Title: Approaches to improve 12-month circuit primary patency and target lesion primary patency in arteriovenous fistulae: an umbrella review of systematic reviews and meta-analyses

Running title: umbrella review of factors affecting AV fistulae

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Abstract:

Background: Clinical practice guidelines endorse arteriovenous fistulae (AVF) as the preferred form of vascular access. Despite recent advancements, concerns persist regarding variable AVF patency rates. This umbrella review aimed to evaluate and synthesize evidence on interventions and strategies associated with improved 12-month patency rates in AVF.

Methods: Systematic review and meta-analyses of randomised control trials(RCTs) providing data regarding primary patency (PP) and target-lesion primary patency(TLPP) of AVF(not grafts) were included. Covidence was used for screening and data extraction, while the AMSTAR-2 rating assessed the methodological quality. Credibility assessment followed Papatheodorou's criteria. Medline, EMBASE, CENTRAL, and CINAHL were searched using a bespoke search strategy from inception to December 2024.

Results: Twenty-two reviews that included 136 RCTs involving 13522 patients were included in the final review. Highly suggestive evidence supports functional end-to-side anastomosis (effect estimate (EE) 1.7) for improving PP. Drug-coated balloon angioplasty (DCB) showed varied results across nine reviews, with effect estimates ranging from 0.49 to 2.47. For TLPP, one review reported significant improvement (EE 2.47, 95% CI 1.53-3.99). Suggestive evidence favours flow-based access monitoring (RR 0.51-0.66), antithrombotic medication (EE 0.53), antiplatelet therapy (EE 0.54), far infrared therapy (EE 1.24-1.27), and pre-emptive correction of "at-risk" AVF (EE 0.5) for prolonging PP. Button hole cannulation and side-to-side anastomosis showed mixed or non-significant results. Heterogeneity varied widely across reviews, ranging from 0% to 81%, and AMSTAR-2 ratings ranged from moderate to high.

Conclusion:

This umbrella review synthesizes evidence on interventions for AVF patency, revealing varying levels of support for different strategies and highlighting areas requiring further investigation.

Introduction:

The global prevalence of kidney failure is increasing significantly, with projections indicating a more than twofold rise in treated cases from 2.6 million in 2010 to an estimated 5.4 million by 2030. (1)This surge is accompanied by a substantial increase in mortality, with kidney failure-related deaths potentially rising by 29% to 68% from the 1.2 million recorded in 2015.(2–5) These statistics underscore the need for improved management strategies in kidney failure treatment, particularly in vascular access for haemodialysis.

Arteriovenous fistulae (AVF) remain the preferred option for vascular access, demonstrating superior longevity, fewer complications, and lower mortality rates compared to alternatives.(6–8) However, AVFs face significant challenges, with early failure rates reaching up to 30% and long-term patency remaining a persistent issue.(9–11) While robust evidence supports interventions enhancing 6-month primary patency, the efficacy of interventions at 12 months is less established.(12)

A comparative analysis of vascular access outcomes revealed that AVF requiring assisted maturation experienced higher rates of patency loss at one year compared to AVFs not requiring assisted maturation which demonstrated the lowest patency loss rate at 38.9%.(13) These findings align with broader observations that primary patency rates at one year range from 50-70%, further declining to 30-40% by the second year.(8,14) Addressing AVF patency is crucial, as vascular access dysfunction is a primary cause of hospitalization among haemodialysis patients, significantly impacting patient outcomes and healthcare resources. (15)

Despite clinical guidelines consistently recommending AVF as the preferred vascular access, the variability in patency rates necessitates a comprehensive examination of factors influencing successful AVF formation and maintenance.(4,16) Given these challenges and the critical importance of maintaining AVF patency, this umbrella review aims to identify and evaluate interventions and strategies with the strongest evidence for improving 12-month circuit and target lesion primary patency in AVFs.

