

Original Article

# Arteriovenous Fistula Creation for Hemodialysis in Patients with End-Stage Renal Disease with and Without Surgical Drain: A Randomized Control Trial

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**Abstract****Introduction**

Failure of an arteriovenous fistula (AVF) disrupts hemodialysis access and reduces the available area for future access. Preventive interventions are necessary to avoid AVF failure. This study evaluates the impact of surgical drainage during AVF creation for hemodialysis in patients with end-stage renal disease (ESRD).

**Methods**

This single-center, phase II, randomized controlled trial was conducted from June 2020 to June 2023. Ninety-four patients were randomly assigned into two groups: Group A (with a surgical drain) and Group B (without a drain). Patients were followed for six months post-surgery. The primary outcome was AVF primary patency, and secondary outcomes included postoperative complications.

**Results**

The average age of participants was 63.7 years, with 50 male patients. The most common cause of renal failure was glomerular disease (29.8%), and most AVFs were located on the left side (57.4%). Brachiocephalic AVFs were the most frequent type (70.2%). Postoperative hematoma was more common in Group B (42.6%) than in Group A (17%) ( $P = 0.007$ ). The primary patency rate at six months was higher in Group A (87.2%) compared to Group B (76.6%), though the difference was not statistically significant ( $P = 0.180$ ).

**Conclusion**

The use of surgical drainage during AVF creation may reduce postoperative complications, such as hematomas, and potentially improve primary patency rates, contributing to better outcomes for patients undergoing hemodialysis.

**1. Introduction**

Renal failure is a serious public health problem, and its incidence is increasing. Nowadays, hemodialysis (HD) and kidney transplantation are the main therapies for end-stage renal disease (ESRD) [1]. Regardless of the rise in kidney transplant surgeries, HD remains the mainstay of treatment. In the majority of cases, a phase of hemodialysis preceded the transplantation [2]. Patients who depend on HD require proper vascular access. According to the National Kidney Foundation-Dialysis

Outcomes Quality Initiative (NKF-DOQI) recommendations, optimal vascular access should offer an appropriate flow rate, durability, and a low risk of complications [3]. There are three main types of chronic vascular access for HD, including native arteriovenous fistula (AVF), arteriovenous shunts employing graft material (AV graft), and central venous catheter (CVC). Among them, AVF stands out as the primary vascular access worldwide, given its superior long-term primary patency rate, minimal need for secondary procedures, and its

association with longer survival rates and lower complication rates [4,5]. The NKF-DOQI recommended the radiocephalic fistula in the nondominant forearm as the primary choice for access [6]. With the growing emphasis on AVF and the evolving dialysis population, which now includes a higher proportion of older patients with cardiovascular comorbidities, upper arm fistulas have gained popularity in recent years [7]. The cephalic vein is superficial in the forearm and is easily injured by previous venipunctures, making the creation of radiocephalic AVF difficult. Hence, with the ability to protect the cephalic vein in the arm, a brachiocephalic AVF becomes a practical alternative procedure. [8]. Currently, brachiocephalic AVF is increasing in popularity because of the higher failure rate of radiocephalic fistulas [9]. Insufficient vascular access and associated consequences have been identified as the cause of mortality in about 25% of all patients initiating HD. [5]. Failure of an AVF not only disrupts functional access but also reduces the available area from which another access may be established. Furthermore, interventional techniques must be performed on the patients to repair the failure of AVFs. As a result, minimizing post-operative complications that impact AVF patency and failure rates is of critical importance [9].

The current study aims to assess the overall outcomes and effects of surgical drainage in AVFs for hemodialysis patients with renal failure.

## 2. Methods

### 2.1. Study design and setting

This was a single-center, phase II, open-label, parallel-arm, randomized controlled trial (RCT) conducted between June 1, 2020, and June 1, 2023, involving ESRD patients in need of AVF for hemodialysis or maintenance hemodialysis. The trial aimed to investigate the outcomes and complication rates of AVFs with and without postoperative surgical drains in patients undergoing AVF creation. The study was conducted in accordance with the Helsinki Declaration. The study proposal was approved by the scientific and ethical committee of *B.P. Koirala Institute of Health Sciences*. All patients consented to participate in the trial and the publication of their information. The study's details have been registered in the Chinese Clinical Trial.

