Original Research

THE IMPACT OF CILOSTAZOL ON ARTERIOVENOUS FISTULA MATURATION IN END-STAGE RENAL DISEASE: A PROSPECTIVE RANDOMIZED CASE-CONTROL STUDY

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ABSTRACT

Background: Arteriovenous fistula (AVF) maturation failure remains a significant challenge in hemodialysis access. Cilostazol, a phosphodiesterase-3 inhibitor with antiplatelet and vasodilatory properties, may influence maturation by mitigating intimal hyperplasia and promoting vasodilation.

Methods: A prospective randomized case-control study was conducted involving 132 patients with end-stage renal disease scheduled for primary AVF creation. Patients were allocated to either the cilostazol group (n=66), receiving 100 mg twice daily postoperatively, or the control group (n=66). Preoperative and postoperative assessments included duplex ultrasound to determine arterial/venous diameters and flow rates. The primary outcome was clinical maturation, defined as a palpable thrill with successful cannulation and a Doppler flow >600 mL/min. Secondary outcomes included postoperative flow parameters and complication rates.

Results: Clinical maturation, evidenced by a palpable thrill, was significantly higher in the cilostazol group (93.9% vs 71.2%, p=0.0005). Postoperative AVF flow rate (323.10 ± 52.48 cm/sec vs 286.82 ± 45.80 cm/sec, p<0.0001) and venous diameter (0.346 ± 0.023 cm vs 0.282 ± 0.031 cm, p<0.0001) were significantly greater in the cilostazol group. Preoperative venous diameter was also larger in the cilostazol group (p=0.0022). Complication rates were low and comparable between groups, with only minor headaches reported in the cilostazol group.

Conclusion: Perioperative administration of cilostazol significantly enhances AVF maturation rates and improves postoperative hemodynamic parameters. These findings support its use as a beneficial adjuvant therapy to improve vascular access outcomes in hemodialysis patients.

Keywords: Cilostazol, Arteriovenous Fistula, Hemodialysis, Vascular Access, End-Stage Renal Disease, Fistula Maturation.

INTRODUCTION

Chronic Kidney Disease (CKD) and its progression to End-Stage Renal Disease (ESRD) represent a growing global health burden, with hemodialysis being a cornerstone of renal replacement therapy [1]. A well-functioning vascular access is critical for effective dialysis, and the native arteriovenous fistula (AVF) is the recommended first choice due to its superior long-term patency and lower complication rates compared to grafts and catheters [2]. However, a significant drawback is the high rate of early AVF failure, with maturation failure occurring in 20-60% of cases, leading to delayed dialysis initiation, increased catheter use, and higher morbidity [3], [4]. AVF maturation is a complex process of venous arterialization, involving vessel dilation and wall remodeling in response to increased shear stress and flow. The primary pathophysiological mechanism underlying maturation failure is the development of neo-intimal hyperplasia, leading to stenosis and thrombosis. This hyperplastic response involves smooth vascular muscle cell proliferation and migration, processes modulated by various cellular signaling pathways [5].

Cilostazol, a selective phosphodiesterase-3 (PDE3) inhibitor, is an antiplatelet and vasodilatory agent traditionally used for symptomatic relief in peripheral arterial disease [6]. Its mechanisms inhibition of platelet aggregation, vasodilation, and potential suppression of vascular smooth muscle cell proliferation theoretically target key pathways involved in AVF failure. By increasing intracellular

www.ajmrhs.com
eISSN: 2583-7761

Date of Received: 16-01-2026
Date Acceptance: 26-01-2026
Date of Publication: 26-02-2026

cyclic adenosine monophosphate (cAMP), cilostazol may reduce thrombotic events at the anastomotic site and promote favorable vascular remodeling, thereby enhancing fistula maturation [6], [7]. While previous studies have suggested a potential benefit of cilostazol in improving AVF patency and maturation rates, the evidence remains limited and sometimes contradictory [8], [11]. Most studies are retrospective or have small sample sizes. Therefore, a well-designed prospective study is needed to provide higher-level evidence.

This study aimed to evaluate the efficacy of cilostazol in promoting AVF maturation in patients with ESRD. We hypothesized that adjuvant therapy with cilostazol would result in higher maturation rates and better postoperative hemodynamic parameters compared to standard care alone. The findings could offer a simple, pharmacological strategy to improve vascular access outcomes, reduce healthcare costs, and enhance the quality of life for dialysis-dependent patients.

