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SYSTEMATIC REVIEW

Ultrasound Guided Versus Conventional Closure Device Deployment Following Transfemoral Endovascular Procedures: A Systematic Review and Meta-analysis

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WHAT THIS PAPER ADDS

This meta-analysis demonstrates that ultrasound guided vessel closure is associated with fewer access site complications, including major access and bleeding complications, compared with conventional closure techniques. These results suggest that ultrasound guided closure could have the potential to improve patient outcomes in transfemoral arterial procedures.

Objective: Femoral access site complications influence short term survival and outcomes in patients undergoing endovascular procedures. While ultrasound guided puncture is a reliable method to reduce such complications, ultrasound guidance is rarely used for closure device deployment.

Data Sources: Web of Science, PubMed, and the Cochrane Library.

Review Methods: A systematic literature search was conducted to assess the safety and efficacy of ultrasound guided vascular closure device deployment compared with vascular closure device deployment without ultrasound guidance, referred to as conventional closure. All studies reporting on ultrasound guided closure in transfemoral arterial interventions were eligible, and those directly comparing ultrasound guided with conventional closure were included in the meta-analysis.

Results: Overall, 2 738 patients receiving ultrasound guided closure were included: 1 025 for introducer sheaths measuring 12 F or larger and 1 713 for introducer sheaths smaller than 12 F. The incidence of access complications was 5.7% (range 0.8 — 21.6%) for large sheath procedures and 2.6% (range 0.9 — 4.7%) for small sheath procedures. The meta-analysis, which included 2 339 patients who received ultrasound guided closure and 1 175 who underwent conventional closure, showed that ultrasound guided closure was associated with reduced access site complications compared with conventional closure (odds ratio [OR] 0.49, 95% confidence interval [CI] 0.37 — 0.65; $p < .001$). This was consistently seen both for small sheath (OR 0.45, 95% CI 0.28 — 0.75; $p = .002$) and large sheath procedures (OR 0.50, 95% CI 0.37 — 0.71; $p < .001$), but with a low certainty of evidence in the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) analysis.

Conclusion: Ultrasound guided vessel closure of the femoral artery appeared to be associated with a lower rate of overall access site complications compared with conventional closure techniques. Therefore, ultrasound guided closure might offer the potential to increase procedural and patient safety in percutaneous arterial access.

Keywords: Percutaneous, PTA, TAVI, Transfemoral, Ultrasound guidance
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INTRODUCTION

Transfemoral arterial access is commonly used in various cardiovascular procedures. However, access site complications remain a challenge that significantly affects patient outcomes.[1,2] Safe arterial access is achieved when the vessel is punctured as intended and, after completion of the procedure, adequate haemostasis is accomplished, while the punctured vessel remains patent. Preventing access site complications is crucial as these are associated with prolonged hospitalisation, increased morbidity, and a higher 30 day mortality risk across several interventional procedures.[3–5]

Despite the well known importance of preventing access site complications and the many efforts to reduce their occurrence over the past several years, their incidence remains significant in transfemoral transcatheter aortic valve implantation (TAVI) and endovascular aortic aneurysm repair (EVAR).[6] For peripheral vascular interventions, a slight decrease in access site complications has been observed over the last decade.[5,7]

Previous meta-analyses have shown that ultrasound guided puncture of the femoral artery in different types of endovascular procedures reduces the risk of access site complications while increasing the correct puncture on first attempt success rate.[8–11] Considering that the success of arterial access depends not only on correct puncture but also on effective closure, efforts have been made to find an optimal method for post-procedural haemostasis. The availability of closure devices has made percutaneous access possible for large introducer sheath interventions and has reduced time to haemostasis after small introducer sheath access. Although the use of a closure device is already widespread and a variety of devices are available, access site complications remain a significant concern.[12]

Reasons for closure device failure are anterior vessel wall calcification or accidental lateral puncture, highlighting the importance of finding a suitable puncture site, for which ultrasound is an ideal tool. Ultrasound guidance during closure device deployment allows for visualisation of the device and especially intraluminal conditions to ensure precise deployment of the closure device at the intended site.[13]

The aim of this study was to summarise the contemporary literature on ultrasound guided closure and to assess its results after transfemoral arterial endovascular procedures, and to evaluate the effect of ultrasound guided closure compared with conventional closure device deployment regarding the incidence of access site complications.

METHODS

Protocol

A systematic review and meta-analysis were conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline and the Meta-analysis of Observational Studies in Epidemiology reporting standards.[14] The protocol was registered with the PROSPERO database (CRD42024535111).

Literature search and study selection

A systematic literature search following a pre-specified search strategy was conducted using Web of Science, PubMed, and the Cochrane Library. The applied search terms were “femoral”, “transfemoral”, “femoral access”, “femoral artery”, “arterial access”, “femoral arteries”, “ultrasound guided deployment”, “ultrasound-guided deployment”, “echo guided closure”, “echo-guided closure”, “ultrasound navigated closure”, “ultrasound-navigated closure”, “ultrasound guidance closure”, “ultrasound assisted closure”, and “ultrasound guided closure” (Supplementary Material). Additionally, a citation search of the identified articles was performed. No restrictions regarding publication date or language were applied. The last search was performed on 15 April 2024. The authors of the included studies were not contacted or known to the investigators. After removal of duplicates and screening of titles and abstracts using the eligibility criteria, an assessment of the full text of the remaining articles was conducted and articles were included if they met the eligibility criteria.

Two independent investigators (I.K. and M.M.M.) conducted the search and the following selection of included studies. In case of discrepancies, an independent investigator (B.M.E.M.) was consulted.

