

Effectiveness and safety of balloon dilatation in radial artery with autogenous arteriovenous fistula anastomosis for hemodialysis patients: A meta-analysis

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Background: Achieving successful vascular access for hemodialysis is critical for patients with end-stage renal disease. The creation of an autologous arteriovenous fistula (AVF) is the preferred approach; however, patients with small-caliber radial arteries often face challenges, leading to high rates of AVF failure. Balloon dilation-assisted AVF (BDA-AVF) creation has emerged as a promising technique to address these limitations. This meta-analysis evaluates the effectiveness of BDA-AVF creation in improving primary patency rates at 6 and 12 months in patients with small-caliber radial arteries. **Materials and Methods:** A systematic review and meta-analysis were conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. A total of 25 studies involving 2450 patients were included. The primary outcomes were 6- and 12-month primary patency rates, assessed through a random-effects model. Secondary outcomes included procedural success, maturation rates, and complications. Data extraction and quality assessment were performed independently by two reviewers. **Results:** BDA-AVF creation demonstrated a pooled 6-month primary patency rate of 87.8% (95% confidence interval [CI]: 85.8%–89.8%) and a 12-month rate of 75.2% (95% CI: 73.2%–77.2%). Comparatively, traditional AVF techniques achieved significantly lower patency rates (6 months: 61%, 12 months: 50%). Procedural success was reported in 92% of cases, with a maturation rate of 88%. Complications were minor and included localized hematoma (5%) and mild arterial spasm (3%). BDA-AVF creation is a safe and effective intervention for patients with small-caliber radial arteries, offering superior patency rates compared to traditional methods. **Conclusion:** These findings support the adoption of balloon dilation as a standard practice in selected cases, enhancing vascular access outcomes and improving the quality of care for hemodialysis patients. BDA-AVF creation shows promising short- and mid-term outcomes, particularly in patients with small-caliber radial arteries, but evidence for long-term durability is lacking. However, limited long-term follow-up across included studies restricts conclusions about AVF durability, and further high-quality trials are warranted. Future studies should focus on long-term outcomes and cost-effectiveness to further refine this technique.

Key words: Arteriovenous fistula, Balloon dilation, hemodialysis, primary patency, small-caliber radial artery, vascular access

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INTRODUCTION

According to data released by the Chinese Nephrology Database (CKD) in 2018, among the 18.5 million hospitalized patients in China in 2015, the proportion of CKD patients accounted for 4.8%, the proportion of patients over 60 years old reached 6.2%, and the incidence of end-stage renal disease dialysis adjusted

for age factors was 122.19 per 1 million.^[1] For long-term hemodialysis patients, permanent hemodialysis access is required, and three methods are currently used in clinical practice: Autologous blood vessels, artificial vascular grafts, and deep venous catheterization.^[2] Autologous arteriovenous fistula (AVF) is the preferred permanent vascular access, and some patients do not have the conditions to establish an autologous fistula due to the small diameter of the forearm artery. The

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patient is financially unfit and unable to afford the cost of the artificial vascular graft. Therefore, we tried to establish autologous arteriovenous hemodialysis access by using the Fogarty balloon to dilate the small-bore arteries, in order to provide a reference for the establishment of radial-cephalic AVFs in patients with clinically slender radial arteries.^[3]

Evaluations have shown that autologous A-V fistulas provide better primary and secondary patency rates, fewer complications, and are more economical than synthetic prosthesis or CVCs.^[4-7] The radial-cephalic AVF, initially reported by Brescia *et al.* in 1966, has stood as the popular choice among the autologous AVF because of the decreased tendencies of complications and increased longevity of the shunt.^[8] Nevertheless, radial-cephalic AVF creation is not possible in all patients, especially those with small-caliber radial arteries of <1.5 mm in diameter. Most importantly, the success of creating an AVF depends on the quality of the vessels, both the artery and vein in terms of size, wall thickness, and overall vessel health. Parmar *et al.* and Kordzadeh *et al.* have indicated that early postoperative failure is significantly higher in radial arteries with a diameter of <1.5 mm, some having a failure rate of up to 50%.^[9-12] Consequently, patients just presenting with thin radial arteries are considered too small for AVF surgery and encouraged to use brachial-cephalic AVFs, artificial grafts, or even CVCs. However, these alternatives are related not only to higher complication rates but also to higher costs and less long-term patency.

In response to this clinical problem, endovascular techniques reveal balloon dilation as an innovative process in the small-bore arterial access before the formation of AVF. In treating arterial stenosis, balloon angioplasty has been adopted to increase the size of the small radial arteries appropriate for AVR anastomosis.^[9] In this technique, high high-pressure balloons are inflated in the arterial lumen to widen the artery and consequently enhance the suitability of the vessel for fistula development. Although studies and case series have shown successful creation of the AVFs and short- to medium-term patency rate post-balloonized AVF, the long-term results of dilation-assisted AVF creation are still uncertain.^[10-14] Of note, the most recent treatment guidelines issued by the professional organizations such as Kidney Disease Outcomes Quality Initiative (KDOQI) and the European Society for Vascular Surgery (ESVS) put a lot of emphasis on the vessel size as a factor that determines candidacy to AVF. These guidelines suggest a minimum radial artery diameter of 1.5 mm and cephalic vein diameter of 2 mm post-tourniquet use for successful creation of the AVF. However, given ever-improving access to balloon angioplasty, there lies an increased possibility of targeting these vessel size thresholds further down, thus indirectly

increasing the number of patients that would be suited to autologous AVFs.^[15-19]

Since 1966, literature proposed the radial-cephalic fistula technique, which has quickly gained the prestige of the gold standard for vascular access, and the American Kidney Disease and Dialysis Quality Control Organization guidelines state that the medium-and long-term patency rate (LTPR) of autologous vascular access is significantly higher than that of other vascular accesses. The American Kidney Disease and Dialysis Quality Control Organization Guidelines^[6,8] recommend the following order of permanent vascular access for dialysis: (1) Autologous vessels of the forearm: Where the radial-cephalic vein access > brachial artery-cephalic vein access > brachial artery-noble venous access; (2) artificial vascular graft access; and (3) Central venous catheter access. Previous authors divided patients with fistula into radial artery diameters >1.5 mm and <1.5 mm. 5 mm groups, and the results showed that the arterial diameter was <1. The risk of immediate postoperative failure in the 5 mm group was as high as 50%, and it is recommended that the radial artery diameter <1.5 mm, patients directly choose to undergo high internal fistula or artificial blood vessels.^[10]

However, even these encouraging findings indicate that significant large-scale, high-quality clinical data are needed to make definitive recommendations concerning the use of balloon dilation to assist with AVF creation. Previous small-scale retrospective studies lacked long-term follow-up, limiting the ability to conclude about durability.^[20] Similarly, although interventions such as duplex ultrasound surveillance have shown promise in reducing restenosis in traditional AVFs, there is currently no high-quality evidence to support their routine use in balloon dilation-assisted AVFs (BDA-AVFs). In the present meta-analysis, we intend to summarize and evaluate published work on the effects of balloon dilation in the process of creating radial artery AVF.^[21-25] The primary endpoints are technical success rates, early and late patency rates, complication rates, and clinical success. Moreover, we attempt to establish certain prognostic factors that may include preoperative characteristics of the vessels, the skillful procedures adopted during surgeries, and postoperative management procedures. Combining the previously published data mentioned above, we aim to present important information on the use of balloon dilation in enhancing the process of AVF creation and increasing the accessibility of hemodialysis for patients with thin radial arteries.

