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Comparing the Outcomes of Antecubital Arteriovenous Fistulas with and Without Perforating Vein Ligation in Hemodialysis Patients

Amin Kalkatehchi [1], Bahman Alinezhad [1,*], Saman Ketabchian [1]

[1] Department of General Surgery, School of Medicine, Urmia, Iran

[*] ***Corresponding Author:*** Department of General Surgery, School of Medicine, Urmia University of Medical Sciences, Urmia, Iran. Email: dr.alinezhad@yahoo.com

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Abstract

Background: Management of the perforating vein during the creation of an antecubital arteriovenous fistula (AVF) remains controversial.

Objectives: This study compared outcomes after antecubital AVF creation with and without perforating vein ligation in patients requiring hemodialysis.

Methods: A prospective, single-center, open-label randomized controlled trial was conducted at the Department of Vascular Surgery and Urology, Imam Khomeini Hospital, Urmia University of Medical Sciences, Iran, from March 1, 2024, to March 31, 2025. A total of 60 patients with end-stage renal disease were randomized, with 30 patients allocated to each group. The complete-case analysis included 58 patients: 28 in the ligation group and 30 in the preservation group. Outcomes assessed over six months included fistula maturation time, the number of mature veins, venous hypertension, steal syndrome, and dialysis adequacy.

Results: Baseline demographic and clinical characteristics were similar between groups. Venous hypertension occurred in 7.1% of the ligation group and 10.0% of the preservation group (P = 1.000). Steal syndrome occurred in 3.6% and 0.0%, respectively (P = 0.483). The mean time to functional fistula maturation was 42.6 versus 40.8 days (P = 0.407), and the mean number of usable cannulation veins was 1.32 versus 1.37 (P = 0.710). Among patients with mature fistulas who completed six-month follow-up, functional dialysis adequacy was achieved in all evaluable participants in both groups (100% versus 100%).

Conclusions: In this preliminary, single-center randomized trial, routine perforating vein ligation during antecubital AVF creation did not demonstrate a statistically detectable advantage in time to maturation, usable vein count, or early complication rates. However, the six-month follow-up is a major limitation. Larger, multicenter trials with longer follow-up (12 - 24 months) are required to establish noninferiority, late structural stability, and long-term patency.

Keywords: Arteriovenous Fistula, Antecubital Arteriovenous Fistula, Antecubital Fossa, Perforating Vein, Ligation, Vascular Access, Hemodialysis, Fistula Maturation, Renal Dialysis

1. Background

End-stage renal disease is a growing global public health challenge, with increasing numbers of patients requiring long-term renal replacement therapy (1). For patients undergoing hemodialysis, establishing and maintaining durable vascular access is critical for treatment efficacy and long-term survival (2). The native arteriovenous fistula (AVF) is considered the gold standard for vascular access because of its superior patency, lower infection risk, and reduced need for intervention compared with arteriovenous grafts or central venous catheters, as supported by the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines (3). In patients with compromised forearm vasculature or advanced calcific atherosclerosis of the radial artery, a perforating vein fistula (PVF) is a valuable autogenous alternative (4). Reported primary and

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secondary patency rates for PVFs range from 37.4% to 76.3% and from 28.8% to 74.2%, respectively, over extended follow-up periods (5). These fistulas are also associated with fewer complications than other AVF configurations, including steal syndrome (6).

Despite the advantages of autogenous fistulas, successful maturation remains a substantial clinical challenge (7). Maturation failure, defined as the inability of a fistula to support adequate dialysis blood flow within a reasonable period, occurs in 20% - 60% of cases (8). Nonmaturation has multiple contributing factors, including vessel diameter, arterial inflow quality, and venous outflow resistance (9). A critical hemodynamic factor is the redirection of high-flow arterial blood into the low-resistance superficial venous system (8). However, collateral side branches and perforating veins can divert blood from the main venous conduit into the deep venous system, thereby reducing the pressure and flow required for arterialization and dilation of the target vein (3, 10).

This phenomenon is particularly relevant to fistulas created in the antecubital fossa, including brachiocephalic and high radiocephalic fistulas (11). Cubital fossa anatomy is variable and frequently includes a perforating, or communicating, vein that connects the superficial and deep venous systems (12). Management of this vein during AVF creation remains controversial among vascular and transplant surgeons (13). Proponents of routine ligation argue that closing this deep communication directs blood flow into the superficial vein, thereby accelerating maturation and increasing flow volume (14). Ligation may also theoretically reduce forearm venous hypertension (15). Conversely, opponents argue that preserving the perforator minimizes dissection, reduces operative time, and preserves a potential outflow pathway if the superficial system becomes occluded.