Eligibility criteria

All studies reporting outcomes of ultrasound guided closure device deployment in more than 20 patients after a transfemoral arterial endovascular procedure were considered eligible for the qualitative analysis. For the meta-analysis, studies comparing ultrasound guided closure device deployment with conventional closure device deployment were included. There were no restrictions on the follow up duration, and studies had to report access site complications as an outcome measure. Duplicate publications, case reports, and conference abstracts were excluded.

Data extraction

The data were extracted by two investigators (I.K. and M.M.M.) using a standardised pre-specified data collection form. The study reports and supplementary appendices were reviewed. The pre-specified data elements were categorised as follows: study design, inclusion period, patient data, vascular closure system, procedure characteristics, access complications, and the follow up performed.

Study endpoints

The pre-specified outcomes were access site complications, defined and included as reported in the original studies. These were then divided into subgroups of major or minor access site complications, and into bleeding and ischaemic complications. The severity of bleeding complications was not recorded. The definition of each endpoint was extracted as reported in the original studies (Supplementary Table S1). The individual types of access site complications were also defined and included as reported in the

original studies. Closure device failure was defined and included as reported in the original studies. The procedures were categorised as small (< 12 F) and large (≥ 12 F) sheath procedures for the analysis of all endpoints.

Assessment of bias

The risk of bias at study level was assessed using the National Heart, Lung, and Blood Institute study assessment tool for observational cohort and cross sectional studies.[15] The tool provides a standardised checklist to evaluate the internal validity and methodological quality. The assessment addresses attributes including bias, confounding, and reporting quality, categorising studies as good when the results are considered to be robust, fair when a bias is likely, and poor when the risk of relevant bias is high (Supplementary Table S2). The assessment was again conducted by two independent investigators (I.K. and M.W.), and in cases of discrepancy a third independent investigator (B.M.E.M.) was consulted.

Statistical methods

Random effects meta-analyses were performed using the Mantel—Haenszel method for dichotomous event data owing to the quality of the evidence. Given the likelihood of heterogeneity, pooled odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for each analysis at a two sided significance level of $p < .050$ using RevMan 5.3 (John Wiley & Sons, Hoboken, NJ, USA). A Grading of Recommendations Assessment, Development, and Evaluation (GRADE) analysis was conducted to clarify certainty and confidence in the meta-analysed outcomes.

The extent of heterogeneity was approximated using I^2 test, considering 0 — 40% as non-important, 30 — 60% as moderate, 50 — 90% as substantial, and 75 — 100% as considerable heterogeneity.[16] A pre-specified analysis of publication bias by funnel plot was not performed owing to the small number of studies included. Studies with poor methodological quality were excluded as part of a sensitivity analysis, removing one study at a time.

RESULTS

Study selection

A total of 762 articles were identified with the described search strategy (Fig. 1). Following the exclusion of duplicates, the titles and abstracts of the remaining 572 articles were screened for the above specified criteria. Of these, 553 articles were excluded, leaving 19 references for full text eligibility assessment. No duplicate publications were identified. Two additional full text articles were included for eligibility assessment after a citation search. Ultimately, 11 studies were included in the qualitative analysis for the systematic review, of which six fulfilled the criteria to be included in the meta-analysis.

Systematic review

Eleven studies were included in the qualitative analysis,[17—27] of which nine were published between 2021 and 2024.[18,19,21—27] All included studies were single centre studies, six being from Asia[17—19,22,25] and five from Europe.[20,21,23,24,26] There were no randomised controlled trials. Two studies were conducted prospectively.[17,18] Five studies were case series with at least 21 patients.[18,19,22,24,26] One retrospective study conducted a propensity score matched analysis.[21]

Patients and procedure characteristics

Overall, 2 738 patients who received ultrasound guided closure were included. The patient characteristics of each study are summarised in Supplementary Table S3. The anticoagulation and antithrombotic medication of patients are also shown in Supplementary Table S4. All included studies stated that the puncture was conducted using ultrasound. Five studies did not specify how the closure device was chosen.[17,19,23,25,27] Four studies used the same closure device in all patients for study purposes.[20,22,24,26] One study stated that the operator chose the closure device.[21] One study included only patients at risk of access site complications in which the use of a specific closure device was investigated.[18] Six studies stated that the operator was experienced with the ultrasound guided closure technique and the closure device,[18,20—23,25] while the remaining five studies did not state how experienced the operator was.[17,19,24,26,27]

A large sheath procedure (≥ 12 F) was conducted in 1 025 patients, of whom 1 004 received ultrasound guided closure for the primary access site after a TAVI procedure and 21 to close the arterial puncture site of an arterial extracorporeal membrane oxygenation cannula.[17,21,23,26] A total of 836 of these patients received a Manta closure device (Teleflex, Wayne, PA, USA),[21,26] and 189 a PerClose device (Abbott Vascular, Santa Clara, CA, USA).[17,23]

Additionally, 1 713 patients underwent a small sheath (< 12 F) procedure.[18—20,22,24,25,27] Of these, 1 318 underwent a percutaneous transluminal peripheral artery angioplasty or stenting procedure. In two studies, overall including 185 patients, the procedure was not specified. In three studies, various types of endovascular procedures (e.g., chemo-embolisation for hepatocellular carcinoma, embolisation for arterial bleeding, and diagnostic angiograms) were performed and pooled.