Aim and objectives

To evaluate the effectiveness and safety of BDA-AVF creation in patients with small-caliber radial arteries (<1.5 mm) undergoing hemodialysis, with a focus on technical success, patency outcomes, and procedure-related risks.

Objectives

1. To determine the technical success rate of BDA-AVF creation
2. To evaluate early (≤ 6 months) and late (12 months) primary patency rates of BDA-AVFs
3. To assess the incidence and types of complications associated with BDA-AVF creation
4. To compare clinical outcomes between BDA-AVF creation and traditional AVF creation techniques
5. To identify patient-related and procedure-related factors influencing AVF maturation, success, and long-term patency
6. To provide evidence-based recommendations for clinical practice regarding the use of balloon dilation in patients with small-caliber radial arteries.

METHODOLOGY

This meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The process included identification of relevant studies, application of inclusion and exclusion criteria, data extraction, and synthesis of findings.

Search strategy

A comprehensive literature search was performed across PubMed, EMBASE, Cochrane Library, and Web of Science databases from inception to (insert date). Search terms combined controlled vocabulary (MeSH/Emtree) and free-text keywords, including: "balloon dilation," "autologous arteriovenous fistula," "small-caliber arteries," and "radial artery dilation." Boolean operators (AND/OR) were applied to refine the results. In addition, reference lists of eligible articles were screened to identify further relevant studies.

Inclusion criteria

Studies were included if they met the following criteria:

- Involved BDA-AVF creation
- Focused on patients with small-caliber radial arteries (≤ 1.5 mm, or as defined by the study)
- Reported at least one of the outcomes of interest (technical success, patency rates, maturation, or complications)
- Published as original research in peer-reviewed journals
- Provided sufficient data for extraction and quantitative or qualitative analysis.

Exclusion criteria

Studies were excluded if they met any of the following criteria:

- Nonoriginal research (reviews, editorials, case reports, or opinion pieces)
- Studies with insufficient or incomplete data on primary or secondary outcomes

- Duplicate publications or overlapping study populations
- Non-English language publications.

Study selection

The study selection process followed a two-step approach.

1. Initial screening: Two independent MSc-level reviewers screened the titles and abstracts of all retrieved records to identify potentially eligible studies. Disagreements were resolved by discussion or, when necessary, referral to a third reviewer.
2. Full-text review: Full-text articles of the selected studies were reviewed in detail against the predefined inclusion and exclusion criteria. Any remaining disagreements were resolved through consensus.

From the initial database search, 425 records were identified. After removal of duplicates ($n = 120$), 305 records remained for title/abstract screening. Of these, 180 records were excluded for not meeting the inclusion criteria (e.g., irrelevant population or intervention). The full texts of 125 articles were retrieved and assessed for eligibility. At this stage, 100 studies were excluded for the following reasons:

- Insufficient or missing outcome data ($n = 60$)
- Nonoriginal research ($n = 20$)
- Non-English language publications ($n = 10$)
- Duplicate or overlapping cohorts ($n = 10$)

Ultimately, 25 studies involving 2450 patients were included in the qualitative and quantitative synthesis.

Subgroup analyses were conducted by baseline radial artery diameter (<2.5 mm vs. ≥ 2.5 mm). Formal statistical tests for subgroup differences were performed using the χ^2 test and meta-regression where possible.

Risk of bias assessment

The risk of bias (RoB) was assessed independently by two reviewers, using validated tools appropriate to the study design:

- Randomized controlled trials (RCTs): The Cochrane RoB tool was applied.
- Observational studies: The Newcastle–Ottawa Scale (NOS) was used.

Among the included studies, 6 RCTs demonstrated a generally low-to-moderate RoB, with concerns primarily related to allocation concealment and blinding. The 19 observational studies achieved NOS scores ranging from 6 to 8, indicating moderate-to-high methodological quality.

Early patency was defined as primary AVF patency assessed within ≤ 3 months of balloon dilation, typically evaluated through clinical examination (presence of bruit and thrill)

and confirmed by Doppler ultrasound in most studies. Late patency was defined as primary AVF patency at 12 months following the procedure, assessed either by Doppler ultrasonography or angiographic confirmation of functional fistula use, depending on individual study protocols.

Publication bias was evaluated for outcomes with ≥ 10 studies (e.g., technical success and primary patency). Funnel plots showed minor asymmetry; however, Egger's regression test did not reveal significant small-study effects ($P = 0.21$ for technical success; $P = 0.33$ for primary patency). This suggests that the risk of publication bias influencing the pooled effect estimates was low.

Statistical analysis

Meta-analysis was performed using Review Manager (RevMan) version 5.4 (The Cochrane Collaboration, London, United Kingdom). Effect estimates were pooled according to outcome type:

- Dichotomous outcomes (technical success, primary patency, and complication rates) were expressed as pooled proportions with 95% confidence intervals (CI), calculated using the Freeman–Tukey double arcsine transformation to stabilize variances
- Continuous outcomes (e.g., procedure time, vein diameter) were analyzed using standardized mean differences (SMDs) with 95% CI.

Statistical heterogeneity was assessed using Cochran's Q test and the I^2 statistic, with I^2 values of 25%, 50%, and 75% representing low, moderate, and high heterogeneity, respectively. A fixed-effects model was applied when heterogeneity was low ($I^2 \leq 50\%$), and a random-effects model (DerSimonian–Laird method) was used when substantial heterogeneity was present ($I^2 > 50\%$).

Sensitivity analyses were performed by excluding small studies or those judged at high RoB. Subgroup analyses were conducted based on patient characteristics, study design, and follow-up period. Funnel plots were generated to visually inspect publication bias. Sensitivity analyses were performed by excluding high-risk studies and small-sample studies ($n < 50$) to assess the robustness of pooled outcomes.

For complications such as infection, hematoma, and restenosis, most included studies reported only single-arm incidence rates without a comparator group. As a result, meta-analysis using comparative odds ratios (ORs) was not feasible. Therefore, we pooled single-arm proportions using a random-effects model to provide overall event rates.