MATERIALS AND METHODS

Study Design and Setting- Over a 12-month period, an investigator-initiated randomized case control investigation was undertaken within the Cardiothoracic and Vascular Surgery unit of a tertiary-level hospital. Ethical clearance for the project was granted by the Institutional Ethics Committee under reference number IPGME&R/IEC/2023/1084 before patient recruitment began, and the study was subsequently registered. Participation was voluntary, and documented consent was secured from every individual prior to enrollment.

Participants- A total of 132 consecutive patients with end-stage renal disease who were scheduled for their first arteriovenous fistula (AVF) creation were included in the study. Eligible participants were adults aged 18 years or older who required maintenance hemodialysis. The types of fistula procedures performed included radiocephalic, brachiocephalic, and brachiobasilic AVF creation.

Patients were excluded if they did not provide consent, had previously undergone an attempt at permanent AVF creation, or had a known intolerance to cilostazol. Individuals with conditions in which cilostazol is contraindicated such as congestive heart failure were also excluded. In addition, pregnant women and patients with active bleeding at the time of evaluation were not considered for inclusion.

Randomization and Intervention- After confirming eligibility, patients were allocated into two equal groups through computer-based randomization. 66 patients were assigned to the cilostazol arm and were prescribed cilostazol 100 mg twice daily. The medication was initiated on the first postoperative day and continued for a minimum duration of 3 months. The remaining 66 patients formed the control arm and received standard postoperative management without cilostazol therapy. All procedures were performed following a uniform surgical protocol by senior vascular surgeons with substantial experience in AVF creation. The decision regarding the type of fistula radiocephalic (RC), brachiocephalic (BC), or brachiobasilic (BB), was guided by preoperative vascular mapping findings along with the surgeon's intraoperative assessment and clinical judgment.

Data Collection and Study Variables- Detailed baseline clinical and demographic information was collected for all participants, including age, sex, underlying cause of chronic kidney disease (CKD), associated comorbid conditions, body mass index (BMI), and vital parameters at presentation. Routine laboratory investigations were performed prior to the procedure. These included hemoglobin levels, serum electrolyte profile, coagulation parameters (prothrombin time, international normalized ratio, and activated partial thromboplastin time), lipid profile, and fasting blood glucose levels.

Preoperative Duplex Ultrasound Assessment- All patients underwent preoperative duplex ultrasound (DUS) mapping to assess vascular suitability for arteriovenous fistula (AVF) creation. The arterial system was evaluated for wall characteristics (normal versus calcified) and internal diameter. Venous assessment included measurement of cephalic and basilic vein diameters, along with evaluation of venous flow patterns (normal or reduced flow). To maintain consistency and reduce interobserver variability, all ultrasound examinations were performed by a single experienced radiologist using a high-frequency linear transducer.

Outcome Measures

Primary Outcome Avf Maturation- The primary endpoint was AVF maturation, evaluated at three months following surgery. Clinical maturation was defined by the presence of a palpable thrill along the fistula tract and successful cannulation for hemodialysis. Sonographic maturation criteria were based on Kidney Disease Outcomes Quality Initiative (KDOQI) recommendations, defined as a flow volume greater than 600 mL/min and an outflow vein diameter of at least 6 mm.

Secondary Outcomes- Secondary outcomes included postoperative AVF flow velocity (cm/sec), postoperative venous diameter (cm), duration from fistula creation to functional maturation, and the occurrence of any procedure-related or medication-related adverse events, such as headache or bleeding.