An ExoSeal (Cordis Corporation, Miami Lakes, FL, USA) was deployed in 141 patients,[18,19] a FemoSeal (Terumo, Tokyo, Japan) in 54 patients,[20] an AngioSeal (Terumo, Tokyo, Japan) in 1 372 patients,[20,24,27] a StarClose (Abbott Vascular, Santa Clara, CA, USA) in 96 patients,[20] and a PerClose device in 145 patients.[20,25] Details are summarised in Table 1. Within the group of small sheath procedures, four studies evaluated retrograde punctures, while three studies evaluated antegrade punctures.[22,24,27] One study only analysed the use of ultrasound guided closure in common femoral arteries at high risk of access site complications due to pre-existing implanted stents, severe calcification, or plaques involving the puncture site.[18]

Outcomes

Access site complications following ultrasound guided closure were included as they were reported in the studies. Three

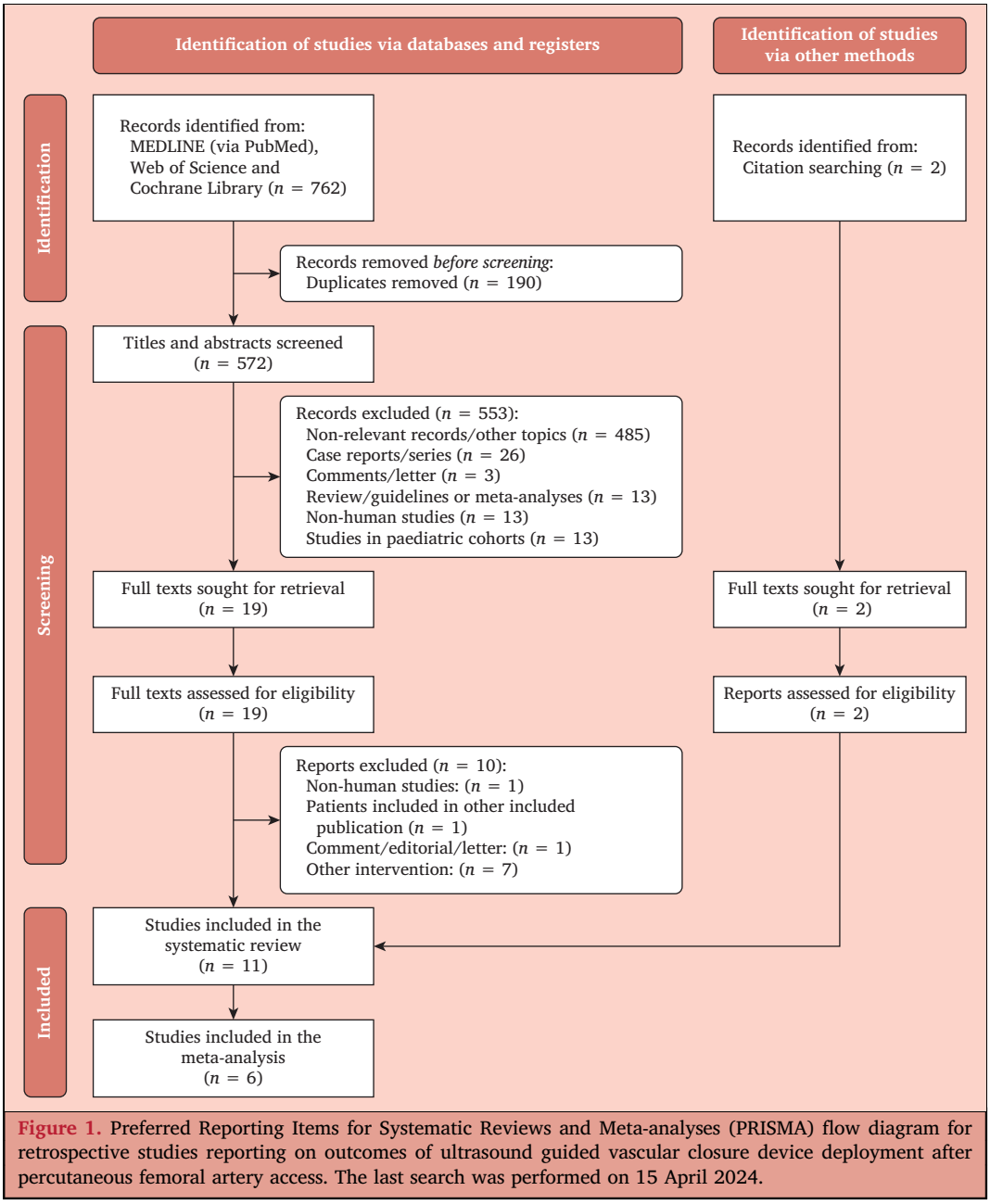

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for retrospective studies reporting on outcomes of ultrasound guided vascular closure device deployment after percutaneous femoral artery access. The last search was performed on 15 April 2024.

studies investigating patients undergoing TAVI, reported their results according to the Valve Academic Research Consortium 2 or 3 criteria.[28,29] All included studies performed a clinical follow up. Ultrasound follow up was performed in three studies, in two studies during hospital stay[19,20] and in one study during follow up after 4 — 6 weeks (Table 1).[22]

The overall incidence of access complications after ultrasound guided closure was 3.1% (95% CI 2.45 — 3.75%). In large sheath procedures it was 5.7% (95% CI 4.28 — 7.11%) compared with 2.6% (95% CI 1.84 — 3.35%) in small sheath procedures. A major access complication occurred in 0.9% (95% CI 0.55 — 1.25%) of patients; after large sheath procedures the incidence was 1.4% (95% CI 0.68 — 2.11%), and in small sheath procedures it was 0.2% (95% CI 0 — 0.41). The overall incidence of minor access site complications was 2.2% (95% CI 1.7 — 2.7%), being 2.1% (95% CI 1.22 — 2.97%) after large sheath procedures and 2.3% (95% CI 1.59 — 3.01%) after small sheath procedures. No ischaemic vascular complications were seen after ultrasound guided closure. Bleeding complications occurred in 2.2% (95% CI 1.65 — 2.74%) of overall cases, in 2.6% (95% CI 1.62 — 3.57%) after large sheath procedures and 1.1% (95% CI 0.61 — 1.59%) after small sheath procedures. Failure of the closure device was reported in 3.0% (95% CI 2.36 — 3.63%); in 3.7% (95% CI 2.54 — 4.86%) of large sheath procedures and in 1.8% (95% CI 1.17 — 2.42%) of small sheath procedures. The types of complications are summarised in Table 2.