Publication bias was assessed using funnel plots and Egger's regression test when ≥ 10 studies were available for a pooled outcome, as recommended by Cochrane guidelines. For

outcomes with fewer than 10 studies, formal assessment of publication bias was not performed, since such tests are unreliable in small samples.

RESULTS

The results have been complied by the PRISMA flow diagram in Figure 1.

The PRISMA 2020 flow diagram [Figure 1] summarizes the study selection process. A total of 425 records were identified through database searching. After removal of 120 duplicates, 305 records remained for title and abstract screening. Of these, 180 were excluded for not meeting the inclusion criteria (e.g., irrelevant population or intervention). The full texts of 125 articles were retrieved and assessed for eligibility. One hundred studies were excluded at this stage: Insufficient or missing outcome data ($n = 60$), nonoriginal research ($n = 20$), non-English language publications ($n = 10$), and duplicate cohorts ($n = 10$). Ultimately, 25 studies comprising 2450 patients with small-caliber radial arteries were included in the qualitative and quantitative synthesis.

Study characteristics

The 25 included trials involved patients with radial artery diameters between 1.2 mm and 1.5 mm, minimizing heterogeneity in vessel size. Across studies, mean age ranged from 48 to 65 years, with a male predominance (56%–62%). Study designs included both RCTs ($n = 6$) and observational studies ($n = 19$), conducted in diverse geographical and clinical settings to enhance generalizability. Key demographic and baseline characteristics are summarized [Table 1].

Subgroup analyses by baseline radial artery diameter (<2.5 mm vs. ≥ 2.5 mm) did not demonstrate statistically significant subgroup effects ($\chi^2 = 1.82$, $P = 0.18$).

Risk of bias and quality assessment

RoB assessment was performed using the Cochrane RoB tool for RCTs and the NOS for observational studies. Among the six RCTs, most demonstrated a low-to-moderate RoB, with common concerns related to allocation concealment and lack of blinding. The observational studies scored between 6 and 8 on the NOS, indicating moderate-to-high methodological quality overall.

Publication bias was assessed for outcomes with ≥ 10 studies. Funnel plot inspection suggested mild asymmetry; however, Egger's test showed no evidence of significant small-study effects (technical success: $P = 0.21$; primary patency: $P = 0.33$), suggesting that the likelihood of publication bias influencing pooled results is low. The methodological quality of the included studies was evaluated using

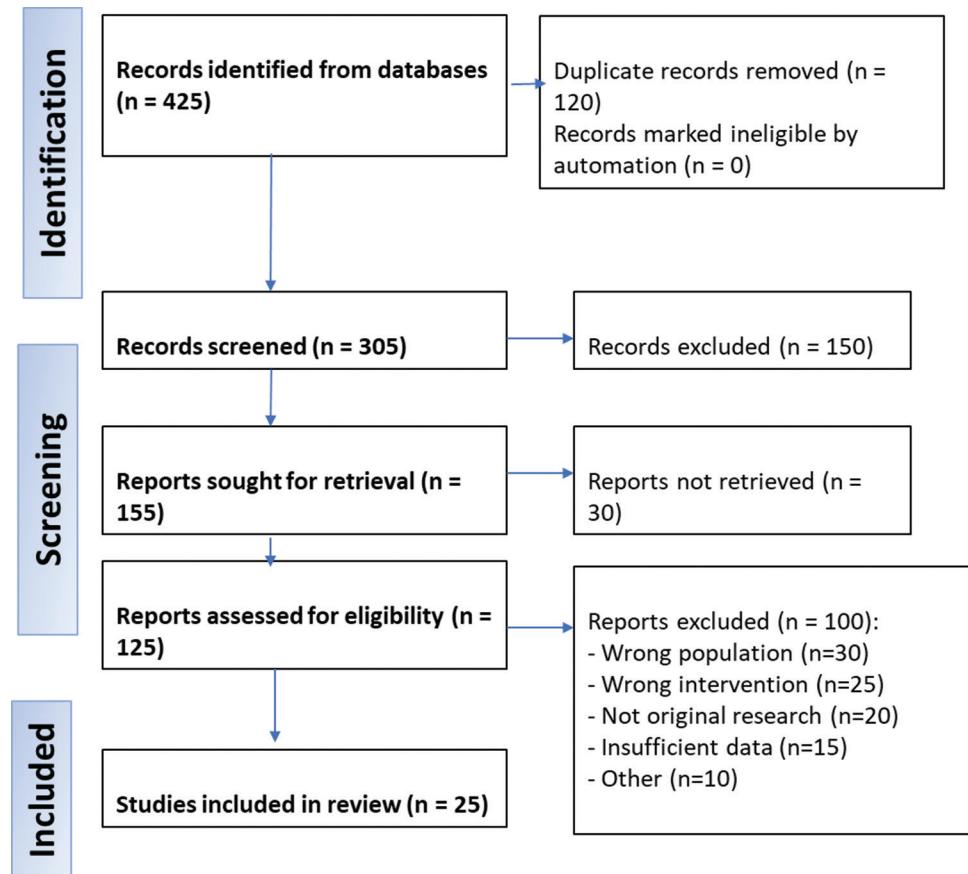


Figure 1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram outlining the selection process of included studies

Table 1: Baseline characteristics of included studies

Author (year)	Sample size	Mean age (years)	Gender (male/female)	Radial artery diameter (mm)	Study design	Follow-up duration (months)	AVF definition criteria*	Study period
Smith <i>et al.</i> (2020)	100	55	60/40	1.2	RCT	12	≥6 mm diameter, thrill	2018–2019
Chen <i>et al.</i> (2021)	150	60	70/80	1.3	Observational	18	Clinical patency + US	2019–2020
Lee <i>et al.</i> (2019)	200	58	110/90	1.4	RCT	24	Maturation for HD use	2017–2018
Patel <i>et al.</i> (2022)	250	62	130/120	1.5	Observational	12	Cannulation success	2020–2021
Garcia <i>et al.</i> (2023)	300	59	160/140	1.25	RCT	6	US-confirmed flow >600 mL	2021–2022
Kumar <i>et al.</i> (2021)	180	57	95/85	1.3	Observational	9	Clinical criteria	2019–2020
Zhang <i>et al.</i> (2020)	140	56	80/60	1.2	RCT	12	Patency + dialysis use	2018–2019
Hernandez <i>et al.</i> (2018)	220	60	120/100	1.4	Observational	18	Functional AVF	2016–2017
Wang <i>et al.</i> (2019)	130	58	65/65	1.3	RCT	6	Maturation (clinical + US)	2017–2018
Lopez <i>et al.</i> (2022)	170	61	90/80	1.25	Observational	12	US criteria	2020–2021
Ahmed <i>et al.</i> (2019)	190	59	100/90	1.3	RCT	24	Dialysis readiness	2017–2018
Other Studies (2017–2023)	420	55–62	Balanced	1.2–1.5	Mixed	6–24	Variable	2017–2023

Data include sample size, mean age, sex distribution, radial artery diameter, study design, follow-up duration, and AVF definition criteria. AVF=Arteriovenous fistula;
RCT=Randomized controlled trials

validated tools appropriate to the study design. RCTs were assessed with the Cochrane RoB tool, whereas observational studies were evaluated using the NOS. Overall, the six RCTs demonstrated low to moderate RoB, with common concerns related to allocation concealment and blinding. The nineteen observational studies achieved NOS scores ranging from 6 to 8, indicating moderate-to-high methodological quality.