### 2.2. Participants

All patients who underwent native AVF creation were included in this study. Participants were excluded if they matched any of the following criteria: (1) having a bleeding disorder; (2) history of antiplatelet use; (3) previous AVF creation; (4) cephalic vein diameter less than 3 mm.

### 2.3. Randomization and masking

Once eligibility was established, the patient's electronic file was initially admitted to a designated mailbox in hospital's database. The second registration was completed after confirming all preoperative requirements for inclusion by computerized assignment. The participants were assigned randomly (1:1) into two groups, Group A (inserting a surgical drain at the site of the

AVF) or Group B (without a surgical drain). The final registration was done when the patient was discharged home, followed up regularly, and met all the inclusion criteria. No masking of the operators or participants in the allocation was performed.

### 2.4. Preoperative assessment

All patients underwent clinical examination to assess the adequacy of the venous and arterial systems of the upper limbs. If the vein was not visible, duplex scanning was requested. Basic investigations, including a complete blood count, viral markers, and electrolytes, were done for all of the cases. Preoperative antibiotic (Cefepime 1gm iv) was given to all of the patients.

### 2.5. Procedure

In the supine position, under local anesthesia (15 cc lidocaine 2%) using a transverse antecubital incision, an end-to-side AVF was created. One cc of heparin (5000 IU) was injected before arterial clamping, and no reversal agent was used in the completion of the procedure. Six zero Prolene with an 8 mm needle was used as the suture material in all procedures. A Redivac drain (size 18 in brachiocephalic and size 16 in radiocephalic AVF) was inserted in the subcutaneous tissues inferolateral to the incision. The patient remained in the hospital overnight. Postoperatively, they were given oral analgesics and antibiotics for five days in accordance with the hospital infection prevention protocol.

### 2.6. Outcome

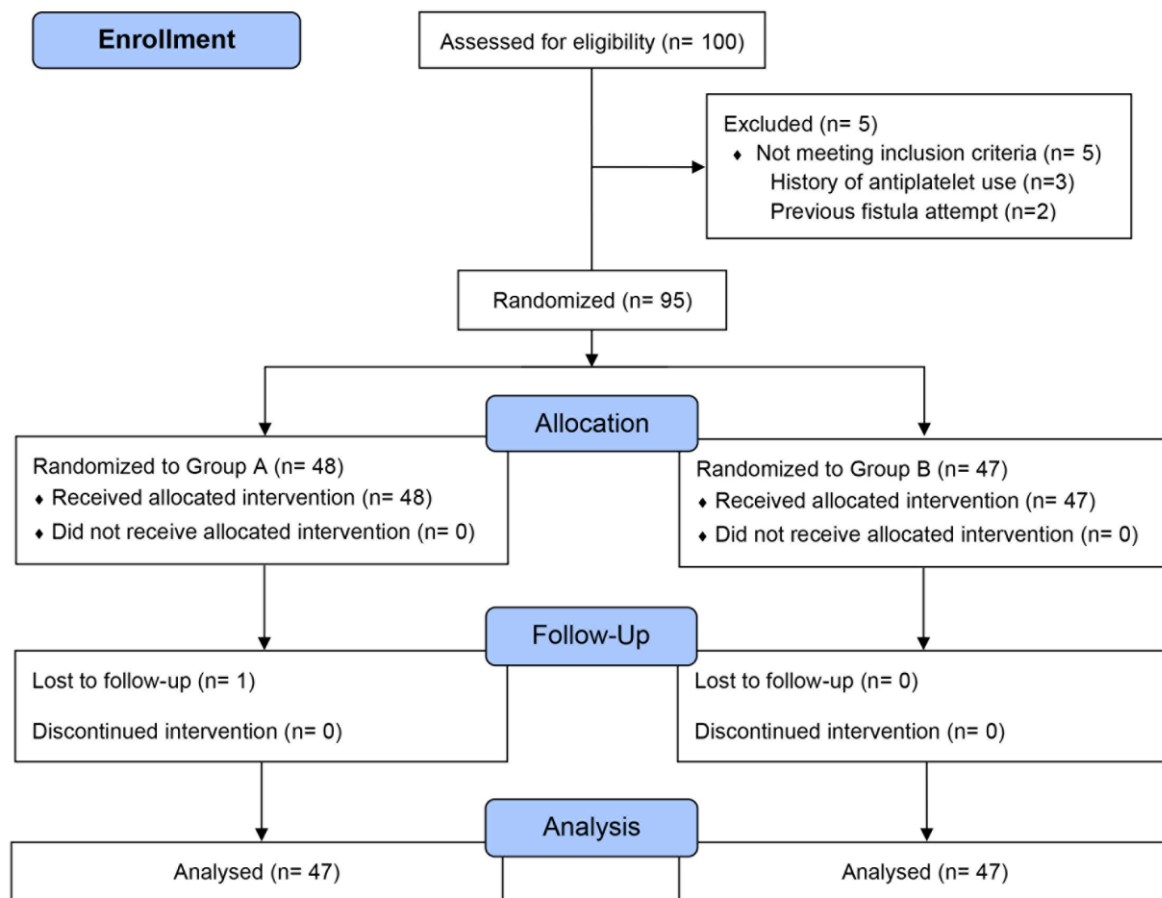
Postoperatively, patients were followed up regularly for six months. The primary outcome was the primary patency of the AVF, while the secondary outcomes included postoperative complications such as hematoma, pain, reopening, and wound infection.