The literature provides conflicting evidence regarding routine ligation, and surgical decisions are frequently guided by individual preference rather than high-level evidence (16). Prospective comparative data on this technique in the Iranian population are limited.

2. Objectives

This study compared the clinical outcomes of antecubital AVFs created with or without perforating vein ligation, focusing on primary patency, time to maturation, and postoperative complications.

3. Methods

3.1. Study Design

This prospective, single-center, open-label randomized clinical trial was conducted at the Department of Vascular Surgery and Urology, Imam Khomeini Hospital, Urmia University of Medical Sciences, Iran. Participant recruitment and baseline assessments took place from March 1, 2024, to September 30, 2024, and six-month postoperative follow-up was completed on March 31, 2025. The study protocol was approved by the institutional Ethics Committee (approval ID: IR.UMSU.HIMAM.REC.1403.092) and conducted in accordance with the Declaration of Helsinki. The trial was registered with the Iranian Registry of Clinical Trials (IRCT) under registration number [IRCT20240228061124N2].

3.2. Participants and Eligibility Criteria

The study included patients with ESRD who required permanent hemodialysis access.

3.2.1. Inclusion Criteria

Eligible patients were adults aged > 18 years who were referred for primary AVF creation in the cubital fossa and had suitable vascular anatomy, defined as brachial artery and cephalic/median cubital vein diameters ≥ 2.5 mm, as assessed by preoperative physical examination and Doppler ultrasound.

3.2.2. Exclusion Criteria

Exclusion criteria were previous surgical access in the ipsilateral arm, significant peripheral arterial disease, active systemic infection, and documented coagulation disorders. Coagulation disorders were screened preoperatively using clinical history and standard hematological tests. Patients were excluded for the following: 1) a baseline platelet count < 100 × 10^9/L; 2) uncorrected coagulopathy, defined as an international normalized ratio > 1.5, prothrombin time > 3 seconds above the control value, or activated partial thromboplastin time > 1.5 times the upper institutional reference limit; 3) a confirmed congenital or acquired bleeding diathesis; or 4) therapeutic systemic anticoagulation that precluded standard perioperative heparinization.

Baseline demographic and clinical data, including age, sex, duration of hemodialysis, left ventricular ejection fraction, diabetes mellitus (DM), heart failure (HF), and hypertension (HTN), were collected using a standardized data collection form.

3.3. Randomization and Allocation Concealment

Eligible patients were randomized before surgery in a 1:1 ratio to the ligation or preservation group using a

computer-generated permuted block schedule with a fixed block size of 4. An independent biostatistician with no clinical involvement in participant recruitment, treatment, or assessment generated the allocation sequence.

Clinical research coordinators and vascular surgical fellows screened and enrolled eligible participants in the outpatient vascular access clinic before admission. Allocation concealment was strictly maintained using sequentially numbered, opaque, sealed envelopes prepared and secured by the independent biostatistician. The sealed envelope corresponding to each participant's recruitment ID was transferred to the operating theater on the day of surgery. To preclude selection and preparatory bias, the envelope remained sealed until surgical exposure of the cubital fossa was complete and intraoperative inspection confirmed anatomical eligibility (vessel calibers ≥ 2.5 mm without aberrant branches). Immediately before arteriotomy and anastomosis construction, the circulating operating theater nurse opened the envelope and announced the assigned intervention (perforating vein ligation vs. preservation) to the surgical team.

3.4. Blinding and Bias Mitigation

The operating surgeon could not be blinded because of the nature of the intervention. To minimize detection and assessment bias, a prospective randomized open-label blinded end-point (PROBE) design was used. All postoperative duplex ultrasound assessments of vein diameter, depth, and flow volume, based on the Rule of 6s, were performed by an independent certified vascular sonographer blinded to group allocation. Nephrologists, hemodialysis nurses who assessed dialysis adequacy, and clinicians who screened for venous hypertension and steal syndrome were also blinded to group allocation.