Methods

This umbrella review was conducted following the guidelines of the Joanna Briggs Institute(JBI) for umbrella reviews. The JBI approach emphasizes a comprehensive search strategy, rigorous study selection, and quality assessment of included reviews. Key aspects of the JBI methodology we adhered to include: developing a clear, focused review question; conducting a systematic search across multiple databases and grey literature sources; using pre-defined inclusion and exclusion criteria for study selection; employing independent reviewers for study selection and data extraction; assessing

the methodological quality of included reviews using standardized tools, synthesizing findings narratively and, where possible, statistically; and interpreting results in the context of overall evidence quality and applicability. This structured approach ensures a comprehensive and transparent synthesis of the existing evidence on interventions for improving AVF patency.(17)

This umbrella review aimed to evaluate interventions for improving circuit primary patency (PP) and target lesion primary patency (TLPP) in AVF at 12 months. We focused on systematic reviews that included patients with kidney failure requiring haemodialysis using AVF. We examined various interventions designed to maintain or improve AVF patency, comparing them to standard care or alternative interventions. Our primary outcomes were PP and TLPP at 12 months.

Search Strategy:

The search strategy was developed to capture all pertinent studies without any date restrictions. Our search strategy employed a combination of terms related to arteriovenous fistula, renal dialysis, and systematic review, along with their respective synonyms and related concepts. The search strategy is elaborated in supplementary file 1. Our search encompassed major databases including Medline, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) from inception to December 2024

Furthermore, we utilized snowball searching techniques by thoroughly hand-searching the reference lists of all screened full texts and relevant systematic reviews. This manual cross-referencing served as a secondary measure to identify potentially overlooked studies of importance. To ensure methodological rigor, all stages of the search process, including strategy development and execution, were conducted by a designated information specialist (TS).

Inclusion Criteria:

Our review specifically included English-language systematic reviews that included randomised controlled trials(RCTs) focusing on AVF, excluding studies on arteriovenous grafts. We included reviews that included both AVG and AVF only if complete data and/or subgroup analyses was available for RCTs focussing on AVFs. Eligible studies needed to provide detailed data on primary and target lesion primary patency rates at specific times post-intervention including 12-month patency rates. We looked for studies that investigated interventions designed to either preserve or improve AVF patency.

Exclusion Criteria:

We excluded non-randomised studies, observational cohorts, and quasi-experimental designs to minimize bias and ensure a higher level of evidence. Studies lacking clear patency measurement time

points, focusing on non-AVF vascular access types, or pertaining to dialysis modalities other than haemodialysis were also omitted.

Definitions:

Circuit PP refers to the duration of time from the creation of the AVF until any intervention aimed at maintaining or restoring adequate blood flow is required. This measure is essential as it indicates the lifespan of the entire haemodialysis circuit without the need for repair or revision.(18) On the other hand, TLPP pertains specifically to the patency at the precise site of surgical or endovascular intervention within the dialysis circuit. It is defined as the interval from the intervention on the target lesion to the subsequent stenosis or re-intervention on the same lesion. TLPP is a more focused measure, evaluating the effectiveness of the treatment at a specific problematic segment of the vascular access.(19,20)

After the search, titles and abstracts were independently screened by two reviewers (BR and AL), with any discrepancies resolved through consensus or intervention of a third reviewer(AH or SN or MP) when necessary. Three independent reviewers also performed data extraction to minimize bias and errors.

Both screening and data extraction phases were carried out using Covidence, a web-based software platform designed for systematic reviews.(21) To ensure methodological quality of the included studies, we used the meaSurement Tool to Assess systematic Reviews, version 2 (AMSTAR 2) checklist, a critical appraisal tool for systematic reviews.(22) Credibility of the findings was assessed following Papatheodorou's criteria, which outlines standards for judging the dependability of evidence, particularly in health-related interventions.(23)

The AMSTAR-2 checklist is a critical appraisal tool designed to assess the methodological quality of systematic reviews, including those that incorporate randomized and non-randomized studies of healthcare interventions. For this paper, the checklist was used to evaluate the included studies rigorously, focusing on 16 domains that cover various aspects of review construction such as the comprehensiveness of the literature search, the justification for excluding individual studies, the assessment of publication bias, and the presence and impact of any conflicts of interest. The AMSTAR-2 checklist helps to ensure that the systematic reviews we have included adhere to high-quality standards, providing confidence in the validity and reliability of their conclusions in the context of identifying factors that influence AVF primary patency outcomes.