### 2.7. Statistical analysis

The database of the hospital was used to collect patient data. The collected data were analyzed using the Statistical Package for the Social Sciences 25.0 software. The qualitative data were presented in the form of frequency and percentages, and the Chi-square (X<sup>2</sup>) test was used to compare them. A P-value of less than 0.05 is considered significant.

## 3. Results

During the follow-up period, 94 patients were registered for the trial. The mean age of the patients was 63.7 years ranging from 44 to 81 years. Fifty cases (53.2%) were male and 44 (46.8%) were female. The most common cause of renal failure was glomerular disease (29.8%), followed by diabetic nephropathy (22.3%), and analgesic nephropathy (11.7%). Fifty-four (57.4%) patients had a history of temporary vascular access (CV line) (Table 1). The majority of the AVFs were located on the left side (57.4%). Brachiocephalic was the most common type of AVF (70.2%) followed by radiocephalic fistula (18.1%) (Table 2). Postoperative hematoma was more common in Group B (42.6%) than in Group A (17%) and reached a significant level (P-value



= 0.007). About 10.6% of cases in Group B underwent reopening of the fistula while none of the cases of Group A underwent reopening. Although the difference wasn't statistically significant, the primary patency rate at six months was relatively higher in Group A (87.2%) than in Group B (76.6%) (P-value 0.180) (Table 3). One patient developed an infection which was in the experimental group. In the

experimental group, individuals experiencing primary failure were somewhat older, with ages ranging from 55 to 74 years, compared to the total participants. Five of the six cases of primary failure in the experimental group were female (83.3%).

**Table 1.** The baseline characteristics of the participants.

Variables	Group A	Group A	P-value
Age, years, mean ± SD	62.6 ± 8.99	64.9 ± 9.25	0.954
<b>Sex</b>			
Male	24 (51.1%)	26 (55.3%)	0.679
Female	23 (48.9%)	21 (44.7%)	
<b>On hemodialysis</b>			
Yes	25 (53.2%)	29 (61.7%)	0.404
No	22 (46.8%)	18 (38.3%)	
<b>Primary renal disease</b>			
Glomerular	15 (31.9%)	13 (27.7%)	0.924
Interstitial	3 (6.4%)	2 (4.3%)	
Analgesic nephropathy	6 (12.8%)	5 (10.6%)	
Diabetic nephropathy	8 (17%)	13 (27.7%)	
ADPKD	4 (8.5%)	3 (6.4%)	
Vascular	5 (10.6%)	4 (8.5%)	
Others	6 (12.8%)	7 (14.9%)	