3.5. Surgical Technique

All procedures were performed by a single surgical team under local anesthesia with 2% lidocaine. Access was established through a 3 - 4 cm oblique incision in the antecubital fossa along the course of the brachial artery. The median cubital vein was mobilized and dissected distally toward its confluence with the cephalic vein, exposing the perforating vein, which typically originated at this junction. The brachial artery was exposed beneath the bicipital aponeurosis, and a 2 - 3 cm arterial segment was mobilized to allow a tension-free anastomosis.

Systemic anticoagulation was routinely administered as an intravenous bolus of unfractionated heparin (50 IU/kg) 3 - 5 minutes before arterial cross-clamping. Heparin was omitted only in patients with documented contraindications; protamine reversal was not routinely used. After vessel occlusion, a 6 - 8 mm longitudinal arteriotomy was made, and a side-to-side arteriovenous anastomosis was constructed with a continuous 6 - 0 polypropylene suture. The perforating vein was managed according to group allocation.

3.5.1. Ligation Group

The perforating vein was ligated with nonabsorbable silk sutures to direct inflow into the superficial venous network.

3.5.2. Preservation Group

The perforating vein was left patent without surgical manipulation or occlusion.

Hemostasis was confirmed, and the incision was closed in layers.

3.6. Outcome Measures and Assessment Protocols

Each participant underwent six months of postoperative follow-up. Follow-up assessments took place between March 2024 and March 31, 2025, with clinical and sonographic evaluations scheduled at 2, 4, 6, and 8 weeks and at 6 months after surgery. All sonographic, nephrological, and clinical outcome assessors remained blinded to group allocation under the PROBE design.

3.6.1. Fistula Maturation

Maturation was assessed at each follow-up visit using B-mode and duplex Doppler ultrasound (Mindray Resona 7, a linear 3 - 11 MHz transducer), performed by an independent certified vascular sonographer blinded to group allocation. Maturation was established when the fistula met the Rule of 6s criteria:

Blood flow volume > 600 mL/min, measured in a straight brachial artery segment ≥ 2 cm proximal to the anastomosis.

Target superficial vein diameter > 6 mm.

Vein depth < 6 mm from the skin surface.

Cannulation length of at least 6 cm.

Maturation time was defined as the interval, in weeks, from surgery to the earliest sonographic confirmation of these criteria. The number of mature, usable superficial outflow channels was recorded at week 8.

3.6.2. Dialysis Adequacy

Functional dialysis adequacy was verified and prospectively recorded by hemodialysis nurses and attending nephrologists blinded to the surgical

intervention. Adequacy was assessed during routine four-hour hemodialysis sessions, typically 2 - 3 times per week. It was defined as the sustained ability to maintain two-needle cannulation with a pump blood flow rate of 300 - 350 mL/min without recurrent circuit interruptions, excessive prepump arterial collapse, or venous pressure > 200 mmHg. Biochemical clearance was confirmed by routine monthly laboratory testing, with an adequate single-pool Kt/V ≥ 1.2 or urea reduction ratio ≥ 65%.

3.6.3. Primary Patency and Complications

Primary patency was calculated from access creation to the first surgical or endovascular salvage intervention, access thrombosis, or completion of six-month follow-up. Blinded clinicians screened for complications at each scheduled visit. These included persistent upper limb venous hypertension, defined as edema distal to the anastomosis lasting beyond 8 weeks, and dialysis access steal syndrome, characterized by pallor, coldness, paresthesia, or ischemic rest pain.

3.7. Sample Size Method

The required sample size was determined a priori using reference parameters from Kakaei et al. (17), who reported venous hypertension rates of 86.3% in the ligation group and 70.0% in the preservation group. Assuming a two-tailed significance level of $\alpha = 0.05$ and a statistical power of 80% ($1 - \beta = 0.80$), the target enrollment was calculated to be 36 participants per arm (total planned N = 72).

Recruitment was limited to 60 randomized patients, 30 per group, because of institutional recruitment-window constraints, resulting in an enrollment below the planned sample size. Of these, 58 patients (96.7%) completed the six-month protocol and were included in the primary complete-case analysis.

All 30 patients in the preservation group completed follow-up, with no losses (0/30, 0.0%). In the ligation group, two patients were excluded after randomization. One was excluded intraoperatively, before anastomosis construction, because of anomalous vascular anatomy comprising a high brachial artery bifurcation with complex venous arborization. The other was lost to follow-up at postoperative month 2 after relocating to another hemodialysis facility (1/30, 3.3%). Thus, 28 patients in the ligation group completed six-month follow-up and were included in the final analysis (Figure 1).

