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Research Article

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# Comparing Efficacies of Drug-eluting versus Non-medicated Balloons in Arteriovenous Fistula Stenosis

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## Abstract

**Purpose:** Arteriovenous fistulas (AVFs) are the preferred method for patients receiving hemodialysis treatment. However, AVFs are prone to developing stenosis, creating difficulties with proper functioning for hemodialysis. Percutaneous balloon angioplasty (PBA) is the mainstay of treatment for stenosis, yet there remains debate regarding the use of drug-eluting balloons (DEBs) containing paclitaxel compared to non-medicated balloons (NMBs). This study examined whether any significant differences exist in patient outcomes with the use of DEBs as compared to NMBs.

**Methods:** A retrospective cohort study was conducted on a sample of 60 patients who received PBA for the treatment of AVF stenosis over 5 years. The analysis included the impact of balloon type used (DEB or NMB), demographic factors such as age, biological sex, location of the stenosis, and history of prior AVF on clinical outcomes at 6 and 12 months post-procedure. Statistical analysis was completed using Statistical Package for the Social Sciences (SPSS) via Fisher's exact and chi-square tests.

**Results:** No significant differences in PBA outcomes were observed with the use of DEBs versus NMBs. Age, sex, stenosis location, and history of previous intervention also demonstrated no significant impacts on patient outcomes (all p-values > 0.05).

**Conclusions:** The outcomes of AVF stenosis treatment did not appear to be impacted by the type of balloon used, age, biological sex, location of stenosis, or vessel naivety in this retrospective study. Future research is warranted, given conflicting findings within literature.

## Keywords

Arteriovenous fistula, Stenosis, Drug-eluting balloon, Plain balloon angioplasty

## Introduction

AVFs are the preferred method of hemodialysis access for patients with end-stage renal disease [1]. AVFs are abnormal arteriovenous connections, which may be congenital or acquired [2]. When congenital or post-traumatic, they can occur in virtually any organ system - including the lungs, coronary arteries, liver, uterus, and gastrointestinal tract - as documented in reports of uterine arteriovenous malformations and other rare vascular anomalies [2, 3]. In such locations, AVFs and related arteriovenous malformations can lead to complications such as bleeding, ischemia, or multiorgan dysfunction [4].

The intentional creation of an AVF is a surgical procedure involving the anastomosis of an artery and vein, which is normally done in the upper extremities

[5, 2] (Figure 1). Alternatives for hemodialysis include arteriovenous grafts(AVGs) which use synthetic tubes, and central venous catheters(CVCs), and indwelling tubes in central veins [6]. AVFs remain the gold standard due to lower infection risk and better patency [7], though they require months to mature and have higher failure rates than AVGs or CVCs [5]. In contrast, AVGs are ready within weeks, and CVCs can be used immediately [8, 9].

AVFs are prone to stenosis from neointimal hyperplasia [10] figure 1, which can compromise dialysis access or cause thrombosis [10]. Contributing factors include turbulent blood flow, repeated venipuncture, uremia, or trauma from angioplasty [11]. While AVFs and AVGs are prone to stenosis development, CVCs may occlude due to mechanical obstruction [12].

PBA is the preferred treatment for AVF stenosis, which involves advancing a guidewire to the lesion and inflating a balloon to restore blood flow [13] (Figure 2). There is ongoing debate regarding the use of DEBs versus NMBs [14].

NMBs, which expand the stenotic area to restore blood flow without delivering medication, have been successful in AVF stenosis treatment [14]. However, AVFs have a high risk of restenosis - sometimes requiring repeat interventions - prompting interest in DEBs [15]. DEBs deliver paclitaxel, an antineoplastic and antiproliferative agent that prevents microtubule degradation, prolongs the G2 phase, and results in apoptosis [16, 17]. Despite growing research, data on DEB use in Canadian patient populations remain limited.