Assessment of bias

The results of the assessment of bias are summarised in Supplementary Table S2. Overall, four studies had a good

Table 1. Details of procedures, closure, and follow up in the studies reporting outcomes of ultrasound guided closure (USG) device deployment after percutaneous femoral artery access included in the systematic review.

Study	Patients	USG	CC	Procedure	Sheath size – F	USG closure device	CC closure device	Planned compression bandage USG	Ultrasound follow up
Honda *et al.*, 2018[17]	171	63	58	TF-TAVI	14–18	PerClose (63 SS)	PerClose (11 SS)	0	n.s.
Honda *et al.*, 2021[18]	35	35	n.a.	n.s.	5–7	ExoSeal	n.a.	n.s.	n.s.
Lee *et al.*, 2021[19]	114	106	n.a.	Chemo-embolisation ($n = 62$), embolisation ($n = 38$), angiography ($n = 6$)	5	ExoSeal	n.a.	114	114 (after 48 h)
Lucatelli *et al.*, 2015[20]	300	150	150	n.s.	n.s.	AngioSeal (54) FemoSeal (27) PerClose (22 SS) StarClose (47)	AngioSeal (57) FemoSeal (25) PerClose (19 SS) StarClose (49)	n.s.	150 (after 24 h and 3 mo)
Miyashita *et al*,. 2022[21]	1 242	815	335	TF-TAVI	18	Manta	Manta	n.s.	n.s.
Ha *et al.*, 2021[22]	50	50	n.a.	n.s.	6–8	FemoSeal	n.a.	50	50 (after 4–6 weeks)
Ross *et al.*, 2024[23]	571	126	391	TF-TAVI	14–18	PerClose (DS)	PerClose (DS)	n.s.	n.s.
Ipema *et al.*, 2023[24]	187	187	n.a.	PTA	4–8	AngioSeal	n.a.	1	n.s.
Kwak *et al.*, 2025[25]	104	54	50	Chemo-embolisation ($n = 65$), embolisation ($n = 32$), angioplasty ($n = 4$), angiography ($n = 2$), covered stent insertion ($n = 1$)	n.s.	PerClose (SS)	PerClose (SS)	n.s.	n.s.
Rahman *et al.*, 2023[26]	21	21	n.a.	ECMO	18	Manta	n.a.	0	n.s.
Ong *et al.*, 2023[27]	1 322	1 131	191	PTA	n.s.	AngioSeal	AngioSeal	n.s.	n.s.

Date are presented as numbers unless stated otherwise. USG = ultrasound guided closure; CC = conventional closure; TF-TAVI = transfemoral transcatheter aortic valve implantation; SS = single suture; n.s. = not stated; n.a. = not applicable; DS = double suture; PTA = percutaneous transluminal angioplasty; ECMO = extracorporeal membrane oxygenation.

quality score,[21,23,25,26] four were rated as fair quality,[17,19,24,27] and three were of poor quality.[18,20,22]

Meta-analysis

Studies. The pooled data meta-analysis included six studies, encompassing a total of 3 514 patients.[17,20,21,23,25,27] A total of 2 339 patients received ultrasound guided closure and 1 175 conventional closure. Of these studies, three included large sheath procedures, overall investigating 1 788 patients undergoing TAVI.[17,21,23] Small sheath procedures, such as percutaneous transluminal angioplasty, or pooled small sheath endovascular procedures were evaluated in three studies including 1 726 patients.[20,25,27] Baseline characteristic details and procedural data are summarised in Supplementary Table S3.

Outcomes. The risk of an access site complication was statistically significantly decreased in patients who received ultrasound guided closure after any endovascular procedure (OR 0.49, 95% CI 0.37 – 0.65; $p < .001$) (Fig. 2A) (GRADE certainty of evidence, low). This was seen consistently both in patients who received a small sheath procedure (OR 0.45, 95% CI 0.28 – 0.75; $p = .002$) and in those who underwent

Table 2. Access complications (AC) after ultrasound guided closure (USG) device deployment after percutaneous femoral artery access reported in studies included in the systematic review.

Study	USG	Overall AC	Major AC	Minor AC	IC	BC	HT	AV-F	PSA	DC	DF	LL	SR
Honda *et al.*, 2018[17]	63	13 (21.6)	1 (1.6)	12 (19)	0	1 (1.6)	n.s.	n.s.	n.s.	0	1 (1.6)	n.s.	n.s.
Honda *et al.*, 2021[18]	35	1 (2.9)	0	1 (2.9)	0	0	1 (2.9)	0	0	n.s.	1 (2.9)	n.s.	n.s.
Lee *et al.*, 2021[19]	106	1 (0.9)	0	1 (0.9)	0	0	1 (0.9)	0	0	0	4 (3.6)	n.s.	0
Lucatelli *et al.*, 2015[20]	150	7 (4.7)	1 (0.7)	6 (4)	0	6 (4)	6 (4)	0	1 (0.7)	0	3 (2)	0	0
Miyashita *et al.*, 2022[21]	815	55 (6.8)	28 (3.4)	27 (3.3)	n.s	48 (5.9)	n.s.	n.s.	n.s.	n.s.	32 (3.9)	n.s.	33 (4)
Ha *et al.*, 2021[22]	50	1 (2)	0	1 (2)	0	0	1 (2)	0	0	0	0	0	0
Ross *et al.*, 2024[23]	126	1 (0.8)	0	1 (0.8)	0	1 (0.8)	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	1 (0.8)
Ipema *et al.*, 2023[24]	187	2 (1.0)	1 (0.5)	1 (0.5)	0	1 (0.5)	2 (1)	0	2 (1)	0	1 (0.5)	0	0
Kwak *et al.*, 2025[25]	54	2 (1.9)	0	ns	0	2 (1.9)	0	n.s.	0	n.s.	2 (1.9)	0	0
Rahman *et al.*, 2023[26]	21	3 (14.2)	1 (4.8)	2 (9.5)	0	4 (19)	2 (9.5)	0	0	n.s.	1 (4.8)	0	0
Ong *et al.*, 2023[27]	1 131	41 (3.6)	3 (0.3)	38 (3.3)	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	3 (0.3)