The Papatheodorou criteria serves as a framework for credibility assessment, rigorously reviewing the strength, consistency, and robustness of evidence presented in health-related interventions. In this

paper, the criteria were applied to discern the dependability of the existing data. This includes examining the directness of evidence, precision of the results, risk of publication bias, and coherence across the reported findings.

Our initial plan was to conduct umbrella meta-analyses and meta-regression, with a strategy to assess heterogeneity using the I^2 statistic and χ^2 test. We intended to use fixed-effects or random-effects models based on the level of heterogeneity, and planned sensitivity analyses to ensure robustness. Our inclusion criteria were designed to mitigate heterogeneity by selecting reviews with similar outcomes and comparable post-intervention time points.

However, upon analysis, we encountered substantial methodological heterogeneity across the included reviews. Significant variations in outcome measures, follow-up durations, patient populations, and intervention specifics precluded meaningful data aggregation. The high degree of heterogeneity would have rendered any pooled estimates potentially misleading.

Consequently, we were unable to proceed with the planned meta-analyses or meta-regression. Instead, we adopted a narrative synthesis approach to present our findings. This method allowed us to summarize the evidence while maintaining transparency about the constraints encountered in the synthesis process. We carefully acknowledged the limitations imposed by the diverse nature of the included studies and their data, ensuring a thorough and accurate representation of the current evidence base despite the inability to conduct quantitative synthesis.

Results:

The search strategy identified a total of 570 studies. After removing duplicates, 304 studies underwent title and abstract screening. Of these, 69 articles were selected for full-text review, resulting in the final inclusion of 22 systematic reviews. These reviews collectively incorporated 136 RCTs involving 13522 patients. Our grey literature search did not yield any additional studies that met our inclusion criteria based on the review question. The evidence varied, with interventions showing differing levels of effectiveness as outlined table 1. The heterogeneity in the studies ranged from 0% to 81%, indicating considerable variability in study outcomes. The AMSTAR-2 ratings for the majority of interventions ranged from moderate to high, denoting generally good methodological quality across the included trials. However, the credibility of the evidence varied, with several results considered to have weak evidence, while others ranged from suggestive to highly suggestive.

Four separate studies reviewed the impact of flow-based access monitoring compared with clinical assessment-based surveillance, including a review that encompassed 4 RCTs assessing 395 patients

and found a risk ratio of 0.64(95% CI: 0.41 - 1.01) favouring flow-based monitoring.(24) A review by Tessitore et al, demonstrated a more compelling risk ratio of 0.51 in favour of flow-based monitoring.(25) Ali et al reported similar findings with 5 RCTs and 287 patients, showing a risk ratio of 0.55.(26) Georgiadis et al analysed 4 RCTs with 242 patients and also supported flow-based monitoring with a risk ratio of 0.66 (95% CI 0.42-1.03).(27)

Regarding adjuvant antithrombotic medication, Ullah et al found a risk ratio of 0.53 favouring the use of antithrombotic medications in 3 RCTs covering 339 patients.(28) Coleman et al assessed antiplatelet therapy across 10 RCTs with 1493 patients and found support for its efficacy. (29)

The evidence regarding the method of cannulation, showed mixed results. One review reported a favourable effect (RR 0.4, 95% CI 0.2-0.8) in 6 RCTs with 412 patients, (30)while another showed no significant difference (RR 1.06, 95% CI 0.45-2.5) in 3 RCTs with 382 patients.(31)