#### 4. Discussion

Around the world, there is a continuous increase in the number of ESRD patients admitted for renal replacement therapy. Because HD is the recommended treatment for the great majority of these patients, permanent vascular access is the only means to survive. As a result, the effective creation of permanent functional vascular access is essential for providing adequate HD therapy in ESRD [10]. A well-functioning AVF is ideal vascular access for HD and has a major influence on patient outcome and survival [11]. Patients' survival and quality of life are also impacted by vascular access complications. Therefore, the appropriate management to decrease the complications is mandatory [12]. However, as the life expectancy of patients undergoing HD has increased over time, many of them will require additional vascular access operations throughout their lives [6]. The distal radiocephalic AVF is the preferred vascular access, followed by other alternative accesses. However, multiple factors, including obesity, unavailability, exhaustion, and calcified vessels make alternative vascular access mandatory [13]. The primary issue with AVF has always been

**Table 2.** Site and type of AVF.

Variables	Group A	Group A	P-value
<b>Site of AV fistula</b>			
Right site	18 (38.3%)	22 (46.8%)	0.404
Left site	29 (61.7%)	25 (53.2%)	
<b>Type of fistula</b>			
BC	33 (70.2%)	33 (70.2%)	0.510
RC	10 (21.3%)	7 (14.9%)	
RB	4 (8.5%)	7 (14.9%)	

the high risk for early thrombosis, which results in early failure [1]. Other common consequences influencing AVF patency include stenosis, thrombosis, bleeding, infection, and flow problems [13].

Ates et al. discovered that the brachiocephalic group had higher

**Table 3.** Postoperative outcomes of group A and B.

Variables	Group A	Group A	P-value
<b>Hematoma</b>			
Yes	8 (17%)	20 (42.6%)	0.007
No	39 (83%)	27 (67.4%)	
<b>Reopening</b>			
Yes	0 (0%)	5 (10.6%)	0.022
No	47 (100%)	42 (89.4%)	
<b>Pain</b>			
Mild	38 (80.9%)	36 (76.6%)	0.590
Moderate	8 (17%)	8 (17%)	
Severe	1 (2%)	3 (6.4%)	
<b>Primary patency</b>			
Yes	41 (87.2%)	36 (76.6%)	0.180
No	6 (12.8%)	11 (23.4%)	

complications than the radiocephalic group. However, for hematoma, the situation was reversed, as it occurred in 5.9% of the brachiocephalic group and 6.9% of the radiocephalic group without a significant effect [2]. Thabet et al. reported hematoma in 20 (8.4%) of their patients. Seventeen (85%) patients were effectively treated with hematoma evacuation and repair of the puncture site. Because of late presentation with possibly contaminated hematomas, the remaining three (15%) patients had their access ligated [14]. The bleeding rate in the studies by Magar et al., Elamurugan et al., and Madhhachi et al. were 9.75%, 11.5%, and 5.3% respectively [5,6,10]. In the current study, hematoma was more common in the experimental group than in the control group, and the result was statistically significant (P-value = 0.007).