Date are presented as the number of events as reported. Values in parenthesis are the percentages for each complication with regard to the study population. USG = ultrasound guided closure; AC = access complications; IC = ischaemic complications; BC = bleeding complications; HT = haematoma; AV-F = arteriovenous fistula; PSA = pseudoaneurysm; DC = dissection; DF = device failure; LL = limb loss; SR = surgical revision; n.s. = not stated.

a large sheath procedure (OR 0.50, 95% CI 0.37 — 0.71; $p < .001$). The heterogeneity of all three analyses was low ($I^2 = 0\%$).

The risk of major (OR 0.28, 95% CI 0.15 — 0.53, $p < .001$; $I^2 = 11\%$) (Fig. 2B) (GRADE certainty of evidence, low), minor (OR 0.60, 95% CI 0.42 — 0.85, $p = .004$; $I^2 = 0\%$) (Fig. 2C) (GRADE certainty of evidence, low), and bleeding complications (OR 0.50, 95% CI 0.33 — 0.76, $p = .001$; $I^2 = 0\%$) (Fig. 3A) was statistically significantly reduced in patients who received ultrasound guided closure compared with conventional closure. Additionally, ultrasound guided closure resulted in a reduction of closure device failure compared with conventional closure (OR 0.47, 95% CI 0.29 — 0.76, $p = .002$; $I^2 = 0\%$) (Fig. 3B) (GRADE certainty of evidence, low). There was no statistically significant difference regarding ischaemic access complications (OR 0.20, 95% CI 0.04 — 1.15, $p = .070$; $I^2 = 0\%$) (Fig. 3C) (GRADE certainty of evidence, very low). The sensitivity analysis for overall access complications, conducted by excluding all studies one by one, revealed that excluding any of the studies had no relevant effect on the results. After exclusion of the study by Miyashita *et al.*,[21] which had the greatest weight, access complications were still statistically significantly reduced after ultrasound guided closure (OR 0.46, 95% CI 0.30 — 0.69, $p < .001$) (Supplementary Figure S1). Furthermore, a sensitivity analysis was conducted excluding the studies by Lucatelli *et al.*[20] and Honda *et al.*[18] owing to their poor methodological quality (OR 0.49, 95% CI 0.35 — 0.68, $p < .001$; Supplementary Figure S1). Subgroup analyses separating small and large sheath procedures for each outcome are presented in Supplementary Figure S2. The GRADE analysis showed a low to very low certainty of evidence for all outcomes of the meta-analysis (Fig. 4).

DISCUSSION

This review and meta-analysis of observational studies comparing ultrasound guided closure device deployment and conventional closure strategies after transfemoral arterial endovascular procedures demonstrated that ultrasound guided closure has been performed in various large and small sheath endovascular procedures using a variety of closure devices. Ultrasound guided closure was also used in both retrograde and antegrade punctures and in calcified femoral arteries. Ultrasound guided closure device deployment was associated with fewer access site complications compared with conventional closure in both large and small sheath procedures.

The 2024 European Society for Vascular Surgery (ESVS) guidelines on the management of peripheral arterial disease recognised the influence of peri- and post-procedural complications on long term outcomes and identified puncture site complications as one of the main reasons for re-admissions.[30] However, in these latest peripheral arterial disease guidelines, no recommendations on puncture and closure technique were provided.

In 2009, a randomised controlled trial by Abu-Fadel *et al.* compared fluoroscopy guided closure device deployment with conventional closure and found no significant reduction in access site complications.[31] In a further attempt to reduce complications, ultrasound guided closure device deployment was first reported in 2009 with a metal clip based closure device.[32] Since then, ultrasound as an adjunct to closure device deployment has been described for all varieties of closure devices. This systematic review included 11 studies reporting on ultrasound guided deployment in diverse types of interventions and various types of closure devices. In a total of 2 738 patients, an overall low incidence of access site complications was reported. The studies included in the analysis were conducted in Europe and Asia, thereby including patients with a wide range of femoral artery diameters, as the mean diameter tends to be smaller in individuals of Asian descent.[33] A greater proportion of patients from Europe were included in the conventional closure group than in the ultrasound guided group (74% *vs.* 46%). Given that a greater sheath to vessel ratio is