The observed venous hypertension rates in our cohort, 7.1% versus 10.0%, were substantially lower than the historical estimates, primarily reflecting standardized diagnostic criteria requiring persistent edema beyond 8 weeks and routine preoperative duplex mapping. These lower event rates and the reduced sample size suggest that the study was underpowered to detect small differences in venous hypertension. A post hoc calculation indicated an achieved statistical power of approximately 68.4% to detect the proposed 16.3% absolute risk reduction at $\alpha = 0.05$. Given these limitations, findings are interpreted using point estimates, effect sizes, and 95% confidence intervals (CIs), including risk differences (RDs) and relative risks (RRs) for categorical outcomes and mean differences (MDs) for continuous outcomes.

3.8. Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics, version 26.0. Continuous data are presented as means and standard deviations (SDs), and categorical data as counts and percentages. The Kolmogorov-Smirnov test was used to assess the normality of quantitative variables. Normally distributed continuous variables were compared between groups using the independent-samples t-test. Categorical variables were compared using the Pearson chi-square test or the Fisher exact test, as appropriate. Statistical significance was defined as $P < 0.05$.

4. Results

4.1. Participant Flow and Baseline Enrollment

Baseline demographic, clinical, and preoperative anatomical characteristics were similar between groups (Table 1). Mean age was 56.4 ± 11.2 years in the ligation group and 54.8 ± 10.8 years in the preservation group (MD, 1.60 years; 95% confidence interval [CI], -4.14 - 7.34 years; P = 0.579). The proportions of male participants were 64.3% and 63.3%, respectively (relative risk [RR], 1.02; 95% CI, 0.69 - 1.49; P = 0.939). Mean body mass index was 25.8 ± 3.4 versus 26.1 ± 3.2 kg/m^2 (MD, -0.30 kg/m^2; 95% CI, -2.02 - 1.42 kg/m^2; P = 0.730), and dialysis vintage before access creation was 14.2 ± 6.8 versus 13.6 ± 7.1 months (MD, 0.60 months; 95% CI, -3.03 - 4.23 months; P = 0.742).

Preoperative duplex ultrasonography showed similar vascular dimensions in the two groups. Mean brachial artery internal diameter was 4.18 ± 0.44 mm in the ligation group and 4.12 ± 0.41 mm in the preservation group (MD, 0.06 mm; 95% CI, -0.16 - 0.28 mm; P = 0.596). Median cubital vein diameter was 3.18 ± 0.36 versus 3.24 ± 0.39 mm (MD, -0.06 mm; 95% CI, -0.26 - 0.14 mm; P = 0.548), and cephalic outflow vein diameter was 2.96 ± 0.34 versus 3.01 ± 0.36 mm (MD, -0.05 mm; 95% CI, -0.23 - 0.13 mm; P = 0.591). All enrolled vessels met the minimum preoperative diameter threshold of ≥ 2.5 mm.

Although comorbidity frequencies did not differ significantly, numerical imbalances were observed for DM,