Several studies, varying in numbers, extensively reviewed drug-coated balloon angioplasty (DCB) versus conventional percutaneous transluminal angioplasty (PTA). The results were mixed, with effect estimates ranging from 0.49 to 2.47. For TLPP, one review reported a significant improvement (RR 2.47, 95% CI 1.53-3.99).(32–40)

Far infrared therapy was advocated by two reviews across 6 RCTs and 835 patients, showing risk ratios of 1.24 and 1.27 favouring the therapy.(41,42) One review provided highly suggestive evidence for functional end-to-side anastomosis over traditional end-to-side approaches, with a risk ratio of 1.7.(43) One review provided suggestive evidence for side-to-side anastomosis over end-to-side anastomosis with a risk ratio of 0.72, though this was not statistically significant (95% CI 0.47-1.1)(44). Other interventions included pre-emptive correction of "at-risk" AVFs which showed suggestive evidence supporting their use.(45)

Some interventions showed weak or inconsistent evidence. Two reviews on drug-coated balloon angioplasty reported non-significant results (RR 0.99, 95% CI 0.25-3.92 and RR 0.96, 95% CI 0.77-1.19)(56,33)(34,37). The review on side-to-side anastomosis demonstrated a non-significant trend favouring the intervention (RR 0.72, 95% CI 0.47-1.1). (44)

Discussion:

The findings from the selected 22 reviews, encompassing 136 RCTs and involving 13522 patients, revealed a range of interventions aimed at improving the patency of AVF. This review highlights two distinct categories of evidence: those with highly suggestive evidence, such as functional end-to-side anastomosis, which was shown to improve primary patency, and those interventions with suggestive evidence, which included routine flow-based access monitoring, various forms of antithrombotic

medication, far infrared therapy, and pre-emptive correction for 'at-risk' AVFs. The evidence for DCB in improving target-lesion primary patency was mixed, with some reviews showing highly suggestive evidence and others showing weak or non-significant results.

However, there is a notable disparity in the strength and consistency of the reported evidence across the interventions. Variations in the effect estimates, heterogeneity, and AMSTAR-2 ratings suggest that while some interventions are apparently effective, the level of certainty surrounding these findings is far from uniform. For instance, the evidence for buttonhole cannulation and side-to-side anastomosis was mixed or non-significant. This highlights the need for careful interpretation of the data and indicates that while there is promise in these interventions, further research to harmonize and corroborate findings is essential.

Despite these disparities, the synthesized evidence from this umbrella review does offer valuable insights that inform clinical practice. The compelling cases of high-quality evidence for certain interventions point toward actionable strategies that practitioners can adopt or emphasize in the management of AVF patency. For instance, favouring functional end-to-side anastomosis during AVF creation could be further integrated into practice, potentially leading to improved outcomes. (43)

The presence of weak evidence and overlapping confidence intervals for some interventions underscores the complexity of interpreting results in this field. For instance, the mixed findings for drug-coated balloon angioplasty, with some reviews showing strong evidence and others showing weak or non-significant results, highlight the need for cautious interpretation. These discrepancies may be due to differences in study populations, follow-up periods, or specific techniques used within the broad category of drug-coated balloon angioplasty.

The overlapping confidence intervals observed in some studies, particularly for flow-based access monitoring, suggest that while point estimates may differ, the true effect of these interventions may be more similar than initially apparent. This emphasizes the importance of considering the full range of possible effects, rather than focusing solely on point estimates.