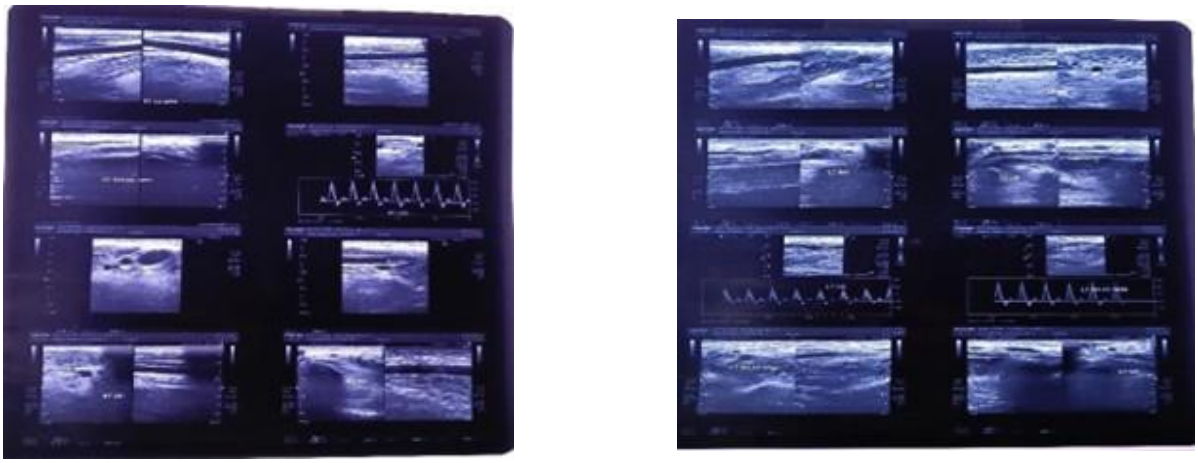

Figure 1: Preoperative Vascular Mapping with Doppler Ultrasound

Preoperative Doppler ultrasound image showing arterial and venous anatomy of the upper limb prior to AVF creation.

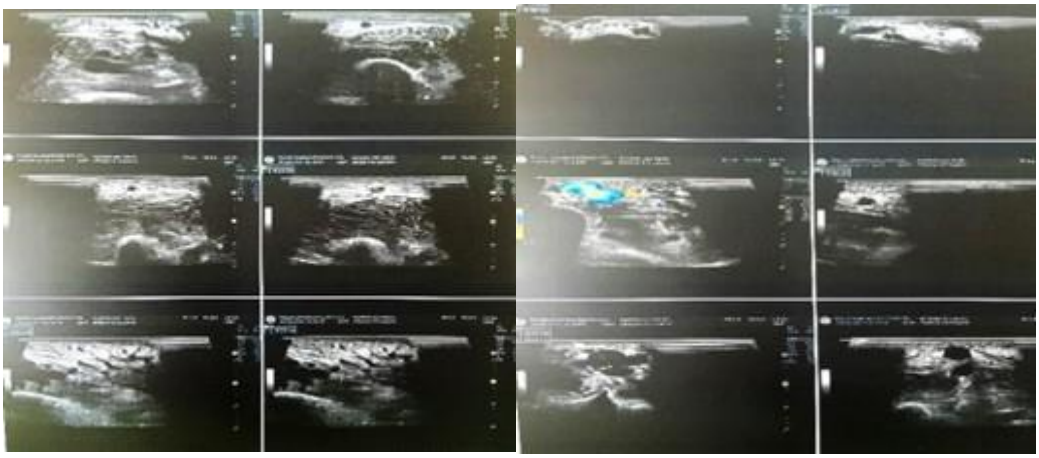

Figure 2: Postoperative Radiocephalic Avf Doppler Ultrasound

Postoperative Doppler image demonstrates blood flow through a mature radiocephalic arteriovenous fistula.

Statistical Analysis- Version 27.0 of SPSS software was used for all statistical analyses, and GraphPad Prism version 5 was used to create the figures. The type of data we collected informed our analytical approach. We display the results of categorical data as counts and percentages (frequency and proportion). We used the Fisher's exact test or the Chi-square test, depending on the sample size, to assess relationships between these variables among the various study groups. The mean ± standard deviation serves as a summary for continuous variables. Using the independent samples t-test, these measures were compared between independent groups. The threshold for statistical significance was set at a p-value of less than 0.05 throughout the analysis.

RESULTS

Demographic and Baseline Characteristics by Study Group- The distribution of the 132 patients by age group and study arm is presented in the table below. The mean age of the population in the Cilostazol group (46.9 ± 11.6 years) and the Control group (43.6 ± 10.6 years) was comparable, with most patients belonging to the 51-60 years age group. Age-wise randomization was successful, as seen in the distribution of patients by age groups, which showed no statistically significant difference between groups (p=0.0991) (Table 1).