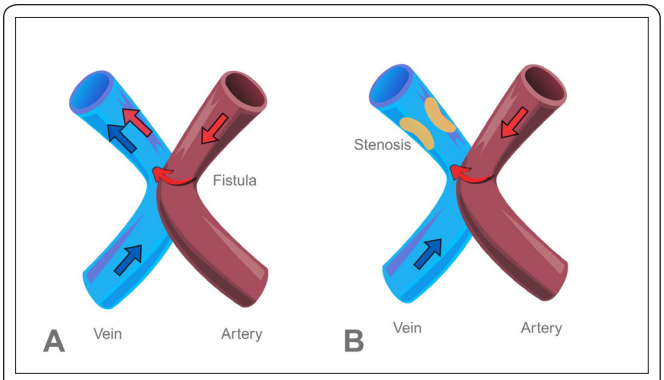



**Figure 1:** Schematic illustration of AVF anatomy and stenosis. **(A)** A normal AVF shows a direct surgical connection between an artery and a vein, facilitating high-flow access for hemodialysis. **(B)** An AVF with stenosis is characterized by a focal narrowing of the venous outflow tract, which can impair blood flow and lead to hemodialysis access dysfunction.

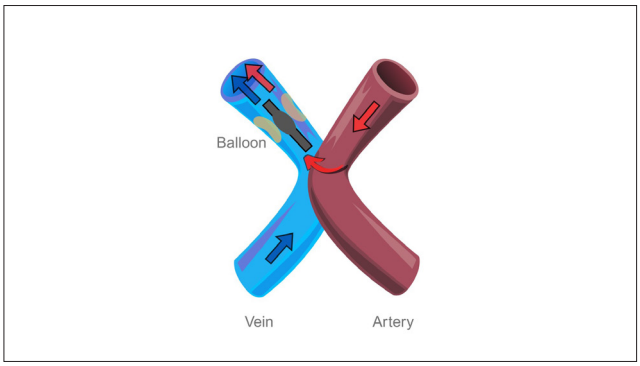



**Figure 2:** Schematic illustration of PBA for the treatment of AVF stenosis. Restoration of blood flow is seen following inflation of the balloon and dilation of the narrowed stenotic segment.

This study aimed to compare the effectiveness of AVF stenosis treatment using DEBs versus NMBs at two Canadian institutions.

## Methods

This retrospective chart review included all patients who underwent PBA for AVF stenosis treatment at two Canadian institutions from January 1, 2018 to December 31, 2022. Ethical approval was obtained from the local Health Research Ethics Board (file #20240723) and the Research Proposals Approval Committee (file #2023.167). Inclusion criteria further specified patients aged ≥ 18 years residing in a single Canadian province. Follow-up data from 2023 were included only for patients treated in 2022 to allow 6 or 12-month outcome assessment.

Exclusion criteria evolved during the study and included: inaccessible data; sepsis or intensive care unit care preceding AVF failure; thrombolysis-treated patients; thigh-loop AVG use; elective use of alternative access despite a functional AVF; stent placement; and AVF maturation failure requiring PBA rather than stenosis. Picture Archiving and Communication System was searched using the phrase "AV DIALYSIS" with the "XA" filter to document the initial PBA and any subsequent interventional radiology procedures. Data were collected, stored, and analyzed in a secure local database.

For patients with multiple PBAs during the study period, only the most recent procedure was included in the analysis to reflect current procedural techniques, balloon selection, and clinical outcomes, while avoiding correlations from repeated measures within patients. Physician documentation was reviewed to classify the purpose of PBA, presence and location of stenosis, balloon type (DEB or NMB), and clinical outcomes. Outcome categories ("Pass" vs "Fail") were defined as follows: patients were categorized as "Fail" at 6 or 12 months if they required repeat PBA of the same AVF, hemodialysis catheterization, or surgical intervention to create or improve the AVF; conversely, "Pass" indicated that they experienced none of these adverse outcomes. All key variables were extracted and categorized by a single reviewer, so a formal inter-rater reliability assessment was not applicable.

Patient records were further analyzed via Meditech (Medical Information Technology Inc., Westwood, Massachusetts, USA) to identify mortality during the study period and to assess AVF function post-PBA based on clinical documentation.