It is essential to address why PP and TLP were chosen as focal points for our review. PP and TLPP are considered the most important parameters in evaluating the success of vascular access for haemodialysis because they directly impact patient outcomes. PP assesses the overall unassisted functionality of the vascular access, acting as a cumulative indicator of an AVF's efficacy and durability.(46) This measurement is crucial, as prolonged patency correlates with fewer interventions, less patient discomfort, and reduced medical costs. TLPP, meanwhile, zeroes in on the specific site of intervention within the AVF, providing valuable insights into the localized effectiveness of treatments

at the lesion level and giving an indication of the expected longevity of a particular therapeutic approach. By focusing exclusively on PP and TLPP, our review targets the most clinically relevant outcomes that reflect both broad and specific measures of AVF performance, thereby providing insights that are highly actionable for the improvement of patient care in the treatment of kidney failure .(47,48)Despite the argument that functional patency (FP) may offer a more patient-centred measure, as it assesses whether an AVF functions as access without considering the need for interventions, reporting standards have historically favoured PP as the preferred marker. (49,50) This preference has led most trials to report PP rather than FP, influencing our decision to adopt PP and TLPP as the primary markers for this review. The challenges associated with measuring FP, including variability in definitions and the complexity of capturing functional success over time, further justify this choice. However, it is acknowledged that FP's direct impact on patient outcomes by ensuring continuous, effective dialysis access remains significant.(7,47,51–53)

While this umbrella review provides valuable insights into factors affecting arteriovenous fistula patency, several limitations must be acknowledged. Systematic reviews and meta-analyses, though considered high-level evidence, may accumulate and amplify biases present in primary studies. The inherent time lag between primary study publication and their inclusion in reviews may result in the omission of recent, potentially high-quality studies. Variability in primary study quality, including differences in study design, assessment techniques, population characteristics, and follow-up periods, introduces uncertainty in interpreting pooled results. Significant heterogeneity across included reviews in terms of interventions, outcome measures, and follow-up durations precluded meaningful meta-analysis, necessitating a narrative synthesis approach.

Our focus on PP and TLPP, while justified by reporting standards and data availability, may not fully capture patient-centred outcomes. FP, which may offer a more patient-centred measure, was not consistently reported in the primary literature. This focus on PP may not always align with the priorities of the original RCTs and could affect the clinical applicability of our findings. Our search strategy, while comprehensive for published systematic reviews, was limited to PROSPERO for ongoing studies and review protocols, potentially missing relevant trials or reviews registered in other databases.

Despite these limitations, the rigorous methodology, including comprehensive search strategies, quality assessment using AMSTAR-2, and credibility assessment following Papatheodorou's criteria, aims to provide a reliable synthesis of the available evidence. However, the advanced analytical methods employed must be considered alongside the varied methodological quality of the underlying RCTs, necessitating cautious interpretation of the strength of evidence. Future research in vascular

access should address these limitations through enhanced methodological rigor in primary studies, standardization of outcome measures, and comprehensive assessment of both primary and functional patency. Clinicians should exercise judicious interpretation of pooled results from umbrella reviews, considering them in conjunction with the methodological quality of individual studies to inform evidence-based decision-making. By highlighting these complexities, we aim to provide a balanced view of the current evidence and identify key areas for improvement in future research and clinical practice.

In conclusion, this umbrella review has explored a spectrum of approaches and interventional strategies, exploring their potential to enhance the 12-month patency of AVFs. The review not only provides strong evidence for particular practices but also sheds light on the areas where evidence remains mixed or sparse.

Table 1: Characteristics of the included studies

Author	Year	Intervention	Comparator	No of RCTs	No of patients	Effect estimates (95% CI)	Favouring	Heterogeneity	AMSTAR-2 rating	Credibility assessment
Muchayi(24)	2015	flow based access monitoring	Clinical assessment-based surveillance	4	395	0.64 (0.41,1.01)	flow based access monitoring	7.2	Moderate	Weak evidence
Tessitore(25)	2019	flow based access monitoring	Clinical assessment-based surveillance	5	554	0.51 (0.35,0.73)	flow based access monitoring	0	Moderate	Suggestive evidence
Ali(26)	2021	flow based access monitoring	Clinical assessment-based surveillance	5	287	0.55 (0.33,0.89)	flow based access monitoring	21.1	High	Weak evidence
Georgiadis(27)	2015	flow based access monitoring	Clinical assessment-based surveillance	4	242	0.66 (0.42,1.03)	flow based access monitoring	0	Moderate	Suggestive evidence
Ullah(28)	2021	Adjuvant	No antithro	3	339	0.53	Adjuvant	0	High	Suggestive