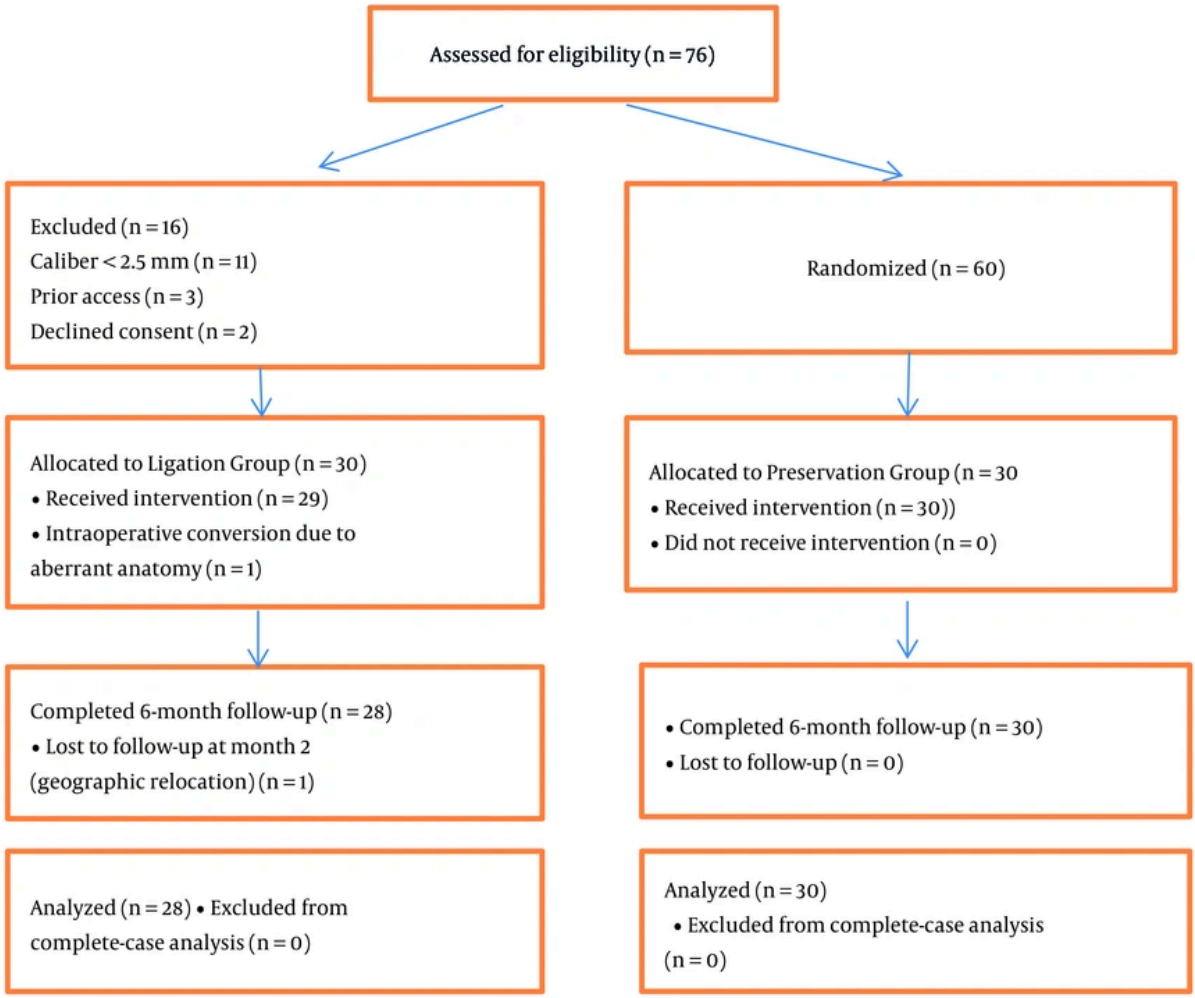

Figure 1. CONSORT Flow Diagram of Participant Progression Through Trial Phases.

which was present in 39.3% of the ligation group and 20.0% of the preservation group (RR, 1.96; 95% CI, 0.84 - 4.60; P = 0.165), and congestive HF, which was present in 14.3% and 3.3%, respectively (RR, 4.29; 95% CI, 0.51 - 36.08; P = 0.198). These differences warrant clinical consideration because diabetes-related microvascular sclerosis and impaired cardiac output may influence systemic perfusion and vascular remodeling. The frequencies of systemic hypertension (82.1% versus 80.0%; P = 0.835) and tobacco smoking history (28.6% versus 23.3%; P = 0.648) were similar between groups.

4.2. Postoperative Outcomes and Fistula Maturation

Primary and secondary clinical outcomes over six months are summarized in Table 2.

Mean time to functional fistula maturation was 42.6 ± 8.4 days in the ligation group (range, 28 - 62 days; 95% CI, 39.35 - 45.85 days) and 40.8 ± 7.9 days in the preservation group (range, 26 - 58 days; 95% CI, 37.85 - 43.75 days). The between-group MD was 1.80 days (95% CI, -2.50 - 6.10 days; P = 0.407). Successful clinical maturation at six weeks occurred in 78.6% (n = 22) of ligated fistulas and 83.3% (n = 25) of preserved fistulas (RR, 0.94; 95% CI, 0.74 - 1.20; P = 0.747). The mean number of usable cannulation veins was 1.32 ± 0.48 versus 1.37 ± 0.49 (MD, -0.05; 95% CI, -0.30 - 0.21; P = 0.710).

