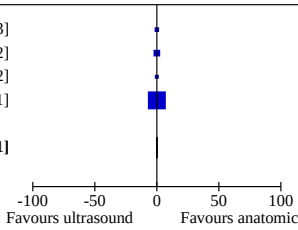
Comparison 10. Dissection

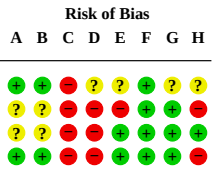
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.1 Dissection	4	1453	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.01, 0.01]
10.2 Dissection: sensitivity analysis excluding rescue U/S	2	241	Risk Difference (M-H, Random, 95% CI)	-0.01 [-0.04, 0.02]

Analysis 10.1. Comparison 10: Dissection, Outcome 1: Dissection

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	4.9%	0.00 [-0.03 , 0.03]
Gedikoglu 2013	0	108	0	100	16.6%	0.00 [-0.02 , 0.02]
Marquis-Gravel 2018	0	64	2	65	2.2%	-0.03 [-0.08 , 0.02]
Seto 2010	2	503	3	501	76.2%	-0.00 [-0.01 , 0.01]
Total (Wald[a])		**731**		**722**	**100.0%**	**-0.00 [-0.01 , 0.01]**
Total events:	2		5			

Test for overall effect: Z = 0.57 (P = 0.57)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 1.53, df = 3 (P = 0.68); I² = 0%





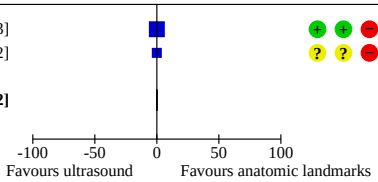
Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 10.2. Comparison 10: Dissection, Outcome 2: Dissection: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	65.7%	0.00 [-0.03 , 0.03]
Marquis-Gravel 2018	0	64	2	65	34.3%	-0.03 [-0.08 , 0.02]
Total (Wald[a])		**120**		**121**	**100.0%**	**-0.01 [-0.04 , 0.02]**
Total events:	0		2			

Test for overall effect: Z = 0.65 (P = 0.51)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 1.19, df = 1 (P = 0.27); I² = 16%



Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

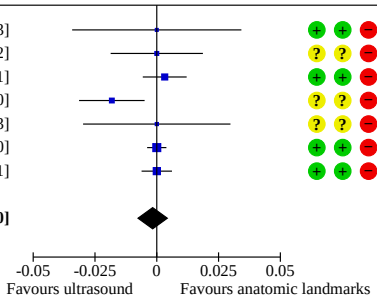
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

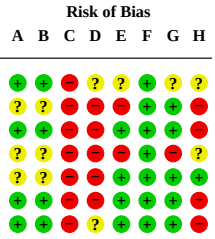
Comparison 11. AV fistula

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1 AV fistula	7	3648	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.01, 0.00]
11.2 AV fistula: sensitivity analysis excluding rescue U/S	4	1815	Risk Difference (M-H, Random, 95% CI)	-0.01 [-0.02, 0.01]

Analysis 11.1. Comparison 11: AV fistula, Outcome 1: AV fistula

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	2.8%	0.00 [-0.03 , 0.03]
Gedikoglu 2013	0	108	0	100	7.8%	0.00 [-0.02 , 0.02]
Jolly 2022	1	311	0	310	19.2%	0.00 [-0.01 , 0.01]
Katircibasi 2018	1	449	10	490	12.5%	-0.02 [-0.03 , -0.00]
Marquis-Gravel 2018	0	64	0	65	3.5%	0.00 [-0.03 , 0.03]
Seto 2010	0	503	0	501	29.4%	0.00 [-0.00 , 0.00]
Stone 2020	0	319	0	316	24.7%	0.00 [-0.01 , 0.01]
Total (Wald[a])		**1810**		**1838**	**100.0%**	**-0.00 [-0.01 , 0.00]**
Total events:	2		10			





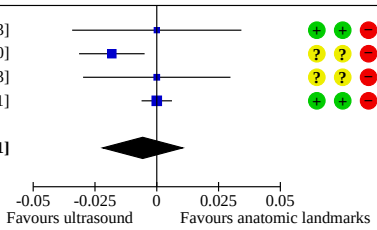
Test for overall effect: Z = 0.55 (P = 0.58)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 13.31, df = 6 (P = 0.04); I² = 55%