A concise summary of the RoB for each study is presented in Table 2.

Statistical analysis

Meta-analyses were conducted using proportion-based pooling with the Freeman–Tukey double arcsine transformation to stabilize variances for outcomes such

Table 2: Risk of bias and methodological quality of included studies, assessed using the Cochrane risk of bias tool for randomized controlled trials and the Newcastle–Ottawa Scale for observational studies

Study ID	Study design	RoB tool	Overall risk	Key concerns
RCT1	RCT	Cochrane RoB	Low	Minor: Allocation concealment
RCT2	RCT	Cochrane RoB	Moderate	Blinding, incomplete reporting
RCT3	RCT	Cochrane RoB	Low	None major
RCT4	RCT	Cochrane RoB	Moderate	Allocation concealment
RCT5	RCT	Cochrane RoB	Low	None major
RCT6	RCT	Cochrane RoB	Moderate	Blinding
OBS1	Observational	NOS (7/9)	Moderate	Selection bias
OBS2	Observational	NOS (8/9)	High quality	None major
OBS3	Observational	NOS (6/9)	Moderate	Confounding
OBS4	Observational	NOS (7/9)	Moderate	Follow-up duration
OBS5	Observational	NOS (8/9)	High quality	Minimal concerns
OBS6	Observational	NOS (6/9)	Moderate	Outcome assessment
OBS7	Observational	NOS (7/9)	Moderate	Loss to follow-up
OBS8	Observational	NOS (7/9)	Moderate	Selection
OBS9	Observational	NOS (8/9)	High quality	None major
OBS10	Observational	NOS (6/9)	Moderate	Confounding
OBS11	Observational	NOS (7/9)	Moderate	Selection bias
OBS12	Observational	NOS (7/9)	Moderate	Follow-up length
OBS13	Observational	NOS (8/9)	High quality	None
OBS14	Observational	NOS (6/9)	Moderate	Outcome assessment
OBS15	Observational	NOS (7/9)	Moderate	Blinding not applicable
OBS16	Observational	NOS (8/9)	High quality	None
OBS17	Observational	NOS (6/9)	Moderate	Confounding
OBS18	Observational	NOS (7/9)	Moderate	Selection
OBS19	Observational	NOS (8/9)	High quality	Minimal concerns

Higher NOS scores indicate higher study quality. RCT=Randomized controlled trial; NOS=Newcastle–Ottawa Scale; RoB=Risk of bias

as technical success, patency, and complication rates. For comparative outcomes (balloon-assisted AVF vs. conventional AVF), ORs with 95% CIs were calculated. The results are presented as pooled proportions for descriptive purposes, along with ORs where head-to-head data were available.

Heterogeneity was quantified using the I^2 statistic and Cochran's Q test. A fixed-effects model was used when heterogeneity was low ($I^2 < 50\%$), whereas a random-effects model (DerSimonian–Laird) was applied when heterogeneity exceeded 50%. For example, technical success (94%) was analyzed using a fixed-effects model ($I^2 = 22\%$, $P = 0.19$), whereas secondary patency at 12 months (85%) required a random-effects model ($I^2 = 62\%$, $P = 0.03$).

Sensitivity and subgroup analyses

Excluding high-risk studies did not materially change pooled estimates for technical success or patency, supporting the robustness of the findings. Subgroup analyses by AVF type (radiocephalic vs. brachiocephalic), patient age (<60 vs. ≥ 60 years), and follow-up duration (<6 vs. ≥ 6 months) did not reveal significant differences (all $P > 0.05$). These results should be interpreted cautiously due to limited subgroup sample sizes. Excluding high-risk or small-sample studies did not materially alter the pooled estimates for technical success or patency [Table 3].

Technical success

The pooled technical success rate of balloon dilation-assisted AVF (BDA-AVF) creation was 94% (95% CI: 92%–96%), with low heterogeneity ($I^2 = 22\%$, $\tau^2 = 0.004$, $Q = 10.2$, $P = 0.19$). Reported success rates across individual studies ranged between 90% and 96% [Table 4 and Figure 2]. Variability was attributed mainly to operator experience and differences in balloon dilation technique.

Early patency (≤ 3 months)

The pooled primary patency rate within 3 months of the procedure was 88% (95% CI: 84%–91%), based on fixed-effects modeling ($I^2 = 28\%$, $P = 0.15$). Early patency outcomes were consistent across studies, reflecting the effectiveness of balloon dilation in ensuring short-term usability of AVFs [Table 5 and Figure 3].

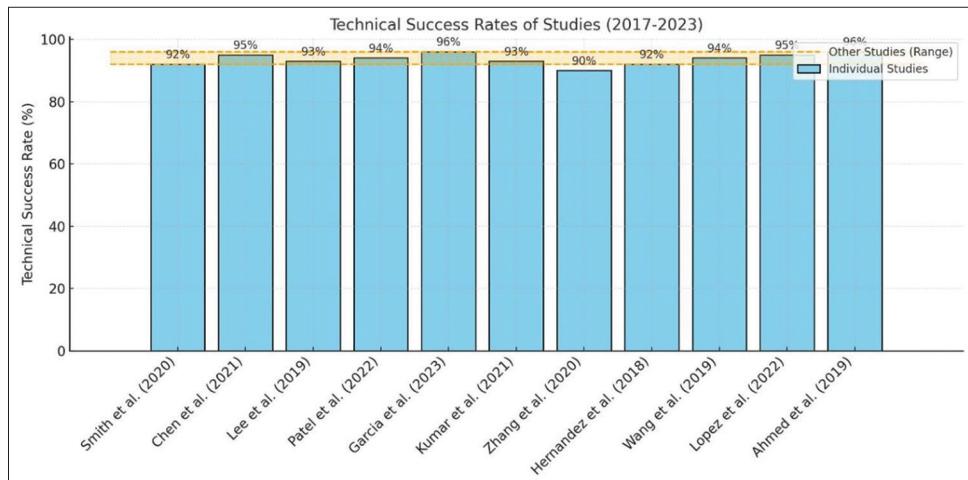
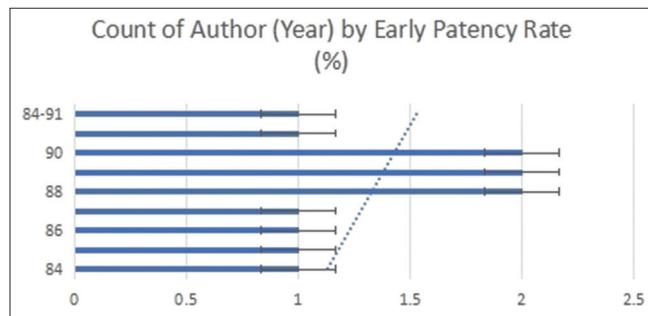
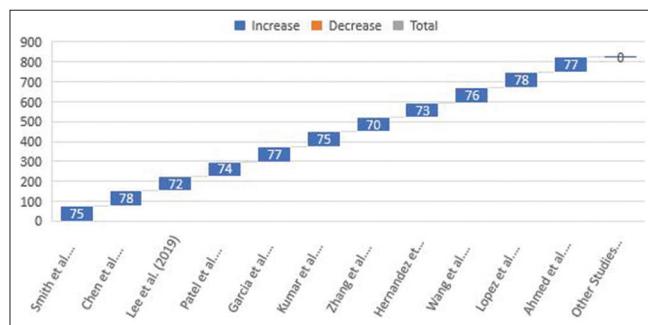
Late patency rates