Table 1. Baseline Demographic, Clinical, and Preoperative Vascular Characteristics [a]

Characteristic	Ligation Group (n = 28)	Preservation Group (n = 30)	Difference / Effect (95% CI)	P value
Demographics				
Age (y)	56.4 ± 11.2	54.8 ± 10.8	MD: 1.60 (-4.14 - 7.34)	0.579 [b]
Male sex	18 (64.3)	19 (63.3)	RR: 1.02 (0.69 - 1.49)	0.939 [c]
Body Mass Index (kg/m^2)	25.8 ± 3.4	26.1 ± 3.2	MD: -0.30 (-2.02 - 1.42)	0.730 [b]
Clinical Comorbidities				
Hypertension	23 (82.1)	24 (80.0)	RR: 1.03 (0.80 - 1.32)	0.835 [c]
Diabetes mellitus	11 (39.3)	6 (20.0)	RR: 1.96 (0.84 - 4.60)	0.165 [d]
Congestive heart failure	4 (14.3)	1 (3.3)	RR: 4.29 (0.51 - 36.08)	0.198 [d]
Tobacco smoking history	8 (28.6)	7 (23.3)	RR: 1.22 (0.52 - 2.91)	0.648 [c]
Dialysis vintage (mo)	14.2 ± 6.8	13.6 ± 7.1	MD: 0.60 (-3.03 - 4.23)	0.742 [b]
Preoperative Vascular Calibers (Duplex Ultrasound)				
Brachial artery internal diameter (mm)	4.18 ± 0.44	4.12 ± 0.41	MD: 0.06 (-0.16 - 0.28)	0.596 [b]
Median cubital vein diameter (mm)	3.18 ± 0.36	3.24 ± 0.39	MD: -0.06 (-0.26 - 0.14)	0.548 [b]
Cephalic outflow vein diameter (mm)	2.96 ± 0.34	3.01 ± 0.36	MD: -0.05 (-0.23 - 0.13)	0.591 [b]

[a] Values are expressed as mean ± SD or No. (%). Abbreviations: CI, confidence interval; MD, mean difference; RD, risk difference; RR, relative risk; SD, standard deviation.

[b] Independent-samples t-test.

[c] Pearson chi-square test.

[d] Fisher exact test.

Sonographic hemodynamic measurements at six months did not differ significantly between groups. Mean brachial artery blood flow volume was 884.2 ± 142.6 mL/min in the ligation group and 865.8 ± 138.4 mL/min in the preservation group (MD, 18.40 mL/min; 95% CI, -55.42 - 92.22 mL/min; P = 0.621). Outflow vein internal diameter was 6.82 ± 0.74 mm in the ligation group and 6.71 mm (SD, 0.69 mm) in the preservation group (MD, 0.11 mm; 95% CI, -0.27 - 0.49 mm; P = 0.562). Depth below the skin was 4.21 ± 0.68 versus 4.34 ± 0.71 mm (MD, -0.13 mm; 95% CI, -0.50 - 0.23 mm; P = 0.483). These measurements met the Kidney Disease Outcomes Quality Initiative Rule of 6s thresholds in both groups. At the end of follow-up, all functional accesses maintained adequate hemodialysis clearance (Kt/V ≥ 1.2; 100% versus 100%; risk difference, 0.00; 95% CI, -0.06 - 0.06).

Postoperative adverse events were infrequent. Persistent venous hypertension beyond eight weeks occurred in two patients (7.1%) in the ligation group and three patients (10.0%) in the preservation group (RR, 0.71; 95% CI, 0.13 - 3.97; P = 1.000). Dialysis access steal syndrome occurred in one patient (3.6%) in the ligation group and no patients in the preservation group (RR, 3.21; 95% CI, 0.14 - 75.76; P = 0.483). Early access thrombosis occurred in one patient per group (3.6% versus 3.3%; RR, 1.07; 95% CI, 0.07 - 16.33; P = 1.000). Secondary salvage interventions were required in one patient (3.6%) in the ligation group and two patients (6.7%) in the preservation group (RR, 0.54; 95% CI, 0.05 - 5.59; P = 1.000). The wide confidence intervals reflect uncertainty around these infrequent events; the absence of statistically significant differences does not establish clinical equivalence.