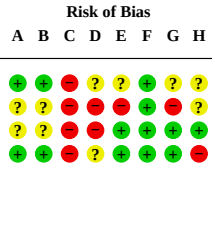
Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 11.2. Comparison 11: AV fistula, Outcome 2: AV fistula: sensitivity analysis excluding rescue U/S

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Dudeck 2004	0	56	0	56	14.3%	0.00 [-0.03 , 0.03]
Katircibasi 2018	1	449	10	490	31.3%	-0.02 [-0.03 , -0.00]
Marquis-Gravel 2018	0	64	0	65	16.9%	0.00 [-0.03 , 0.03]
Stone 2020	0	319	0	316	37.5%	0.00 [-0.01 , 0.01]
Total (Wald[a])		**888**		**927**	**100.0%**	**-0.01 [-0.02 , 0.01]**
Total events:	1		10			





Test for overall effect: Z = 0.69 (P = 0.49)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 11.33, df = 3 (P = 0.01); I² = 74%

Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

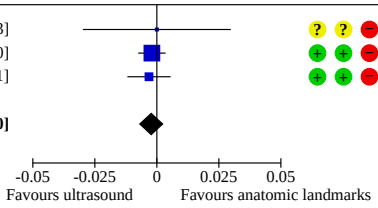
Comparison 12. Occlusion

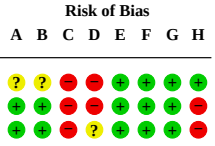
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
12.1 Target vessel occlusion	3	1768	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.01, 0.00]
12.2 Target vessel occlusion: sensitivity analysis excluding rescue U/S	2	764	Risk Difference (M-H, Random, 95% CI)	-0.00 [-0.01, 0.01]

Analysis 12.1. Comparison 12: Occlusion, Outcome 1: Target vessel occlusion

Study or Subgroup	Ultrasound Events	Ultrasound Total	Anatomic landmarks Events	Anatomic landmarks Total	Weight	Risk Difference M-H, Random, 95% CI
Marquis-Gravel 2018	0	64	0	65	2.4%	0.00 [-0.03 , 0.03]
Seto 2010	0	503	1	501	69.7%	-0.00 [-0.01 , 0.00]
Stone 2020	0	319	1	316	27.9%	-0.00 [-0.01 , 0.01]
Total (Wald[a])		**886**		**882**	**100.0%**	**-0.00 [-0.01 , 0.00]**
Total events:	0		2			

Test for overall effect: Z = 0.97 (P = 0.33)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² (DL[b]) = 0.00; Chi² = 0.07, df = 2 (P = 0.96); I² = 0%

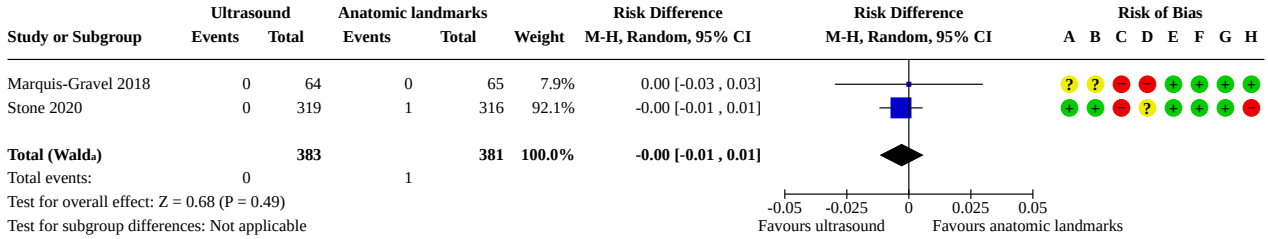




Footnotes
[a]CI calculated by Wald-type method.
[b]Tau² calculated by DerSimonian and Laird method.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 12.2. Comparison 12: Occlusion, Outcome 2: Target vessel occlusion: sensitivity analysis excluding rescue U/S



Footnotes

[a]CI calculated by Wald-type method.

[b]Tau² calculated by DerSimonian and Laird method.