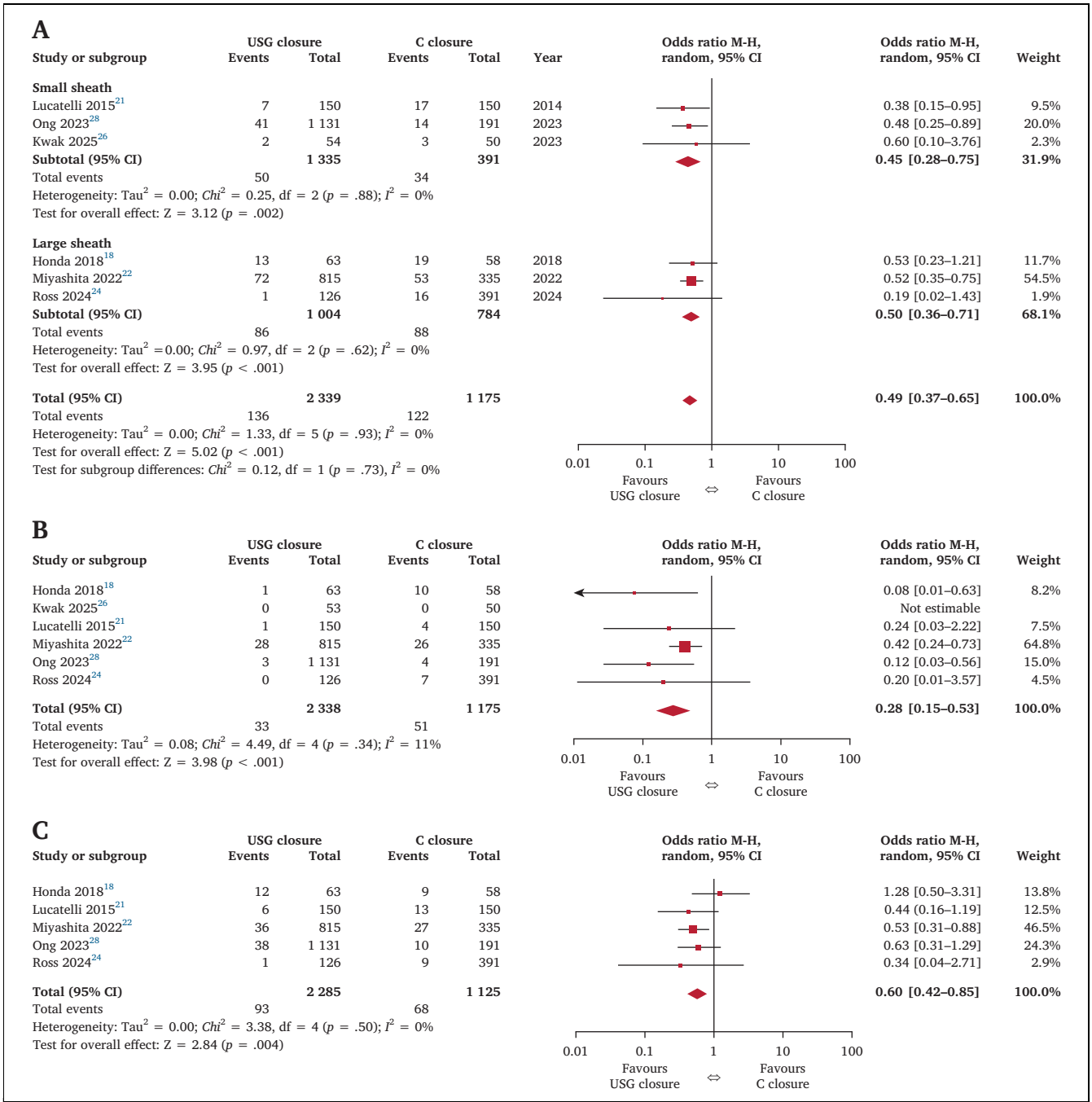

Figure 2. Forest plot of (A) six studies including 3 514 patients for overall access site complications, (B) six studies including 3 514 patients for major access complications, and (C) five studies including 3 410 patients for minor access complications after ultrasound guided (USG) *vs.* conventional (C) vascular closure device deployment after percutaneous femoral artery access. M-H = Mantel–Haenszel; CI = confidence interval.

associated with a higher risk of access complications,[34] the over representation of Asian individuals in the ultrasound guided group may lead to an overestimation of the effect of ultrasound guided closure in a Western population. It is noteworthy that none of the included studies reported ischaemic complications following ultrasound guided closure. Ischaemic access site complications usually result in an immediate re-intervention and may cause prolonged hospitalisation and morbidity. In addition, the results of the ULSOSEAL technique presented by Honda *et al.* raised interest as they successfully performed ultrasound guided closure in common femoral arteries at high risk of an access site complication.[18] It appears that ultrasound guided closure enables safer deployment of closure devices, even in these high risk circumstances. The preconception that ultrasound guided closure prolongs the procedure has been challenged by Kwak and Bum Cho, who demonstrated that time to haemostasis was shorter after ultrasound guided closure.[25]