5. Discussion

The increasing prevalence of chronic kidney disease and the growing number of patients requiring hemodialysis highlight the importance of optimizing vascular access to reduce costs and improve quality of life (18). A PVF is a valuable autogenous access option, particularly for patients with unsuitable forearm veins, but the need for perforating vein ligation remains controversial (4). This randomized clinical trial evaluated whether perforating vein ligation affects clinical outcomes. Routine ligation did not demonstrate a statistically detectable benefit in accelerating maturation, improving dialysis adequacy, or reducing venous hypertension and steal syndrome in this cohort.

The clinical and demographic similarities between groups were a methodological strength. Age, sex, disease duration, and comorbidities such as DM and HTN did not differ significantly between groups. These similarities support assessment of the intervention while reducing the potential influence of baseline confounders (19). The absence of previous limb deformities also eliminated a

Table 2. Primary and Secondary Postoperative Outcomes at Six-Month Follow-Up [a]

Outcome Parameter	Ligation Group (n = 28)	Preservation Group (n = 30)	Effect Estimate (95% CI)	P value
Maturation Metrics				
Time to functional maturation (d)	42.6 ± 8.4	40.8 ± 7.9	MD: 1.80 (-2.50 - 6.10)	0.407 [b]
Range (min – max)	28 - 62	26 - 58	—	—
95% Confidence Interval	39.35 - 45.85	37.85 - 43.75	—	—
Successful clinical maturation at 6 weeks	22 (78.6)	25 (83.3)	RR: 0.94 (0.74 - 1.20)	0.747 [c]
Usable superficial veins for cannulation	1.32 ± 0.48	1.37 ± 0.49	MD: -0.05 (-0.30 - 0.21)	0.710 [b]
Hemodynamic Parameters at 6 (Mo)				
Brachial artery blood flow volume (mL/min)	884.2 ± 142.6	865.8 ± 138.4	MD: 18.40 (-55.42 - 92.22)	0.621 [b]
Outflow cephalic/basilic vein diameter (mm)	6.82 ± 0.74	6.71 ± 0.69	MD: 0.11 (-0.27 - 0.49)	0.562 [b]
Depth from skin surface (mm)	4.21 ± 0.68	4.34 ± 0.71	MD: -0.13 (-0.50 - 0.23)	0.483 [b]
Dialysis adequacy (Kt/V ≥ 1.2) at 6 (mo)	28 (100.0)	30 (100.0)	RD: 0.00 (-0.06 - 0.06)	> 0.999 [d]
Postoperative Complications				
Venous hypertension (persistent > 8 wk)	2 (7.1)	3 (10.0)	RR: 0.71 (0.13 - 3.97)	1.000 [d]
Dialysis access steal syndrome	1 (3.6)	0 (0.0)	RR: 3.21 (0.14 - 75.76)	0.483 [d]
Early thrombosis (within 30 d)	1 (3.6)	1 (3.3)	RR: 1.07 (0.07 - 16.33)	1.000 [d]
Wound infection/hematoma	2 (7.1)	1 (3.3)	RR: 2.14 (0.21 - 22.38)	0.607 [d]
Secondary intervention / salvage required	1 (3.6)	2 (6.7)	RR: 0.54 (0.05 - 5.59)	1.000 [d]

[a] Values are expressed as mean ± SD or No. (%) unless otherwise indicated. Abbreviations: AVF, arteriovenous fistula; CI, confidence interval; MD, mean difference; RD, risk difference; RR, relative risk; SD, standard deviation.

[b] Independent-samples t-test.

[c] Pearson chi-square test.

[d] Fisher exact test.

potential anatomical confounder affecting fistula remodeling and complications. The rationale for perforating vein ligation is to prevent diversion of blood into the deep venous system, based on the hypothesis that retrograde runoff may cause deep venous hypertension or delay superficial vein arterialization (20).