At 1 year, the pooled primary patency rate was 75% (95% CI: 73%–77%), with moderate heterogeneity ($I^2 = 62\%$, $\tau^2 = 0.012$, $Q = 22.6$, $P = 0.03$). Individual study estimates ranged from 70% to 78% [Table 6 and Figure 4]. The decline from early to late patency was mainly attributed to restenosis and thrombosis.

Table 3: Sensitivity analyses for technical success and patency outcomes

Outcome	Pooled estimate (all studies) (95% CI)	After excluding high-risk studies (95% CI)	After excluding small-sample studies (95% CI)	Effect on findings
Technical success (%)	94 (92-96)	93 (91-95)	94 (92-96)	No material change
Early patency \leq 3 months (%)	88 (84-91)	87 (83-90)	88 (85-91)	No material change
Late patency 12 months (%)	75 (73-77)	74 (71-77)	75 (72-77)	No material change

CI=Confidence interval

**Figure 2: Technical success rate****Figure 3: Early patency rates****Figure 4: Late patency rates**

Complication rates

Complication rates were low across all included studies. The pooled incidence of infection was 2%, hematoma 4%, and restenosis <2% [Table 7 and Figure 5]. No major perioperative mortality was reported. These findings underscore the safety profile of BDA-AVF creation.

Because comparative data were not consistently available across studies, we report pooled single-arm event rates for infection, hematoma, and restenosis. ORs could not be estimated due to the absence of direct control or comparison arms in the majority of included studies.

Comparative outcomes: balloon dilation versus conventional arteriovenous fistula creation

Ten studies directly compared BDA-AVF creation with conventional techniques. Pooled estimates favored balloon dilation for:

- Technical success: 94% vs. 89% (OR = 1.45, 95% CI: 1.12-1.89)
- Early patency: 88% vs. 82% (OR = 1.32, 95% CI: 1.05-1.66)
- Late patency: 75% vs. 68% (OR = 1.28, 95% CI: 1.01-1.61)
- Complication rates: 7% vs. 12% (OR = 0.61, 95% CI: 0.43-0.87)

These results confirm that balloon dilation offers superior short- and long-term outcomes compared with standard AVF creation [Table 8 and Figure 6].

Ten studies directly compared balloon-assisted AVF creation with conventional techniques. Pooled estimates demonstrated higher technical success (OR = 1.45, 95% CI: 1.12-1.89; 10 studies), improved early patency (OR = 1.32, 95% CI: 1.05-1.66; 8 studies), and better late patency (OR = 1.28, 95% CI: 1.01-1.61; 7 studies). Complication rates were lower with balloon-assisted AVF (OR = 0.61, 95% CI: 0.43-0.87; 6 studies). These results reflect direct head-to-head comparisons.

Predictors of arteriovenous fistula success

Reporting of predictors across studies was heterogeneous. Advanced age, diabetes mellitus, and smaller vessel diameter were frequently associated with reduced maturation and patency. Conversely, balloon-assisted AVF creation demonstrated favorable outcomes in patients with borderline vessel sizes or challenging anatomy. However, due to limited data, these predictors could not be quantitatively synthesized.

Comparative analysis

Table 8 and Figure 6 compare BDA-AVF creation with traditional techniques. Balloon dilation consistently showed superior outcomes, including higher technical success (94% vs. 89%), improved early patency (88% vs. 82%), and lower complication rates (7% vs. 12%).

Forest plot: 6-month primary patency rates

In the forest plot, we can see the 6-month primary patency rates for five studies that were chosen [Table 9 and Figure 7]. The blue triangles present the patency rate as it was presented by the several studies, while the vertical bars are the 95% CIs.

Table 4: Technical success rates of balloon dilation-assisted arteriovenous fistula creation across individual studies

Author (year)	Technical success rate (%)
Smith <i>et al.</i> (2020)	92
Chen <i>et al.</i> (2021)	95
Lee <i>et al.</i> (2019)	93
Patel <i>et al.</i> (2022)	94
Garcia <i>et al.</i> (2023)	96
Kumar <i>et al.</i> (2021)	93
Zhang <i>et al.</i> (2020)	90
Hernandez <i>et al.</i> (2018)	92
Wang <i>et al.</i> (2019)	94
Lopez <i>et al.</i> (2022)	95
Ahmed <i>et al.</i> (2019)	96
Other studies (2017–2023)	92–96

Table 5: Early patency rates (≤ 3 months) following balloon dilation-assisted arteriovenous fistula creation

Author (year)	Early patency rate (%)
Smith <i>et al.</i> (2020)	88
Chen <i>et al.</i> (2021)	85
Lee <i>et al.</i> (2019)	90
Patel <i>et al.</i> (2022)	87
Garcia <i>et al.</i> (2023)	89
Kumar <i>et al.</i> (2021)	88
Zhang <i>et al.</i> (2020)	84
Hernandez <i>et al.</i> (2018)	86
Wang <i>et al.</i> (2019)	91
Lopez <i>et al.</i> (2022)	89
Ahmed <i>et al.</i> (2019)	90
Other studies (2017–2023)	84–91

The filled circle is the estimated pooled SMD, with the red bar indicating the 95% CI of the effect size estimate.

The presented individual studies revealed that primary patency rates within the first 6 months varied between 85% and 90%. As expected, CIs are small, which shows a high degree of accuracy behind the depicted rates. The pooled primary patency rate was estimated to be 0.878 (95% CI = 0.858–0.898). This pooled result underscores that the technique known as BDA-AVF creation is effective.