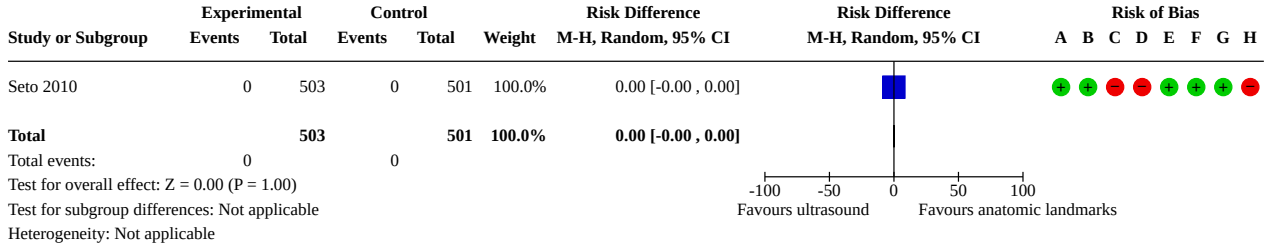
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Comparison 13. Infection

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
13.1 Infection	1	1004	Risk Difference (M-H, Random, 95% CI)	0.00 [-0.00, 0.00]

Analysis 13.1. Comparison 13: Infection, Outcome 1: Infection



Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding (performance bias and detection bias)
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

APPENDICES

Appendix 1. Sources searched and search strategies

Source	Search strategy	Hits retrieved
1. VASCULAR REGISTER IN CRSW (Date of most recent search: 25 July 2022)	#1 Femoral AND INREGISTER #2 ultrason* AND INREGISTER #3 puncture* OR Catheter* AND INREGISTER #4 #1 AND #2 AND #3	Sep 2021: 48 July 2022: 5
2. CENTRAL via CRSO (Date of most recent search: 25 July 2022)	#1 MESH DESCRIPTOR Femoral Artery EXPLODE ALL TREES 1014 #2 femoral*:TI,AB,KY 13621 #3 CFA:TI,AB,KY 373 #4 #1 OR #2 OR #3 13947 #5 MESH DESCRIPTOR Ultrasonography, Interventional EXPLODE ALL TREES 2165 #6 ultrasonograph*:TI,AB,KY 16748 #7 Ultrasound*:TI,AB,KY 30744 #8 #5 OR #6 OR #7 40261 #9 #4 AND #8 1624 #10 MESH DESCRIPTOR Punctures EXPLODE ALL TREES 2943 #11 MESH DESCRIPTOR Catheterization, Peripheral EXPLODE ALL TREES 1005 #12 puncture*:TI,AB,KY 6644 #13 Cathlon:TI,AB,KY 3 #14 Venflon:TI,AB,KY 19 #15 cannula*:TI,AB,KY 5649 #16 (((Catheter* or line or access) adj3 peripher*)):TI,AB,KY 1182 #17 #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 14586 #18 #9 AND #17 189	Sep 2021: 189 July 2022:
3. Clinicaltrials.gov (Date of most recent search: 25 July 2022)	puncture OR Catheter | femoral	Sep 2021: 235 July 2022: 86
4. ICTRP Search Portal (Date of most recent search: 25 July 2022)	femoral AND (puncture* OR Catheter*)	Sep 2021: 23 July 2022: 10
5. Medline (Ovid MEDLINE Epub Ahead of Print, In-Process	1 exp Femoral Artery/ 2 femoral*.ti,ab.	Sep 2021: 221 July 2022: 37

(Continued)

& Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE) 1946 to present (Date of most recent search: 25 July 2022)	3 CFA.ti,ab. 4 or/1-3 5 exp Ultrasonography, Interventional/ 6 ultrasonograph*.ti,ab. 7 Ultrasound*.ti,ab. 8 or/5-7 9 4 and 8 10 exp Punctures/ 11 exp Catheterization, Peripheral/ 12 puncture*.ti,ab. 13 Cathlon.ti,ab. 14 Venflon.ti,ab. 15 cannula*.ti,ab. 16 ((Catheter* or line or access) adj3 peripher*).ti,ab. 17 or/10-16 18 9 and 17 19 randomized controlled trial.pt. 20 controlled clinical trial.pt. 21 randomized.ab. 22 placebo.ab. 23 drug therapy.fs. 24 randomly.ab. 25 trial.ab. 26 groups.ab. 27 or/19-26 28 exp animals/ not humans.sh. 29 27 not 28 30 18 and 29	
6. EMBASE via Ovid (Date of most recent search: 25 July 2022)	1 exp femoral artery/ 2 femoral*.ti,ab. 3 CFA.ti,ab. 4 or/1-3 5 exp interventional ultrasonography/ 6 ultrasonograph*.ti,ab.	Sep 2021: 502 July 2022: 83