Data analysis was performed using SPSS version 29.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for age, sex, stenosis location, history of prior intervention, and balloon type using Chi-square tests. Primary outcomes included effects of these variables on clinical outcomes ("Pass" vs "Fail" rates) and comparisons of DEBs vs NMBs at 6 and 12 months. Fisher's exact tests were used, with $p < 0.05$ considered statistically significant.

## Results

An initial sample size of 164 patients was identified based on the inclusion criteria. Using the exclusion criteria outlined above, a total of 104 patients were excluded from the study, leaving a final sample size of 60 patients with follow-up data available at 6 months, with a median age of 63.4 years. 54 of these patients also had follow-up data available at 12 months; thus, 6 of the 60 patients were lost to follow-up by 12 months (Figure 3). The sample included significantly more males (38; 63.3%) than females (22; 36.7%) (Chi-square test of independence; p = 0.0389). Stenosis was significantly more likely to occur within the fistula or "other" locations (including any single location not characterized, such as the brachiocephalic trunk), rather than in the cephalic arch or multiple locations (Chi-square test of independence; p = 0.00397). Regarding balloon type, significantly more patients received NMBs (38; 63.3%) than DEBs (22; 36.7%) (p = 0.0389). No significant differences were observed in patient age or vessel naivety (Chi-square test of independence; p > 0.05). Demographic information for the 60 patients included in the final analysis (including the 54 patients with 12-month follow-up data available) is summarized in table 1.

Of patients with follow-up data available at 6 months ($N_1$ = 60), 22 patients received DEBs and 38 received NMBs. Among 21 patients classified as "Pass," 5 received DEBs (23.8%) and 16 received NMBs (76.2%). Among 39 "Fail" patients, 17 received DEBs (43.6%) and 22 received NMBs (56.4%). No statistically significant difference was observed between balloon types (Fisher's exact test; p = 0.166). Of those with follow-up data available at 12 months ($N_2$ = 54), 20 patients received DEBs (37.0%) and 34 received NMBs (63.0%). At 12 months post-procedure, patients receiving NMBs displayed an ~86.0% pass rate; meanwhile, the DEB group showed lower favorable outcome rates with only a ~14.0% pass rate. Although exact counts are not provided to protect patient confidentiality, these proportions indicate a trend toward better outcomes with NMBs, though these differences were not statistically significant (p = 0.239). Outcomes for both follow-up time points are summarized in table 2.

Age groups were analyzed for association with outcomes. At 6 months, patients aged 18 - 64 years ($A_1$, n = 29) and ≥ 65 years ($A_2$, n = 31) had pass rates of 42.9% and 57.1%, respectively; fail rates were 51.3% and 48.7%, with no significant association (Fisher's exact test; p = 0.595). At 12 months, patients aged 18 - 64 years ($A_3$, n = 28) and ≥ 65 years ($A_4$, n = 26) had similar distributions with no significant difference observed (Fisher's exact test; p = 1.000).

Biological sex was not significantly associated with outcomes at either follow-up point. At 6 months $M_1$ (males): n = 38; $F_1$ (females): n = 22, the difference was not significant (Fisher's exact test; p = 0.263). Similarly, at 12 months $M_2$: n = 33; $F_2$: n = 21, no significant difference was observed (Fisher's exact test; p = 0.096).

Stenosis location was also not associated with differences in outcomes. At 6 months ($N_1$), 7 patients had stenosis in the cephalic arch (11.7%), 23 in the fistula (38.3%), 21 in any other location (such as the brachiocephalic trunk) (35.0%), and 9 in multiple locations (15.0%). At 12 months ($N_2$), 6 patients had stenosis in the cephalic arch (11.1%), 19 in the fistula (35.2%), and 29 in another location (53.7%), with no significant differences (Fisher's exact test; p = 0.091 and p = 0.341, respectively).