A significant problem with AVFs is the high rate of primary failure, which can be caused by a lack of maturation or early thrombosis [15]. A comprehensive strategy is essential in detecting and addressing the principal causes of primary failure in individuals with ESRD. Despite current research outlining the pathophysiology of the technique and biomechanical challenges connected with maturation, the process of AVF maturation remains complicated and poorly understood. Intimal hyperplasia has been identified as the most severe pathohistological alteration that occurs in blood vessels and has been linked to AVF primary failure [9]. In a study that compared the primary patency of radiocephalic AVF and brachiocephalic AVF,

brachiocephalic AVF had the highest patency rate (79.18%), followed by mid-arm radiocephalic AVF (72%), and distal arm radiocephalic AVF (68.18%) [5]. In a meta-analysis of 46 reports, the probability of primary failure was 23%, but it raised to 37% in old-aged patients [16,17]. According to Zouaghi et al., the actual primary patency rates at six months, 1 year, 2years, 4years, and 5years were 82%, 78%, 69%, 61%, and 42%, respectively [18]. Wong et al. reported that primary patency at three months and one year for brachiocephalic fistula was 87.9% and 63.1%, respectively, and 84.6% and 58.1% for radiocephalic fistula [19]. Mahalkar et al. reported brachiocephalic AVF patency of 88%, 83%, and 71% at 30 days, 90 days, and six months, respectively [20]. The current study's primary patency rate at six months was 87.2% for the control group, which was slightly higher than the control group's rate of 76.6%.

Age, gender, race, diabetes, peripheral vascular disease, history of coronary artery disease, location of the fistula, and obesity are all patient factors that predict primary failure [17]. However, some studies reported that age did not affect primary patency [14,21]. Smith et al.'s review of the literature revealed an increase in access failure in the elderly population [22]. There is limited evidence that AVF patency varies by gender. Several studies discovered that when the patency rate was examined by gender, male patients had a much greater rate than female patients [23]. This finding is explained by the fact that females have a smaller diameter of arteries and so have a lower AVF patency rate than males [22]. However, Mortaz et al. found no evidence that AVF survival was gender-dependent [24]. In the experimental group of the current study, those with primary failure were somewhat older (ages ranging from 55 to 74 years) than the total participants. Five of the six cases of primary failure in control group were female, which might indicate that females are more prone to failure than males.

Infection is responsible for 20% of all AVF consequences. The majority of AVF infections involve perivascular cellulitis, which often appears as localized erythema and edema and is easily treated. An infection linked to anatomical abnormalities such as aneurysms, hematomas, or abscesses is far more dangerous and necessitates surgical excision and drainage [25]. The infection rates in studies by Dekhaiya et al. and Schinstock et al. were 8% and 26.8%, respectively [26,27]. In a study by Shameri et al., infection was observed in 17 (7.4%) of the cases, with the majority of the cases (10, 4.4%) being managed with observation (antibiotic) or aspiration and draining. Other seven (3%) infections progressed to ruptured fistulae, which required emergent surgical treatment [9]. Another study reported that 57 (23.8%) patients had severe infections in the form of abscess formation or active bleeding. As a result, conservative therapy was out of the option, and they all had immediate access closure [14]. Only one patient developed an infection in the current study, which was in the experimental group. The patient was treated conservatively with antibiotics for five days and responded well to the treatment.

One of the present study's limitations was the sample size which was small and only covered participants from a single center. However, because this is a hypothesis-generating study, more study on this concept is needed.

## 5. Conclusion

The use of surgical drainage after AVF surgery might be beneficiary. It may decrease the complications associated with AVF creation and improve the fistula's primary patency.

## Declarations

**Conflicts of interest:** The author(s) have no conflicts of interest to disclose.

**Ethical approval:** The study was approved by the *B.P. Koirala Institute of Health Sciences* Ethical Committee (No.11).

**Patient consent (participation and publication):** Written informed consent was obtained from patients for publication.

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**Role of Funder:** The funder remained independent, refraining from involvement in data collection, analysis, or result formulation, ensuring unbiased research free from external influence.

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**Authors' contributions:** LSJ was significant contributor to the conception of the study and the literature search for related studies. NO and SV were involved in the literature review, the study's design, the critical revision of the manuscript, they participated in data collection, involved in the literature review, study design, and manuscript writing. SV and LSJ confirm the authenticity of all the raw data. All authors approved the final version of the manuscript.

**Use of AI:** AI was not used in the drafting of the manuscript, the production of graphical elements, or the collection and analysis of data.

**Data availability statement:** Not applicable.

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