(Continued)

	7 Ultrasound*.ti,ab. 8 or/5-7 9 4 and 8 10 exp puncture/ 11 exp catheterization/ 12 puncture*.ti,ab. 13 Cathlon.ti,ab. 14 Venflon.ti,ab. 15 cannula*.ti,ab. 16 ((Catheter* or line or access) adj3 peripher*).ti,ab. 17 or/10-16 18 9 and 17 19 randomized controlled trial/ 20 controlled clinical trial/ 21 random$.ti,ab. 22 randomization/ 23 intermethod comparison/ 24 placebo.ti,ab. 25 (compare or compared or comparison).ti. 26 ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. 27 (open adj label).ti,ab. 28 ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. 29 double blind procedure/ 30 parallel group$1.ti,ab. 31 (crossover or cross over).ti,ab. 32 ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab. 33 (assigned or allocated).ti,ab. 34 (controlled adj7 (study or design or trial)).ti,ab. 35 (volunteer or volunteers).ti,ab. 36 trial.ti. 37 or/19-36 38 18 and 37	
7. CINAHL via Ebsco	S34 S18 AND S33	Sep 2021: 57

(Continued)

(Date of most recent search: 25 July 2022)	S33 S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 S32 MH "Random Assignment" S31 MH "Triple-Blind Studies" S30 MH "Double-Blind Studies" S29 MH "Single-Blind Studies" S28 MH "Crossover Design" S27 MH "Factorial Design" S26 MH "Placebos" S25 MH "Clinical Trials" S24 TX "multi-centre study" OR "multi-center study" OR "multicentre study" OR "multicenter study" OR "multi-site study" S23 TX crossover OR "cross-over" S22 AB placebo* S21 TX random* S20 TX trial* S19 TX "latin square" S18 S9 AND S17 S17 S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 S16 TX ((Catheter* or line or access) n3 peripher*) S15 TX cannula* S14 TX Venflon S13 TX Cathlon S12 TX puncture* S11 (MH "Catheterization, Peripheral+") S10 (MH "Punctures+") S9 S4 AND S8 S8 S5 OR S6 OR S7 S7 TX Ultrasound* S6 TX ultrasonograph* S5 (MH "Ultrasonography+") S4 S1 OR S2 OR S3 S3 TX CFA S2 TX femoral* S1 (MH "Femoral Artery")	July 2022: 7

(Continued)

TOTAL before de-duplication	Sep 2021: 1275 July 2022: 266
TOTAL after de-duplication and import to Covidence	Sep 2021: 965 July 2022: 166
TOTAL after combining, de-duplication and import to Covidence	July 2022: 1131

Appendix 2. Updated search report January 2024

Cochrane Central Study Identification Service

Search Report

Ultrasound-guided versus anatomic landmark-guided percutaneous femoral artery access

Search time frame
[25/07/22 to 25/01/24]

Searches by: Charlene Bridges

Search results sent: 25/01/24

Date limits have been applied to try to only retrieve results added to the databases since the last search.

Vascular register:

INREGISTER AND 25/07/2022_TO_25/01/2024:CRSCREATED

CENTRAL:

Date added to CENTRAL trials database 25/07/22-25/01/24

MEDLINE:

31. limit 30 to ed=20220725-20240125

Embase:

39. limit 38 to dd=20220725-20240125
40. limit 38 to rd=20220725-20240125
41. 39 or 40

CINAHL:

Publication date 01/07/2022-31/01/2024

ClinicalTrials.gov:

First posted from 07/25/2022 to 01/25/2024

WHO ICTRP:

Date of registration is between 25/07/2022-25/01/2024

Source	Version/Platform/url	Date of Search	Records retrieved
1. Cochrane Vascular Specialised Register	CRSWeb	25/01/2024	5

(Continued)

2. CENTRAL Issue 1 of 12, January 2024	Cochrane Library	25/01/2024	56
3. MEDLINE ALL 1946-January 24, 2024	Ovid	25/01/2024	21
4. Embase 1996 to 2024, week 3	Ovid	25/01/2024	87
5. CINAHL	EBSCOhost	25/01/2024	4
6. ClinicalTrials.gov	https://clinicaltrials.gov	25/01/2024	25
7. WHO ICTRP	https://trialsearch.who.int/Default.aspx	25/01/2024	12
TOTAL			**210**
TOTAL after software de-duplication			**128**