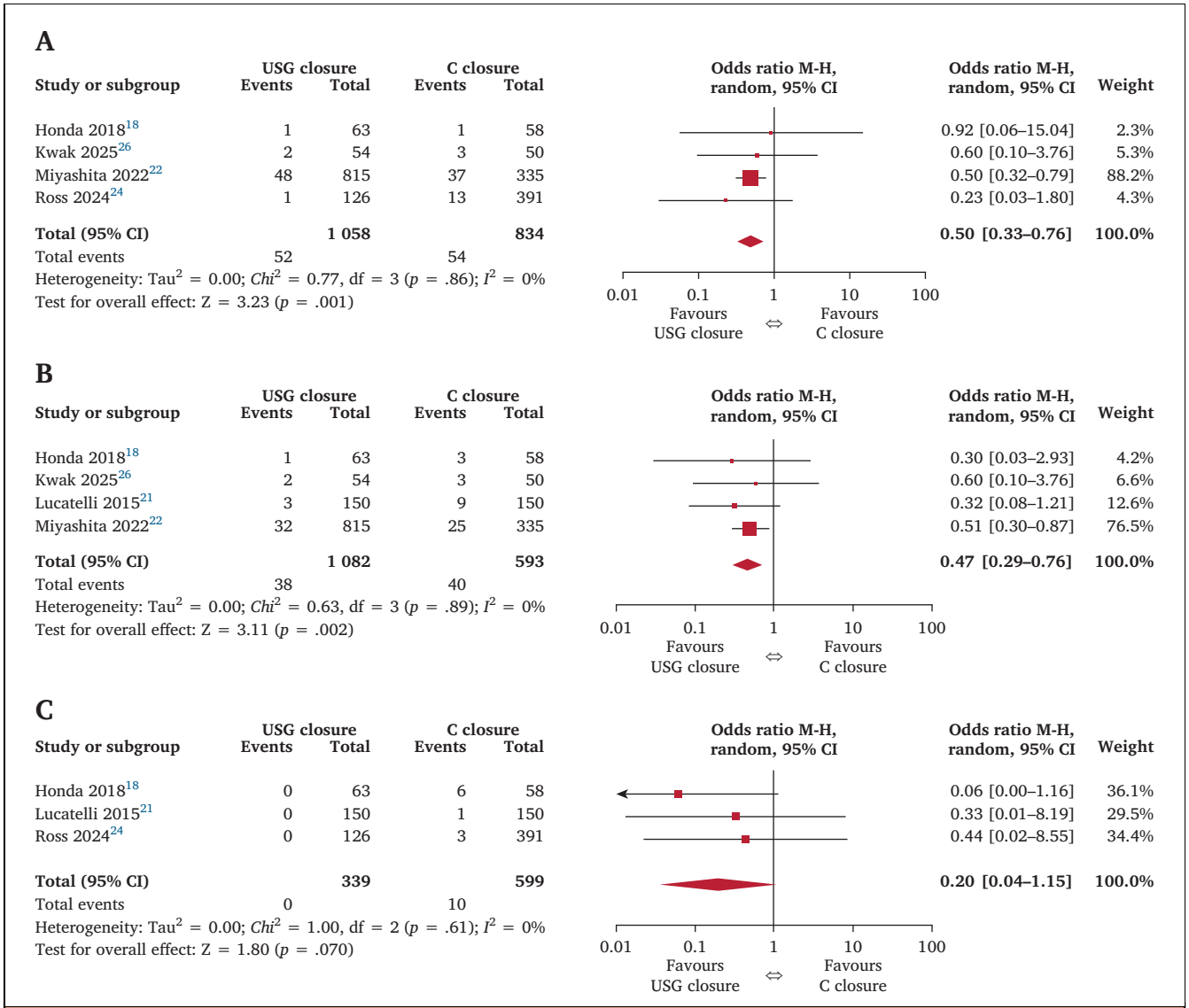

Figure 3. Forest plot of (A) four studies including 1 892 patients for bleeding events, (B) four studies including 1 675 patients for closure device failure, and (C) three studies including 938 patients for ischaemic events after ultrasound guided (USG) *vs.* conventional (C) vascular closure device deployment after percutaneous femoral artery access. M-H = Mantel–Haenszel; CI = confidence interval.

Six comparative studies were included in the meta-analysis, reporting on ultrasound guided deployment of suture based closure devices ($n = 3$), collagen plug based closure devices ($n = 2$), and miscellaneous closure devices ($n = 1$) in both large and small sheath interventions. Overall, a significant reduction in technical device failure was observed in the ultrasound guided cohort compared with the conventional closure cohort. This effect was more pronounced in device deployment during large sheath procedures. All studies in the subgroup of large sheath procedures used the Valve Academic Research Consortium criteria 2 or 3 as a reporting standard, which include similar definitions of major and minor access site complications, ensuring consistent reporting and enhancing the external validity of their reported access complication rates.[28,29]

Before generalising these findings to all large sheath interventions, it is important to note that the large introducer sheath intervention group consisted only of transfemoral TAVI interventions. In particular, EVAR and thoracic endovascular aortic repair were not included. Registry data from comparable time periods show that during TAVI, the prevalence of access complications is higher than in EVAR, which theoretically makes a treatment effect of ultrasound guided deployment of closure devices more easily detectable.[6,35] Additionally, within the large introducer sheath group, the majority of closure devices used were collagen plug based (Manta), while in EVAR predominantly suture based closure devices were being used. Previous non-randomised TAVI studies suggested equal or even superior results of Manta compared with a double suture technique with PerClose.[36] However, recent randomised studies have suggested the opposite, with a higher complication rate in the Manta closure group.[37,38] Therefore, ultrasound guided deployment could be especially valuable in plug based closure after TAVI procedures. Ultrasound guided Manta deployment enables physicians to confirm the position of the anchor and collagen pad against the arterial wall. As the footplate of the

Summary of findings:

Ultrasound guided compared to conventional closure device deployment for transfemoral endovascular procedures

Patient or population: Transfemoral endovascular procedures
Setting: Systematic review and meta-analysis
Intervention: Ultrasound guided
Comparison: Conventional closure device deployment