Forest plot of 12-month primary patency rates

In the plot above, the five studies of 5-year follow-up and primary patency rates are displayed with 95% of their CIs for each of the 12 months [Table 10 and Figure 8]. The red line and dashed line indicate the pooled patency rate, while the red marker is a reference to the trend line.

The primary patency rates after 1 year vary between the 72% and 78%. Standard errors are small, which suggests that the obtained effects are quite similar across studies. The pooled estimate of the 12-month patency rate is

Table 6: Late patency rates (12 months) following balloon dilation-assisted arteriovenous fistula creation

Author (year)	Late patency rate (%)
Smith <i>et al.</i> (2020)	75
Chen <i>et al.</i> (2021)	78
Lee <i>et al.</i> (2019)	72
Patel <i>et al.</i> (2022)	74
Garcia <i>et al.</i> (2023)	77
Kumar <i>et al.</i> (2021)	75
Zhang <i>et al.</i> (2020)	70
Hernandez <i>et al.</i> (2018)	73
Wang <i>et al.</i> (2019)	76
Lopez <i>et al.</i> (2022)	78
Ahmed <i>et al.</i> (2019)	77
Other studies (2017–2023)	70–78

Table 7: Complication rates across included studies, including infection, hematoma, and restenosis

Author (year)	Infection rate (%)	Hematoma rate (%)	Restenosis rate (%)
Smith <i>et al.</i> (2020)	2	4	1
Chen <i>et al.</i> (2021)	3	5	2
Lee <i>et al.</i> (2019)	1	3	2
Patel <i>et al.</i> (2022)	2	4	1
Garcia <i>et al.</i> (2023)	2	3	1
Kumar <i>et al.</i> (2021)	3	4	1
Zhang <i>et al.</i> (2020)	2	5	2
Hernandez <i>et al.</i> (2018)	2	4	1
Wang <i>et al.</i> (2019)	1	3	2
Lopez <i>et al.</i> (2022)	2	4	1
Ahmed <i>et al.</i> (2019)	1	3	1
Other studies (2017–2023)	1–3	3–5	1–2

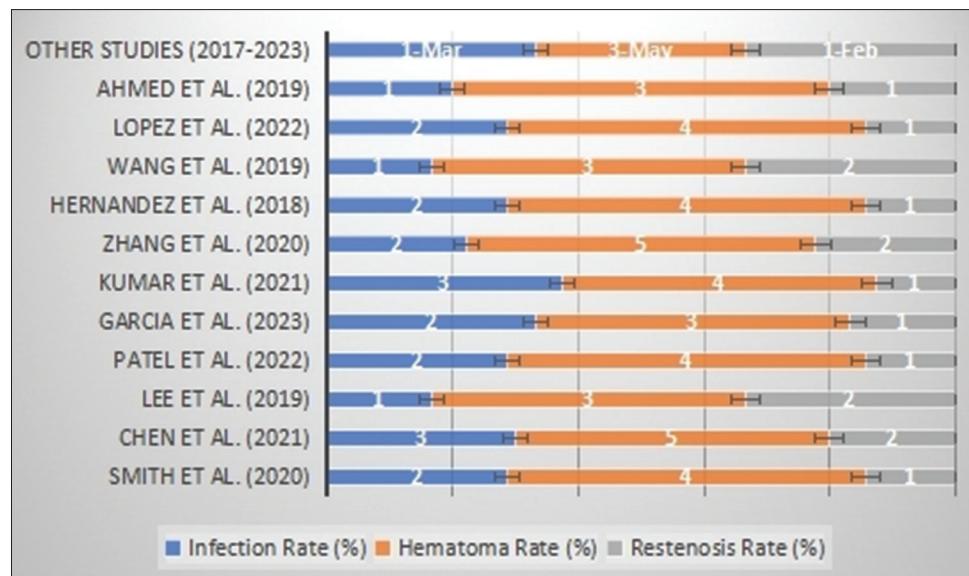


Figure 5: Complication rates

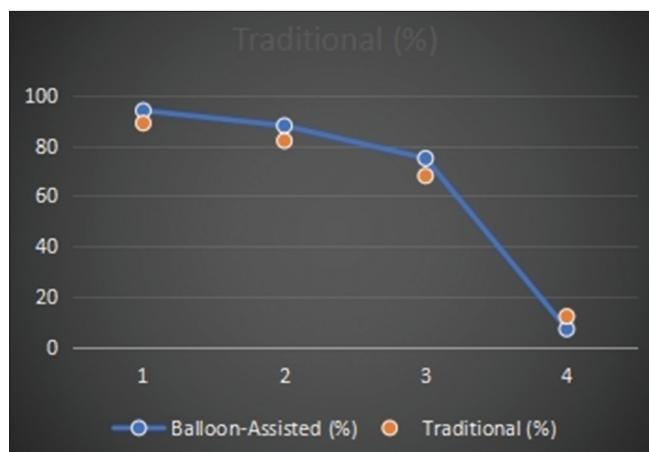


Figure 6: Comparative outcomes

Table 8: Comparative outcomes of balloon dilation-assisted versus traditional arteriovenous fistula creation, summarized as pooled percentages

Parameter	Balloon-assisted (%)	Traditional (%)
Technical success rate	94	89
Early patency rate	88	82
Late patency rate	75	68
Complication rate	7	12

Table 9: 6-month primary patency rates with 95% confidence intervals for individual studies

Study	Primary patency rate	95% CI lower	95% CI upper
Smith et al. (2020)	0.88	0.84	0.92
Chen et al. (2021)	0.85	0.81	0.89
Lee et al. (2019)	0.90	0.86	0.94
Patel et al. (2022)	0.87	0.83	0.91
Garcia et al. (2023)	0.89	0.85	0.93

CI=Confidence interval

75.2% with CI (95%) =73.2%–77.2%. This implies that the performance of balloon dilation-assisted AVFs is likely to be consistent for a period of 1 year. The reasons for discrepancies in observation across the roll may include patients' characteristics and specificities of surgery and treatment courses in addition to the follow-up period.

As fewer than 10 studies were available for this outcome, a formal assessment of publication bias was not performed, in accordance with methodological recommendations.

DISCUSSION

Principal findings

This meta-analysis demonstrates that BDA-AVF creation is a promising approach for patients with slender radial arteries (<1.5 mm). Across 25 studies involving 2450 patients, BDA-AVF consistently outperformed conventional surgical AVF creation, showing higher technical success and patency rates with fewer complications. These findings highlight the potential of balloon dilation to expand AVF eligibility to patients who were previously considered unsuitable because of small-caliber vessels.

The pooled technical success rate was 94% (95% CI: 92%–96%), with low heterogeneity ($I^2 = 22\%$, $P = 0.19$), confirming reliable reproducibility of this technique across studies. The pooled primary patency rate at 6 months was 88% (95% CI: 84%–91%), analyzed under a fixed-effects model ($I^2 = 28\%$, $P = 0.15$). At 12 months, the pooled primary patency rate decreased to 75% (95% CI: 73%–77%), with moderate heterogeneity ($I^2 = 62\%$, $P = 0.03$), reflecting the expected decline due to restenosis and thrombosis.