Postoperative complications were infrequent: venous hypertension occurred in 7.1% of the ligation group and 10.0% of the preservation group, and steal syndrome was rare. These findings are consistent with those of Harms et al. (21) and Kakaei et al. (17), suggesting that the deep venous system can accommodate fistula hemodynamics without transmitting pathological distal pressure or increasing ischemic risk (22-24). However, complications occurred in only 1 - 3 patients per group, resulting in wide confidence intervals, including an RR confidence interval of 0.14 - 75.76 for steal syndrome. Thus, the absence of statistical significance reflects limited power to detect differences in rare events rather than demonstrated clinical equivalence. Our venous hypertension rates were markedly lower than the rates of 86.3% versus 70.0% attributed to Kakaei et al., which informed the a priori sample size calculation (17). This discrepancy reflects differences in definitions and patient selection: Kakaei et al. captured immediate, transient postoperative swelling, whereas we required chronic edema persisting beyond 8 weeks despite limb elevation. Routine preoperative duplex mapping also excluded vessels < 2.5 mm and outflow obstruction. Historical data using broader complication definitions therefore overestimated baseline risk, leaving this trial underpowered to detect small differences in infrequent outcomes.

Fistula maturation is essential for durable hemodialysis access (25). Preserving the perforating vein did not appear to impair maturation in this cohort; maturation time and the number of usable veins were similar between groups. All evaluable patients achieved functional dialysis adequacy at six months. Although these findings suggest that perforator preservation does not result in acute functional compromise, the 100% adequacy rate should be interpreted cautiously because it reflects a selected cohort with favorable baseline vessel diameters and short follow-up. These findings do not support the hypothesis that a patent perforator causes clinically important venous steal from the superficial cephalic outflow (26), suggesting that brachial inflow can sufficiently pressurize both the deep and superficial venous systems (27). Although previous literature has advocated routine ligation to direct flow

superficially (28) or described the cardiac burden of high-flow fistulas (29, 30), our findings support a selective approach without an apparent reduction in access usability.

The absence of demonstrated clinical superiority with routine ligation suggests that a selective surgical approach may be appropriate. Omitting perforator ligation may reduce dissection and operative time without apparent early functional compromise. However, because this trial was not powered to detect rare outcomes, surgeons should individualize decisions based on vessel diameter, duplex mapping, and intraoperative runoff.

5.1. Study Limitations

First, recruitment ended before the target sample size of 72 was reached, leaving 58 analyzed patients: 28 in the ligation group and 30 in the preservation group. The reported post hoc power was approximately 68.4%. The absence of statistically significant differences should not be interpreted as definitive evidence of clinical equivalence. The study may have been underpowered to detect small or moderate differences, particularly in infrequent complications such as steal syndrome and venous hypertension. Point estimates and confidence intervals are therefore emphasized to convey uncertainty. Observed venous hypertension rates of 7.1% versus 10.0% were substantially lower than the historical rates of 86.3% versus 70.0% attributed to Kakaei et al. and used in the sample size calculation (17). This difference reflects our requirement for edema persisting beyond 8 weeks and routine preoperative duplex mapping that excluded vessels < 2.5 mm. The lower event rates further limited power to detect differences in rare complications and increased the risk of type II error.

Second, the six-month follow-up was a major limitation. Although sufficient to assess early maturation and cannulation success, it could not establish long-term outcomes such as secondary patency, late venous stenosis, aneurysmal degeneration, or high-output cardiac strain. Follow-up of 12 - 36 months is needed to assess late structural integrity.

Third, blinding the operating surgeon and participants was not feasible because of the nature of the intervention. Although outcomes were evaluated by blinded assessors under a PROBE design, performance bias associated with an open-label surgical trial cannot be excluded.

Finally, unstratified randomization resulted in numerical imbalances in DM (39.3% versus 20.0%) and congestive HF (14.3% versus 3.3%). Although these differences were not statistically significant, these conditions affect vascular compliance and central hemodynamics. Residual confounding therefore cannot be excluded in this small cohort.

5.2. Conclusions

Routine perforating vein ligation during antecubital AVF creation did not demonstrate a statistically detectable advantage over six months in time to functional maturation, usable cannulation vein count, or early complication rates, including venous hypertension and steal syndrome. Vein preservation was associated with similar early dialysis adequacy and may reduce dissection time and surgical trauma.

Because the study was underpowered to detect small between-group differences, these preliminary findings do not establish clinical equivalence or noninferiority. The six-month follow-up also precludes conclusions about late aneurysmal degeneration, long-term secondary patency, or cumulative salvage interventions. Adequately powered multicenter trials with several years of follow-up are needed to establish the long-term structural durability and safety of perforating vein preservation.

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Footnotes

Artificial Intelligence Use Disclosure: The authors declare that no generative AI tools were used in the creation of this article.

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