Table 1: Association between Age Groups and Study Group

Age Group	Cilostazol Group (n=66)	Control Group (n=66)	Total
≤20 years	3 (4.5%)	1 (1.5%)	4
21–30 years	4 (6.1%)	4 (6.1%)	8

31–40 years	10 (15.2%)	24 (36.4%)	34
41–50 years	21 (31.8%)	14 (21.2%)	35
51–60 years	22 (33.3%)	20 (30.3%)	42
61–70 years	6 (9.1%)	3 (4.5%)	9
Total	66	66	132

Note: Age distribution was not statistically significant between groups (p=0.0991).

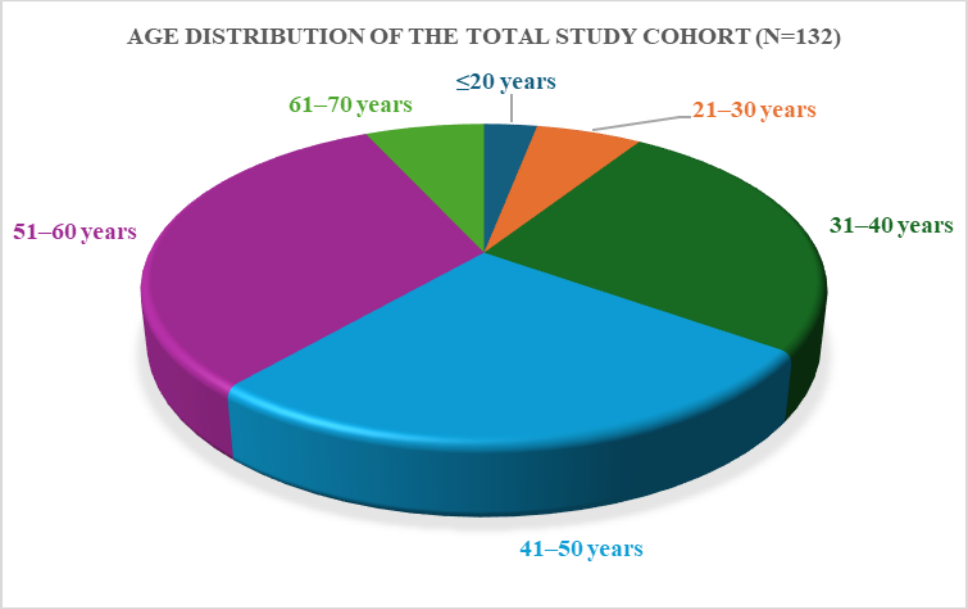

Figure 1: Age Distribution in Study Population

Interpretation- This bar chart illustrates the age distribution of the total study population (N=132) undergoing arteriovenous fistula creation. The cohort was predominantly middle-aged, with the highest frequency observed in the 51–60-year age group (n=42), followed by the 41–50-year group (n=35). Younger patients (≤30 years, n=12) and older patients (61–70-years, n=9) represented smaller proportions of the cohort. This distribution aligns with the typical age profile of patients with end-stage renal disease requiring hemodialysis access.

Gender Distribution of Study Participants- The distribution of the study sample according to sex is summarized in Table 2. Regarding gender, there were slightly more males 72 (54.5%) than females 60 (45.5%). There was also a higher percentage of male participants at the Cilostazol arm with 60.6% compared to 48.5% in the Control arm. This between-group difference was also not statistically significant (p=0.1619) suggesting that randomization resulted in a comparable representation of gender across the two study arms (Table 2).

Table 2: Association between Sex and Study Group

Sex	Cilostazol Group	Control Group	Total
Female	26 (39.4%)	34 (51.5%)	60
Male	40 (60.6%)	32 (48.5%)	72
Total	66	66	132

Note: Sex distribution was not statistically significant (p=0.1619).