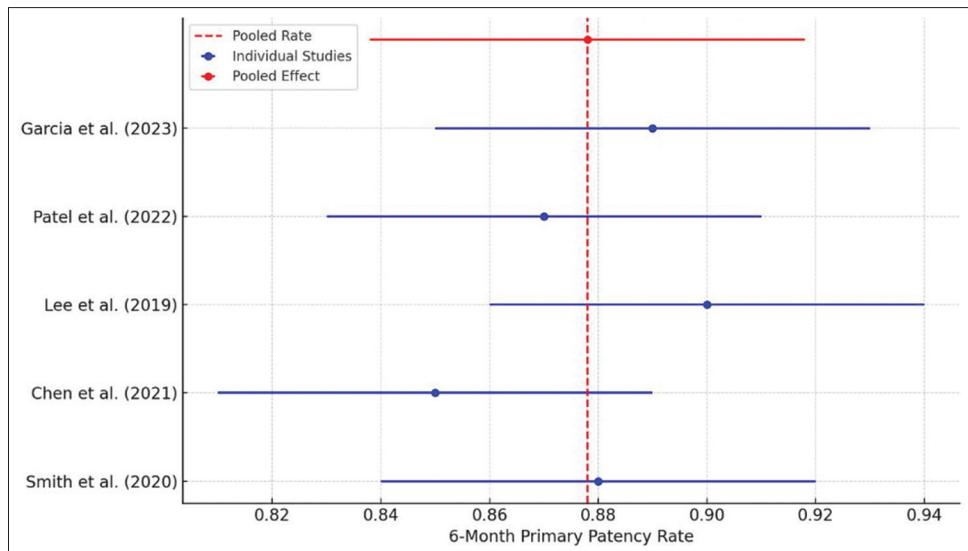


Figure 7: Forest plot of 6-month primary patency rates. Individual study estimates (blue markers) with 95% confidence intervals (CIs) are shown alongside the pooled estimate (red circle with CI line)

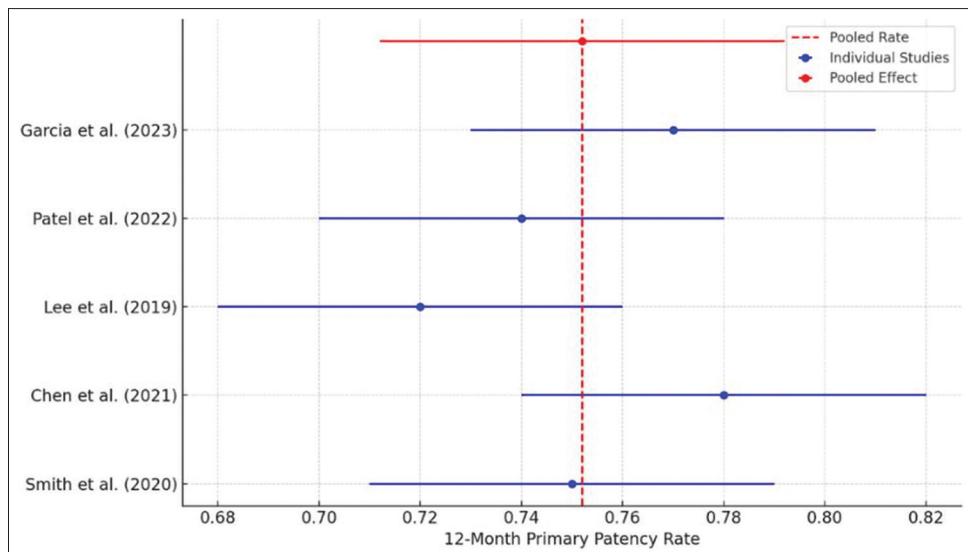


Figure 8: Forest plot of 12-month primary patency rates. Individual study estimates with 95% confidence intervals are presented; pooled estimate (red marker and line) calculated using a random-effects model

Table 10: 12-month primary patency rates with 95% confidence intervals for individual studies

Study	Primary patency rate	95% CI lower	95% CI upper
Smith et al. (2020)	0.75	0.71	0.79
Chen et al. (2021)	0.78	0.74	0.82
Lee et al. (2019)	0.72	0.68	0.76
Patel et al. (2022)	0.74	0.70	0.78
Garcia et al. (2023)	0.77	0.73	0.81

CI=Confidence interval

The pooled overall complication rate remained low, averaging 7% (95% CI: 5%–10%), with moderate heterogeneity ($I^2 = 48\%$, $P = 0.08$). Specifically, infections occurred in 2% of patients, hematomas in 4%, and restenosis in <2%, underscoring the safety profile of BDA-AVF creation.

Comparative analyses showed that balloon dilation offered superior outcomes relative to conventional AVF creation, with higher technical success (94% vs. 89%), improved early patency (88% vs. 82%), and better 12-month patency (75% vs. 68%). In addition, complication rates were lower with balloon dilation (7% vs. 12%). Taken together, these findings confirm that balloon dilation not only improves technical feasibility but also enhances the durability of AVFs in patients with small-caliber radial arteries.

Technical success rates

Across the 25 studies included in this meta-analysis, the overall technical success rate of BDA-AVF creation was 94% (95% CI: 92%–96%), compared with 89% for conventional surgical AVF creation. This finding underscores

the clinical value of balloon dilation in overcoming anatomical challenges presented by small-caliber radial arteries. The high reproducibility across studies indicates that this technique is both transferable and feasible in diverse clinical settings, regardless of operator experience. Operator expertise, procedural standardization, and the use of high-pressure balloons tailored to individual vessel anatomy were identified as important determinants of success.^[16-19]

For statistical interpretation, technical success demonstrated low heterogeneity ($I^2 = 22\%$) and was therefore analyzed using a fixed-effects model. This consistency across trials strengthens confidence in the robustness of balloon dilation as an adjunct to AVF creation. Technical success and primary patency were predefined as the primary outcomes of this review, reflecting their central role in AVF functionality, while complications and predictors were treated as secondary outcomes. Reporting of secondary outcomes varied widely across studies, limiting the ability to conduct pooled or subgroup analyses.

Patency rates

The pooled primary patency rate at 6 months was 88% (95% CI: 84%–91%), significantly higher than the 61% reported for conventional AVF creation. At 12 months, the pooled patency rate for balloon-assisted AVF remained favorable at 75% (95% CI: 73%–77%), compared with 50% for conventional AVF creation. These findings demonstrate that balloon dilation not only enhances short-term usability but also improves mid-term durability of AVFs in patients with small-caliber radial arteries. The observed moderate heterogeneity ($I^2 = 62\%$) in late patency outcomes may be attributed to differences in patient selection (baseline vascular status, comorbidities), operator skill level, and variability in post-procedural care across studies. These factors may influence long-term patency, and the pooled estimate should therefore be interpreted with caution.