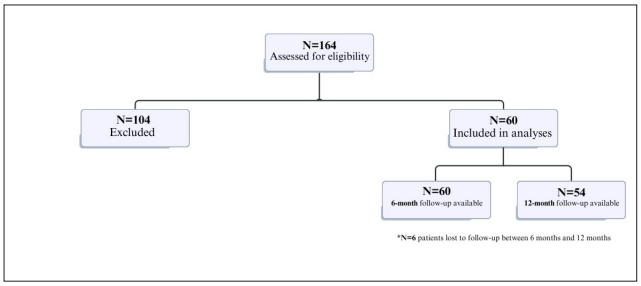



**Figure 3:** Study flow diagram. A total of 164 patients were screened. 104 screened patients were excluded who did not meet any of the inclusion criteria or who met any of the exclusion criteria. 60 patients met inclusion criteria and were included in the final analyses. All 60 patients had 6-month follow-up data available; 54 patients had 12-month follow-up data available, with 6 patients losing follow-up between 6 and 12 months.

**Table 1:** Baseline patient demographics for 60 patients undergoing PBA for treatment of AVF stenosis.

| Variable | Category | No. of patients (%) | p-value |
|---|---|---|---|
| Age | 18 - 64 years | 29 (48.3%) | 0.595 |
| | 65 years or older | 31 (51.7%) | |
| Sex | Male | 38 (63.3%) | 0.0389*) |
| | Female | 22 (36.7%) | |
| Location of stenosis | Cephalic Arch | 7 (11.7%) | 0.00397 (*) |
| | Fistula | 23 (38.3%) | |
| | Other | 21 (35.0%) | |
| | Multiple | 9 (15.0%) | |
| Balloon type | DEB | 22 (36.7%) | 0.00389 (*) |
| | NMB | 38 (63.3%) | |
| History of intervention | Prior intervention | 25 (41.7%) | 0.174 |
| | Naïve vessel | 35 (58.3%) | |

**Note:** Where, * denotes a statistically significant p-value. Baseline demographics are reported for the 60 patients from the initial screened cohort of 164 who met the inclusion criteria, had no exclusion criteria, and were included in the final statistical analysis (including the subset of 54 patients with 12-month follow-up data).

**Table 2:** Outcomes at 6 months and 12 months by balloon type.

| Time point | Outcome | DEB n (%) | NMB n (%) | p-value |
|---|---|---|---|---|
| 6 months (N = 60) | Pass | 5 (23.8%) | 16 (76.2%) | 0.166 |
| | Fail | 17 (43.6%) | 22 (56.4%) | |
| 12 months (N = 54) | Pass | ~14.0% | ~86.0% | 0.239 |
| | Fail | ~40.0% | ~60.0% | |

**Note:** Exact counts for the 12-month follow-up group cannot be reported due to confidentiality and ethical constraints. No statistically significant differences were observed.

The impact of prior vascular interventions in the vessel versus a naïve vessel was analyzed. At 6 months ($N_1$), 25 patients had had at least one prior intervention in the vessel (41.7%), while 35 had naïve vessels (58.3%), with no significant outcome association (Fisher's exact test; p = 0.174). At 12 months ($N_2$), 23 patients had prior interventions (42.6%) and 31 had naïve vessels (57.4%), also showing no significant association (Fisher's exact test; p = 0.218).

## Discussion

This study found no significant differences in clinical outcomes between DEBs and NMBs for AVF stenosis treatment at 6 and 12 months of follow-up (p = 0.166 and p = 0.239, respectively). Although patients receiving NMBs generally had better outcomes at both time points than DEBs, these differences were not statistically significant. These findings align with several studies reporting no improvement with one balloon type over the other [18-20]. Conversely, other studies have suggested improved outcomes with DEBs, including reduced stenotic lesion severity, better AVF patency, and decreased time between interventions [21-24]. Differences in study design, inclusion of AVGs, and retrospective versus prospective methodologies may contribute to these conflicting results, highlighting the need for further research.

Age did not significantly influence outcomes in this study. Younger patients (18 - 64 years) had higher failure rates at 6 months (51.3%) compared to older patients (48.7%) (p = 0.595), but by 12 months, younger patients showed improved pass rates (42.9% to 57.1%), whereas older patients declined (57.1% to 42.9%) (p = 1.000). Although not statistically significant, these results may suggest that younger patients who do respond well initially may maintain better long-term patency. Previous studies generally found age to be a non-significant factor, though some reported higher failure rates in patients over 65 - 80 years old [23, 25-30]. Sample size limitations may have constrained age analysis in the current study.