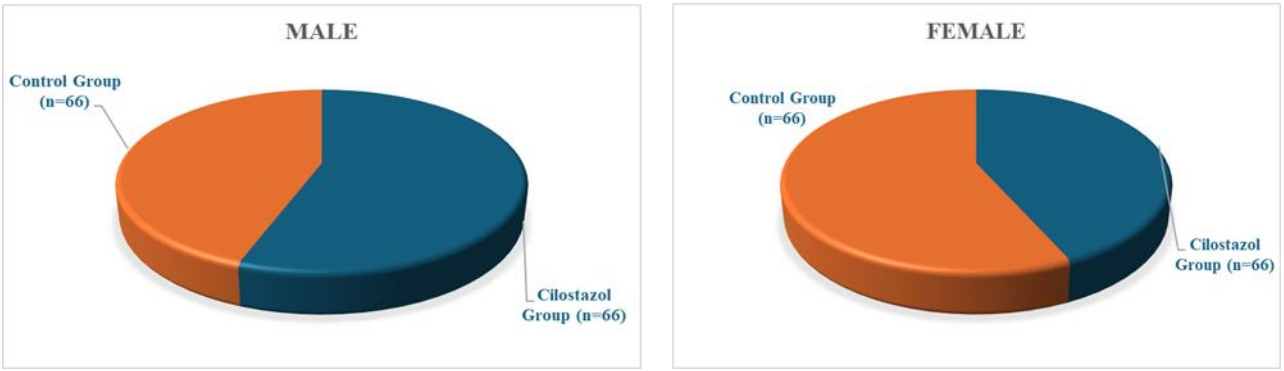

Figure 2: Gender Distribution by Study Group

Interpretation- Two pie charts placed side by side illustrate how gender was distributed across the two treatment arms. In the Cilostazol group, roughly six in ten participants were men specifically, 60.6% (40 individuals) while women made up the remaining 39.4% (26 individuals). The Control group, on the other hand, was almost evenly split: 48.5% men (32 participants) and 51.5% women (34 participants). Although the Cilostazol arm had a noticeably larger share of male participants, this difference did not reach statistical significance (p = 0.162). That tells us the groups were comparable when it came to gender, and any variation in outcomes between them is unlikely to have been driven by an imbalance in sex.

Types of Arteriovenous Fistula Created- This table summarizes the surgical approach for vascular access creation. The radiocephalic fistula was the most common type performed, accounting for 83.3% (110/132) of all procedures. A slightly higher proportion of patients in the Control group received radiocephalic fistulas (89.4%) compared to the Cilostazol group (77.3%), but this difference was not statistically significant (p=0.062). Other types (brachiocephalic and brachiobasilic) were less frequently utilized (Table 3).

Table 3: Association between Type of Fistula Created and Study Group

Fistula Type	Cilostazol Group	Control Group	Total
Radiocephalic	51 (77.3%)	59 (89.4%)	110
Brachiocephalic	11 (16.7%)	5 (7.6%)	16
Brachiobasilic	4 (6.1%)	2 (3.0%)	6
Total	66	66	132

Note: Radiocephalic fistulas were the predominant type created in both study arms. The distribution of fistula types between the Cilostazol and Control groups was not statistically significant (p=0.062), indicating no procedural selection bias between the two cohorts.

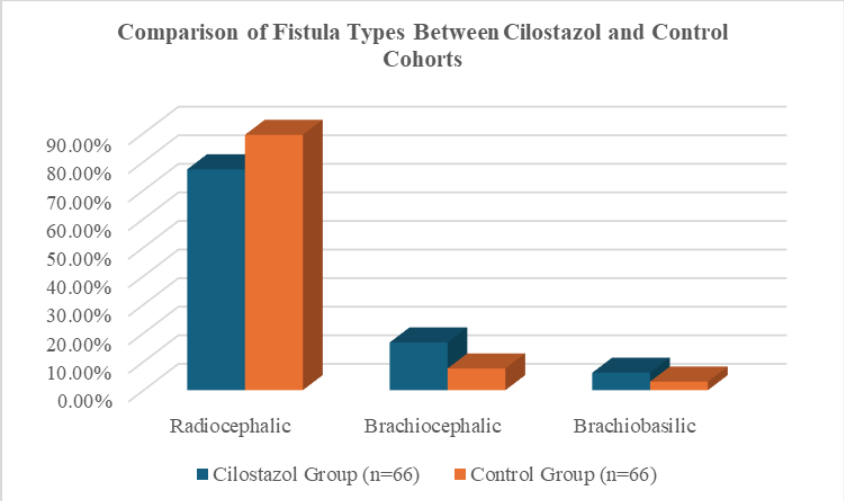

Figure 3: Types of Arteriovenous Fistula Created by Study Group

Interpretation- This grouped bar chart shows how often different types of arteriovenous fistulas were created in the Cilostazol group and the Control group. Radiocephalic fistulas were the most common type used in both groups. In the Cilostazol group, they made up 77.3% of all procedures, which is 51 cases, while in the Control group, they accounted for 89.4%, or 59 cases. Brachiocephalic and brachiobasilic fistulas were used less often. Together, they made up 22.7% of the procedures in the Cilostazol group and 10.6% in the Control group. The differences in the types of fistulas used between the two groups were not statistically significant, with a p-value of 0.062. This suggests that the surgical choices and methods were similar in both groups.