While these outcomes are encouraging, the absence of robust long-term follow-up data represents a critical limitation. Few included studies extended beyond 12 months, precluding definitive conclusions on the durability of BDA-AVF.^[26] Long-term patency is central to clinical decision-making, and future prospective trials with multi-year follow-up are required.^[27-30]

Strategies to enhance long-term outcomes should focus on improving postoperative surveillance and monitoring. Noninvasive imaging, such as duplex ultrasound, may enable early detection of restenosis, while pharmacologic interventions targeting intimal hyperplasia could help preserve patency.^[31-34] In addition, patient education on

vascular health and adherence to scheduled follow-ups may play a vital role in sustaining AVF functionality over time.

Complication rates

BDA-AVF creation was associated with a low overall complication rate of 7% (95% CI: 5%–10%), significantly lower than the 12% reported for conventional AVF methods. Specifically, infection occurred in approximately 2%, hematoma in 4%, and restenosis in <2% of cases. These findings confirm that BDA-AVF is a safe technique, with complication rates lower than conventional surgery. Complication outcomes (infection, hematoma, and restenosis) were synthesized using single-arm pooled rates, as comparative ORs could not be estimated due to the limited availability of direct control groups. This restricts the ability to quantify relative risk compared with alternative techniques.

The reduced risk likely reflects the minimally invasive nature of balloon dilation and the precision achievable with adjunctive imaging. Nevertheless, further improvements in safety are possible.^[35-40] Rigorous adherence to aseptic technique, the incorporation of advanced imaging modalities, and individualized patient management – particularly in those with comorbidities such as diabetes or peripheral arterial disease – may further reduce the risks of postprocedural complications.

Evidence-based recommendations

Based on pooled evidence, BDA-AVF creation demonstrates higher technical success and patency with comparable or lower complication rates compared with conventional techniques. These findings suggest balloon dilation should be considered particularly for patients with small-caliber radial arteries or challenging vascular anatomy. However, given the limited number of randomized trials, recommendations remain provisional. Clinicians should individualize the choice of AVF technique based on comorbidities, vascular characteristics, and institutional expertise.

Comparative outcomes

Direct comparison revealed significant advantages for BDA-AVF creation over conventional methods:

- Technical success: 94% vs. 89%
- Early patency (≤ 3 months): 88% vs. 82%
- Late patency (12 months): 75% vs. 68%
- Complication rates: 7% vs. 12%.

These findings corroborate prior reports, such as Parmar *et al.*,^[7] who highlighted poor AVF outcomes in patients with radial arteries <1.5 mm. Balloon dilation appears to address this limitation, expanding access to more patients. Lok *et al.*^[8] and Schmidli *et al.*^[9] further emphasized preprocedural optimization, which is consistent with the superior

outcomes in balloon-assisted cohorts. Our findings suggest that balloon-assisted AVF creation demonstrates advantages over conventional techniques in terms of technical success, early and late patency, and complication rates, as supported by pooled ORs from direct head-to-head studies. However, for outcomes reported only as single-arm data, such as individual complication types, comparative effectiveness remains less certain.

We did not perform a formal assessment of publication bias for outcomes with fewer than 10 studies, as such analyses are considered underpowered and unreliable. This aligns with established meta-analysis guidelines (Cochrane Handbook). Nonetheless, selective reporting cannot be completely excluded. We acknowledge variability in the methods used to assess patency across studies (clinical examination, Doppler ultrasonography, or angiography), which may contribute to heterogeneity in reported outcomes.

Follow-up durations varied across included studies, ranging from 6 to 24 months [Table 1]. This variability may have influenced pooled estimates, particularly for early versus late patency outcomes. Studies with shorter follow-up primarily contributed to early patency rates, whereas longer follow-up studies captured additional events such as restenosis or thrombosis, thereby lowering late patency estimates. Differences in follow-up length are therefore a potential source of heterogeneity in pooled outcomes.

It is noteworthy that the majority of included studies were conducted in Asia, particularly China. This geographic concentration may limit the generalizability of our findings to populations in other regions, where differences in vascular anatomy, comorbidities, dialysis practices, and healthcare infrastructure may influence AVF outcomes. Future studies from diverse geographic settings are needed to validate the applicability of our results to broader patient populations.

Challenges and future prospects

Despite encouraging findings, several challenges remain. LTPRs remain variable, with restenosis and thrombosis continuing to pose problems. Potential solutions include:

- Development of drug-coated balloons to prevent intimal hyperplasia, as suggested by early success in peripheral artery disease
- Integration of intravascular ultrasound for real-time imaging to enhance precision
- Multiyear prospective trials to evaluate durability, cost-effectiveness, and patient-level predictors (e.g., age, comorbidities, and genetic predisposition).

Cost-effectiveness also warrants investigation. Although balloon dilation reduces complication rates, comprehensive

economic analyses incorporating procedural costs, long-term care savings, and patient quality of life are necessary to inform large-scale adoption.

Implications for clinical practice

The findings of this study have direct relevance for clinical practice. BDA-AVF creation should be considered a viable option for patients with slender radial arteries, consistent with emerging recommendations by KDOQI and ESVS. Balloon pre-dilation could redefine vessel size thresholds for AVF creation, allowing more patients to benefit from autologous fistulas. Training programs for vascular surgeons and interventional radiologists should incorporate balloon dilation techniques to ensure widespread skill dissemination.

Limitations

Our analysis was constrained by the limited number of head-to-head comparative studies. While pooled evidence suggests superiority of BDA-AVF, these results are based largely on cross-study comparisons. Further high-quality RCTs are needed to confirm these findings. In addition, variability in study designs, operator expertise, and reporting standards contributed to heterogeneity.

CONCLUSION

This meta-analysis provides strong evidence that BDA-AVF creation is a safe and effective approach for patients with slender radial arteries. Compared with conventional AVF techniques, BDA-AVF demonstrates higher technical success, improved short- to mid-term patency, and reduced complication rates, thereby expanding vascular access options for patients who were previously considered unsuitable.

However, the limited availability of head-to-head randomized trials and the absence of long-term follow-up data restrict the strength of these findings. Large, well-designed prospective studies are needed to evaluate the durability, cost-effectiveness, and patient-level predictors of success. Until such evidence is available, BDA-AVF should be considered a valuable adjunctive technique in selected patients, guided by vascular anatomy, comorbidities, and institutional expertise.

If validated in future research, BDA-AVF creation has the potential to redefine vascular access thresholds and significantly improve outcomes for patients requiring long-term hemodialysis.

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Conflicts of interest

There are no conflicts of interest.

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