Biological sex also showed no statistically significant association with outcomes. Pass rates at 6 months were 37.9% for males and 50% for females, and at 12 months, 11.1% for males vs 50% for females (p = 0.263 and p = 0.0960, respectively). Prior studies suggest females to have higher AVF failure rates and increased use of AVGs or CVCs [31, 32]. These procedures can damage the vasculature necessary for an AVF [33]; thus, increased AVF failures in females may be partially attributed to prolonged decision-making regarding AVF creation, allowing more vascular damage to occur in the interim. However, our data indicate that females may achieve comparable or better long-term PBA outcomes overall. The male sex has been noted to have a higher incidence of early-onset coronary artery disease than the female sex, which may be a partial explanation for this [34]. Differences in sex distribution and sample size may influence these findings, and future studies should explore inherent sex differences vs potential sampling bias [35].

Stenosis location and prior vascular interventions were also not significantly associated with outcomes, which are less-studied factors. Trends toward higher pass rates in specific locations (such as within the fistula) or in naïve vessels were observed but were not statistically significant (all p-values > 0.05). Previous research suggests juxta-anastomotic stenoses may be prone to early recurrence, though results are inconsistent [36].

Although our data showed general trends suggesting potential differences in outcomes by age and biological sex, it is important to note that these findings should be considered exploratory due to the study's limitations (as described below) and lack of statistical significance. While paclitaxel's antiproliferative properties are theoretically expected to reduce neointimal hyperplasia and restenosis [16], factors such as drug delivery efficiency, local vascular responses, and patient variability may limit its clinical effectiveness in various patient populations. These complexities may explain the inconsistent findings across studies. Given this, clinicians may consider factors such as cost, availability, and patient-specific characteristics when selecting balloon types. The absence of clear superiority of DEBs underscores the need for well-designed clinical guidelines to assist decision-making and optimize resource utilization.

This study demonstrated several limitations, with the main being the study's design as a retrospective analysis. This carries inherent limitations, including possible selection bias and limited generalizability. As well, many patients within the sample had received multiple PBAs over time, with repeat interventions often involving the previously treated lesion; however, only the most recent intervention and outcome per patient were utilized in the analysis. While this minimized within-patient correlations and emphasized current practices, it may introduce selection bias. Specifically, patients with recurrent stenosis or multiple interventions may be overrepresented among those with poorer outcomes. Thus, the potential implications of multiple interventions during and before the study period on AVF outcomes were beyond the scope of the current study's resources, and future studies would benefit from exploring these factors.

Further components limiting our study include the choice of balloon used for PBA. Clinical guidelines do not currently exist regarding the use of a DEB vs a NMB in the treatment of AVF stenosis; such initiatives would be of benefit for informing future choices of balloons. Additionally, data extraction and classification were conducted by a single reviewer (thus, without a formal assessment of inter-rater reliability), which may inherently impact the consistency and objectivity of variable categorization. The sample was also composed of significantly more males than females, which may impact the generalizability of the results to the female sex. Finally, 6 of the final 60 patients included in the statistical analyses were lost to follow-up between 6 months and 12 months post-procedure; thus, the subset of patients analyzed with data at 12 months is slightly smaller. This may comparatively limit the precision and generalizability of the 12-month follow-up outcome estimates. We also acknowledge that important clinical variables such as patient comorbidities and dialysis-related factors were not collected in this retrospective study; however, their inclusion in future research would provide deeper clinical insights and improve the applicability of results [37].

## Conclusion

AVFs are a critical modality for hemodialysis, yet optimal management of associated stenosis via PBA remains debated. This study suggests no significant differences in outcomes between DEBs and NMBs, contrasting with prior reports. Patient age and biological sex were not significantly associated with PBA outcomes, consistent with several previous studies. Further research is needed to clarify the comparative efficacy of balloon types and explore additional patient- and procedure-specific factors influencing outcomes.

## Acknowledgements

None.

## Conflict of Interest

None.

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