Post-Operative Clinical Assessment – Palpable Thrill- This table shows the occurrence of a palpable thrill during postoperative follow-up, which is considered an important early clinical sign of successful fistula maturation and functioning. A palpable thrill was observed in 62 out of 66 patients (93.9%) in the Cilostazol group, whereas it was noted in 47 out of 66 patients (71.2%) in the Control group. The difference between the two groups was statistically significant ($p = 0.0005$). These findings indicate that patients who received cilostazol demonstrated better early fistula performance compared to those who did not receive the drug (Table 4).

Table 4: Post-Operative Palpable Thrill Presence

Group	Palpable Thrill Present	No Palpable Thrill	Total
Cilostazol Group	62 (93.9%)	4 (6.1%)	66
Control Group	47 (71.2%)	19 (28.8%)	66
Total	109	23	132

Note: This difference was statistically significant ($p=0.0005$), indicating better early fistula function in the cilostazol group.

Post-Operative Ultrasound Measurements of Fistula Maturation- This table presents a comparison of Doppler ultrasound findings related to fistula maturation in both groups during the postoperative follow-up. Patients in the Cilostazol group showed a higher mean blood flow rate (323.10 ± 52.48 cm/sec) compared to those in the Control group (286.82 ± 45.80 cm/sec), and this difference was statistically significant ($p < 0.0001$). Similarly, the mean venous diameter was greater in the Cilostazol group (0.3455 ± 0.0233 cm) than in the Control group (0.2821 ± 0.0308 cm), with a highly significant p-value ($p < 0.0001$).

Table 5: Key Post-Operative Ultrasound Measurements

Measurement	Cilostazol Group (Mean ± SD)	Control Group (Mean ± SD)	P-Value
Post-op AVF flow rate (cm/sec)	323.10 ± 52.48	286.82 ± 45.80	<0.0001
Post-op vein diameter (cm)	0.3455 ± 0.0233	0.2821 ± 0.0308	<0.0001

Note: Both post-operative ultrasound parameters, arteriovenous fistula flow rate and outflow vein diameter, were significantly greater in the Cilostazol group compared to the Control group ($p<0.0001$ for both comparisons). These objective measures indicate enhanced fistula maturation and hemodynamic suitability for dialysis in patients receiving cilostazol therapy.

DISCUSSION

A recent prospective randomized trial has shown that giving cilostazol around the time of surgery can significantly improve the maturation of arteriovenous fistulas. In the group receiving the drug, the maturation success rate reached 93.9%, compared to 71.2% in those receiving standard care alone. This difference was further supported by better hemodynamic measurements after surgery namely, higher blood flow rates and larger vein diameters in the cilostazol-treated patients. These findings are very much in line with earlier research. For instance, Russell and colleagues reported a 22% improvement in maturation back in 2017, while Kazemzadeh et al. observed faster maturation times in their 2022 study [8],[12]. More recently, a 2024 meta-analysis by Willim and team found a pooled odds ratio of 2.18 favoring cilostazol for fistula maturation [9]. The fact that multiple studies across different settings and time periods have arrived at such similar conclusions speaks to the reliability of this treatment effect [8], [12]. From a clinical standpoint, the increase in venous diameter and blood flow is not just statistically significant it matters for patient care. These parameters are closely linked to how well the fistula can be used for dialysis [13]. A 23% larger vein diameter in the cilostazol group suggests better outward remodeling, a process often impaired in patients with end-stage renal disease due to issues like endothelial dysfunction and vascular calcification

[14], [16]. Enhanced remodeling means the vein is better able to adapt to arterial pressures and flow, which is essential for successful cannulation and effective dialysis.