Search Strategies:

Source	Search strategy
1. Vascular register	#1 Femoral AND INREGISTER #2 ultrason* AND INREGISTER #3 puncture* OR Catheter* AND INREGISTER #4 #1 AND #2 AND #3
2. CENTRAL	#1 MeSH descriptor: [Femoral Artery] explode all trees #2 femoral*:TI,AB,KW #3 CFA:TI,AB,KW #4 #1 OR #2 OR #3

(Continued)

	#5 MeSH descriptor: [Ultrasonography, Interventional] explode all trees #6 ultrasonograph*:TI,AB,KW #7 Ultrasound*:TI,AB,KW #8 #5 OR #6 OR #7 #9 #4 AND #8 #10 MeSH descriptor: [Punctures] explode all trees #11 MeSH descriptor: [Catheterization, Peripheral] explode all trees #12 puncture*:TI,AB,KW #13 Cathlon:TI,AB,KW #14 Venflon:TI,AB,KW #15 cannula*:TI,AB,KW #16 (((Catheter* or line or access) NEAR/3 peripher*)):TI,AB,KW #17 #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 #18 #9 AND #17
3. MEDLINE	**1** exp Femoral Artery/ **2** femoral*.ti,ab. **3** CFA.ti,ab. **4** or/1-3 **5** exp Ultrasonography, Interventional/ **6** ultrasonograph*.ti,ab. **7** Ultrasound*.ti,ab. **8** or/5-7 **9** 4 and 8 **10** exp Punctures/ **11** exp Catheterization, Peripheral/ **12** puncture*.ti,ab. **13** Cathlon.ti,ab. **14** Venflon.ti,ab. **15** cannula*.ti,ab. **16** ((Catheter* or line or access) adj3 peripher*).ti,ab. **17** or/10-16 **18** 9 and 17 **19** randomized controlled trial.pt. **20** controlled clinical trial.pt. **21** randomized.ab. **22** placebo.ab. **23** drug therapy.fs. **24** randomly.ab. **25** trial.ab. **26** groups.ab. **27** or/19-26 **28** exp animals/ not humans.sh. **29** 27 not 28 **30** 18 and 29
4. Embase	**1** exp femoral artery/ **2** femoral*.ti,ab. **3** CFA.ti,ab. **4** or/1-3

(Continued)

	5 exp interventional ultrasonography/ **6** ultrasonograph*.ti,ab. **7** Ultrasound*.ti,ab. **8** or/5-7 **9** 4 and 8 **10** exp puncture/ **11** exp catheterization/ **12** puncture*.ti,ab. **13** Cathlon.ti,ab. **14** Venflon.ti,ab. **15** cannula*.ti,ab. **16** ((Catheter* or line or access) adj3 peripher*).ti,ab. **17** or/10-16 **18** 9 and 17 **19** randomized controlled trial/ **20** controlled clinical trial/ **21** random$.ti,ab. **22** randomization/ **23** intermethod comparison/ **24** placebo.ti,ab. **25** (compare or compared or comparison).ti. **26** ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. **27** (open adj label).ti,ab. **28** ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. **29** double blind procedure/ **30** parallel group$1.ti,ab. **31** (crossover or cross over).ti,ab. **32** ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab. **33** (assigned or allocated).ti,ab. **34** (controlled adj7 (study or design or trial)).ti,ab. **35** (volunteer or volunteers).ti,ab. **36** trial.ti. **37** or/19-36 **38** 18 and 37
5. CINAHL	S34 S18 AND S33 S33 S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 S32 S32 MH "Random Assignment" S31 MH "Triple-Blind Studies" S30 MH "Double-Blind Studies" S29 MH "Single-Blind Studies" S28 MH "Crossover Design" S27 MH "Factorial Design" S26 MH "Placebos" S25 MH "Clinical Trials" S24 TX "multi-centre study" OR "multi-center study" OR "multicentre study" OR "multicenter study" OR "multi-site study" S23 TX crossover OR "cross-over"

(Continued)