		antithrombotic medication	mbotic medication			(0.32,0.88)	antithrombotic medication			evidence
Coleman(29)	2010	Antiplatelet therapy	No antiplatelets	10	1493	0.54 (0.31,0.94)	Antiplatelet therapy	46	Moderate	Suggestive evidence
Wang(30)	2022	Button hole cannulation	Rope ladder cannulation	6	412	0.4 (0.2,0.8)	Button hole cannulation	0	High	Suggestive evidence
Peralta(31)	2023	Button hole cannulation	Rope ladder cannulation	3	382	1.06 (0.45,2.5)	Button hole cannulation	81	Moderate	Suggestive evidence
Fong(32)	2021	Drug coated balloon angioplasty	Plain balloon angioplasty	11	1347	0.6 (0.42,0.86)	Drug coated balloon angioplasty	65	Moderate	Highly suggestive evidence
Liao(34)	2020	Drug coated balloon angioplasty	Plain balloon angioplasty	6	193	0.96 (0.77,1.19)	Drug coated balloon angioplasty	63	Moderate	Suggestive evidence
Liu(33)	2021	Drug coated balloon angioplasty	Plain balloon angioplasty	107	1752 640	TLPP: 2.47 (1.53,3.99) Circuit patency:	Drug coated balloon angioplasty	46	Moderate	Highly suggestive evidence

						1.91(1.22,3)				
Luo(40)	2022	Drug coated balloon angioplasty	Plain balloon angioplasty	14	1535	1.19(0.97,1.47)	Drug coated balloon angioplasty	40.5	High	Suggestive evidence
Yanwee(36)	2019	Drug coated balloon angioplasty	Plain balloon angioplasty	6	425	0.82 (0.72,0.94)	Drug coated balloon angioplasty	10	High	Suggestive evidence
Salim(38)	2020	Drug coated balloon angioplasty	Plain balloon angioplasty	5	551	0.64 (0.4,1.02)	Drug coated balloon angioplasty	28.26	High	Suggestive evidence
Cao(37)	2020	drug coated balloon angioplasty	Plain balloon angioplasty	5	282	0.99(0.25,3.92)	Drug coated balloon angioplasty	79	High	Weak evidence
Chen(39)	2020	Drug coated balloon angioplasty	Plain balloon angioplasty	9	356	0.54(0.3,0.98)	Drug coated balloon angioplasty	76.8	Moderate	Weak evidence
Kennedy(35)	2019	Drug coated balloon angioplasty	Plain balloon angioplasty	7	449	0.49 (0.32,0.75)	Drug coated balloon angioplasty	0	Moderate	Suggestive evidence

Wan(42)	2017	Far infrared therapy	Placebo	4	612	1.24(1.12,1.37)	Far infrared therapy	0	High	Suggestive evidence
Wu(41)	2024	Far infrared therapy	Placebo	2	223	1.27(1.09, 1.47)	Far infrared therapy	0	High	Suggestive evidence
Weigang(43)	2021	Functional end to side anastomosis	Traditional end to side anastomosis	5	614	1.7(1.09,2.66)	Functional end to side anastomosis	0	High	Highly suggestive evidence
Yu Zhou(44)	2023	End to side anastomosis	Side to side anastomosis	5	564	0.72 (0.47,1.1)	Side to side anastomosis	0	High	Suggestive evidence
Ravani(45)	2016	Pre-emptive correction of "at risk" AVF	Deferred correction	7	515	0.5 (0.35.0.71))	Pre-emptive correction of "at risk" AVF	0	High	Suggestive evidence

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