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N₀ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with conventional closure device deployment	Risk with ultrasound guided				
Access complications overall	10 per 100	**5 per 100** (4 to 7)	**OR 0.49** (0.37–0.65)	3 514 (6 non-randomised studies)	⨁⨁◯◯ Low	The risk of an access complications was significantly decreased in patients who received USG closure after any endovascular procedure, but the evidence is due to the used studies low.
Major access complications	4 per 100	**1 per 100** (0 to 3)	**OR 0.26** (0.10–0.63)	3 514 (6 non-randomised studies)	⨁⨁◯◯ Low	The risk of a major access complications was significantly reduced in patients who received USG closure in comparison to conventional closure, but the evidence is due to the used studies low.
Minor access complications	6 per 100	**4 per 100** (3 to 5)	**OR 0.60** (0.42–0.85)	3 410 (5 non-randomised studies)	⨁⨁◯◯ Low	The risk of a minor access complications was significantly reduced in patients who received USG closure in comparison to conventional closure, but the evidence is due to the used studies low.
Bleeding complications	7 per 100	**3 per 100** (2 to 5)	**OR 0.49** (0.32–0.76)	1 866 (4 non-randomised studies)	⨁⨁◯◯ Low	The bleeding complications were significantly decreased in patients who received USG closure after any endovascular procedures, but the evidence is due to the used studies low.
Closure device failure	7 per 100	**3 per 100** (2 to 5)	**OR 0.47** (0.29–0.76)	1 675 (4 non-randomised studies)	⨁⨁◯◯ Low	The closure device failure was significantly reduced in patients who received USG closure in comparison to conventional closure, but the evidence is due to the used studies low.
Ischaemic complication	2 per 100	**0 per 100** (0 to 2)	**OR 0.20** (0.04–1.15)	998 (3 non-randomised studies)	⨁◯◯◯ Very low	There were no significant ischaemic complications in patients who received USG closure after any endovascular procedure, but the evidence is due to the used studies very low.

***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).

CI = confidence interval; **OR** = odds ratio

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.

Figure 4. Grading of Recommendations Assessment, Development, and Evaluation (GRADE) analysis of studies included in the meta-analysis showed a low to very low certainty of evidence.

Manta is larger than the intraluminal component of the Per-Close device, it is easier to visualise with ultrasound. An advantage of the PerClose technique is that the device can be used at the beginning of the procedure, just after the puncture. This allows the ultrasound probe to be used consecutively for the puncture and device placement at the start of the procedure. Additionally, performing the technique early in the procedure reduces the likelihood of the ultrasound image being hampered by haematoma formation. In the previous studies by Moriyama *et al*. and Miyashita *et al.*[13,21] the recommended ultrasound guided deployment steps, to confirm adequate plug based closure device apposition at the end of the procedure, are described.

One single study with antegrade (off label) common femoral artery closure during distal revascularisation procedures accounted for the majority of subjects studied (1 322 of 1 726 cases), but unfortunately the authors did not report on closure device failure.[27] It should be noted that

closure device failure rates are low in small sheath procedures. Different closure devices have different failure mechanisms. Therefore, the choice of the closure device should also depend on patient and vascular characteristics. A comparison of plug based and suture based closure devices showed that failure was more common with suture based devices.[38] Furthermore, like the Manta device for large introducer sheath closure, the plug based AngioSeal was used most frequently for small introducer sheath closure, which as previously stated, are easier to identify using ultrasound. Thus, caution should be exercised before generalising these findings to metal clip and suture based small sheath closure. Furthermore, prospective research is needed to validate the findings of this meta-analysis of retrospective data.

Cost considerations were not directly addressed in this meta-analysis owing to the inherent complexity and variability across different healthcare settings. Costs associated with vascular closure devices can be influenced by factors such as device pricing, procedure duration, and clinical environment, which requires a dedicated economic analysis to be assessed accurately. Furthermore, while the decision to use manual compression *vs.* closure devices for small puncture sites (<8 F) is an important topic, it involves additional considerations, including the time to achieve haemostasis and procedural efficiency. This analysis focused on clinical outcomes, and while reduced access site complications may suggest potential cost benefits, further studies specifically designed to assess cost effectiveness are required to draw definitive conclusions.

Limitations

Although the outcomes analysed were objectively measurable, several limitations must be considered when interpreting the results of this meta-analysis. Firstly, endpoints addressing complications and closure device failures were not uniformly defined, which increased heterogeneity and decreased the internal validity of this analysis. The sample sizes of the included studies varied, resulting in a larger weighting of the study by Miyashita *et al.*[21] accounting for 49.1% of the endpoint of access complications. Furthermore, all of the studies were conducted as single centre studies and most involved retrospectively collected data. The analysed studies not only used different devices but also performed different interventions. Most studies did not disclose why the closure technique used was selected, which also introduced a risk of bias. However, all punctures of the common femoral artery were performed with ultrasound guidance. Three of the included studies performed a structured ultrasound follow up, which may have introduced an unrecognition and selection bias.

Patient level data were not available; therefore, it was not possible to analyse the influence of anatomical and patient characteristics on the risk of failing conventional closure or ultrasound guided closure. This may have potentially hindered the robustness of the findings. In addition, it is unclear how experienced the interventionists were regarding the ultrasound guided arterial closure device deployment. Therefore, the generalisability may be limited due to performance bias. These factors restrict the external validity of the present results.

Conclusion

Ultrasound guided closure is increasingly being used in various cardiovascular percutaneous interventions. In a pooled meta-analysis of retrospective studies including both large and small sheath procedures, ultrasound guided closure appeared to be associated with fewer access site complications, major access complications, and bleeding complications compared with conventional closure. Therefore, ultrasound guided closure might offer the potential to increase procedural and patient safety in percutaneous arterial access.

CONFLICTS OF INTEREST

M.M. Meertens, R.R. Smeets, and M. Wegner have reported to have no conflicts of interest concerning this manuscript. I. Kalaja has received speaker fees from AstraZeneca. S. Heyne has received a travel grant from Eli Lilly. S. Macherey-Meyer has received travel grants from Bayer AG and a research grant from Elisabeth & Rudolf Hirsch Stiftung. C. Espinola-Klein has received speaker fees or served on advisory boards for Abbott, Amarin, Amgen, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Cordis, Daiichi Sankyo, Novartis, Pfizer, and Sanofi-Aventis. B.M.E. Mees has received consulting and research grants from Cook Medical Inc., Bentley InnoMed, and Philips Electronics.

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APPENDIX A. SUPPLEMENTARY DATA

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