	S22 AB placebo*
	S21 TX random*
	S20 TX trial*
	S19 TX "latin square"
	S18 S9 AND S17
	S17 S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16
	S16 TX ((Catheter* or line or access) n3 peripher*)
	S15 TX cannula*
	S14 TX Venflon
	S13 TX Cathlon
	S12 TX puncture*
	S11 (MH "Catheterization, Peripheral+")
	S10 (MH "Punctures+")
	S9 S4 AND S8
	S8 S5 OR S6 OR S7
	S7 TX Ultrasound*
	S6 TX ultrasonograph*
	S5 (MH "Ultrasonography+")
	S4 S1 OR S2 OR S3
	S3 TX CFA
	S2 TX femoral*
	S1 (MH "Femoral Artery")
5. ClinialTrials.gov	puncture OR Catheter | femoral
6. WHO ICTRP	femoral AND (puncture* OR Catheter*)

HISTORY

Protocol first published: Issue 7, 2021

CONTRIBUTIONS OF AUTHORS

SS: trial report acquisition, trial selection, data extraction, data analysis, data interpretation, review drafting, future review updates

GM: data analysis, data interpretation, review drafting

CS: trial report acquisition, trial selection, data extraction

JS: trial report acquisition, trial selection, data extraction, data analysis, data interpretation, review drafting

SM: data interpretation, review drafting

AT: data interpretation, review drafting

KP: data interpretation, review drafting

EK: data interpretation, review drafting

AK: trial report acquisition, trial selection, data extraction, data analysis, data interpretation, review drafting, future review updates, guarantor of the review

DECLARATIONS OF INTEREST

SS: none.

GM: none.

CS: none.

JS's institution has received educational grants from WL Gore and Becton Dickenson.
SM: declares that they received payment for consultancy work (Cook, Abbott, Philips, Penumbra, Asahi, CordisX, Shockwave).

AT: declares that money was paid to him for serving as a clinical consultant, member of the speaker's bureau, member of a research clinical events committee, and as an independent medical monitor for clinical research trials for Abiomed, and as a clinical consultant and member of the speaker's bureau for Getinge, Shockwave, and Zoll.

KP: declares that their institution received payment from Terumo Inc. for consultancy, speaker's fees, and grants, which are not relevant to this review.

EK: declares that they received payment for the development of educational presentations and lectures (Abbott Vascular, Edwards Lifesciences) and for consultancy (Abbott Vascular, Boston Scientific, Edwards Lifesciences, Medtronic, and Shockwave), which were not directly relevant to the subject matter of the review.

AK: none.

The authors do not believe that these declarations could potentially bias this review, as none of the companies listed are involved in ultrasound imaging technologies or have an interest in promoting a particular technique for common femoral artery access.

SOURCES OF SUPPORT

Internal sources

- New Source of support, Other

External sources

- Chief Scientist Office, Scottish Government Health Directorates, The Scottish Government, UK

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We implemented the following changes to the protocol in the final review.

- Time to CFA access was measured in seconds rather than minutes, since all studies that reported this outcome did so in seconds.
- For the secondary outcome of major complications, major bleeding was redefined as "hematoma requiring transfusion, hematoma extending length of stay, hematoma ≥ 5 cm, unexplained hemoglobin drop, or major/severe bleeding as defined by each trial," and retroperitoneal hematoma/hemorrhage was reported separately, in contrast with the original protocol, which defined major bleeding as "retroperitoneal hemorrhage or groin hematoma requiring transfusion or reintervention." We implemented this change to allow for more precision in the reporting of retroperitoneal hemorrhage as well as more appropriate pooling of severe bleeding outcomes across trials that defined this outcome heterogeneously.
- As outlined in Measures of treatment effect, studies reporting medians rather than means were excluded from the pooled analyses, since they were derived from non-normally distributed data and thus did not lend themselves well to conversion to mean difference or standardized mean difference.

NOTES

Parts of the methods section of this protocol are based on a standard template established by Cochrane Vascular.

INDEX TERMS

Medical Subject Headings (MeSH)

*Anatomic Landmarks; Catheterization, Peripheral [adverse effects] [methods]; Endovascular Procedures [methods]; *Femoral Artery [anatomy & histology] [diagnostic imaging]; *Randomized Controlled Trials as Topic; *Ultrasonography, Interventional [methods]

MeSH check words

Humans