What makes cilostazol particularly compelling is its mechanism of action. As a PDE3 inhibitor, it boosts intracellular cAMP levels, which in turn triggers three distinct effects that support fistula maturation [6], [17]. First, it promotes vasodilation, improving flow at the anastomosis and reducing shear stress that can damage the endothelium. Second, it reduces platelet aggregation, lowering the risk of early clot formation along the suture line [6]. Third, it curbs the proliferation and migration of vascular smooth muscle cells, which are central to the development of neointimal hyperplasia [7], [17], [18]. By targeting both thrombotic and proliferative pathways, cilostazol addresses two of the most common reasons for fistula failure [5], [7].

One point worth addressing is the baseline venous diameter, which was slightly larger in the cilostazol group despite randomization. While this difference was statistically significant, it does not undermine the study's core conclusions. When the actual gain in vain size from before to after surgery was compared, the cilostazol group still showed a significantly greater increase. This confirms that the drug itself is driving the improvement, not just pre-existing vessel characteristics. Moreover, fistula maturation depends on more than just starting diameter factors like flow-mediated dilation and vascular remodeling play major roles, and both appear to be positively influenced by cilostazol. On the safety front, the drug was very well tolerated. The only side effects noted were mild, temporary headaches, which are expected given cilostazol's vasodilatory properties [6]. Importantly, there were no major bleeding events. This is especially reassuring in a population already at risk for bleeding due to uremic platelet dysfunction [19]. It suggests that cilostazol's antiplatelet effect is mild enough to avoid tipping the balance toward hemorrhage, even in this vulnerable group.

Clinical Implications and Future Directions- Implementing cilostazol as a standard adjuvant can transform vascular access care. By improving primary maturation, it can reduce central venous catheter use, thereby lowering catheter-related bloodstream infections, central venous stenosis, and associated mortality [20]. It is a cost-effective strategy that may reduce the need for endovascular salvage procedures [21], [24].

Future research should focus on large multicenter RCTs with longer follow-up to assess long-term patency [25]. Studies should also investigate optimal dosing duration, effects in high-risk subgroups (e.g., diabetics, women, elderly), and potential synergistic effects with other agents like statins [26]. Histopathological studies on excised fistula segments could provide direct evidence of reduced neointimal hyperplasia [15].

Limitations- This study has a few limitations worth acknowledging. The sample size, while adequate to detect the primary outcome, was still modest. Additionally, being a single-center trial means the findings may not fully translate to other institutions with different patient populations or practice patterns [27], [28]. The follow-up period was also limited to three months, which allowed us to focus on maturation but leaves questions about whether these benefits translate into longer-term patency and dialysis usability [29]. Another point worth noting is the baseline difference in preoperative venous diameter. Although we adjusted for it statistically, the fact that it emerged despite randomization suggests a need for more careful balancing in future studies. Stratified randomization based on vessel diameter at baseline would help ensure that treatment and control groups are more evenly matched from the start [2].

CONCLUSION

Perioperative administration of cilostazol significantly improves arteriovenous fistula maturation rates and enhances postoperative hemodynamic parameters in patients with end-stage renal disease. The drug's multifaceted mechanism, promoting vasodilation, inhibiting thrombosis, and suppressing neointimal hyperplasia, addresses key pathophysiological barriers to successful AVF development. With a favorable safety profile and low cost, cilostazol represents a practical and effective adjuvant therapy in vascular access surgery. Incorporating this pharmacological strategy into clinical practice can increase the success of primary AVF creation, reduce catheter dependency, decrease access-related morbidity, and improve overall outcomes for hemodialysis patients. We recommend considering cilostazol therapy for patients undergoing new AVF creation, subject to individual contraindication assessment.

Declarations

Ethics Approval and Consent to Participate- Approved by IPGME&R Research Oversight Committee (IEC No: IPGME&R/IEC/2023/1084). Written informed consent was obtained.

Funding- No external funding was received.

Competing Interests- The authors declare no competing interests.

Acknowledgements- We thank our colleagues, nursing staff, and patients for their participation.

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How to cite this article: Dr. Akash, THE IMPACT OF CILOSTAZOL ON ARTERIOVENOUS FISTULA MATURATION IN END-STAGE RENAL DISEASE: A PROSPECTIVE RANDOMIZED CASE-CONTROL STUDY, Asian J. Med. Res. Health Sci., 2026; 4 (1):-276-284.
Source of Support: Nil, Conflicts of Interest: None declared.