Important Contributions to the Interventional Radiology Dialysis Literature, 2014–2015

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Semin Intervent Radiol 2016;33:46–51

Abstract

Keywords

- interventional radiology
- literature
- stent grafts
- angioplasty
- dialysis

Dialysis access interventions remain a vital component of long-term care for the dialysis population. Several advances have been published in the past two years, including both advances in the creation of accesses as well as treatment of specific processes leading to dialysis access failures. Advances in tools and other techniques used in dialysis access maintenance have also led to significant improvements in outcomes in this patient population. The purpose of this article is to provide synopses of some of the most important literature published in 2014–2015, and to provide objective data for the reader to make their own decisions regarding interventions performed in this patient population.

Objectives: Upon completion of this article, the reader will be able to discuss the important contributions to the dialysis literature over the past two years, and be able to translate those advances to their own dialysis population.

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There have been several advances in the literature regarding interventions performed in the dialysis patient population over the last two years. In addition to the medical and surgical management of such patients, endovascular procedures continue to play a vital role in this patient population. Research continues to be performed at a brisk pace in this population, with 547 citations on a Pubmed search using the term “dialysis access interventions” between 2014–2015 (representing nearly one publication per day during this time period). When the

search was limited to clinical trials and randomized controlled trials (RCT), 67 articles were returned. The abstracts from these articles were reviewed, and it was from this cohort that the articles were chosen for this manuscript. This manuscript is an attempt to provide a synopsis of some of the more important papers to be published in the literature.

No strict methodology was used to create this list, but rather the authors subjectively chose the articles based on their likely impact on current treatments for these patients. In addition, the potential for future impact following more widespread use of the procedures or management schemes presented in this literature were considered. After vetting the IR and non-IR literature, a total of eight publications were chosen for this review. They are presented here in alphabetical order.

Chan MG, Miller FJ, Valji K, Bansal A, Kuo M. Evaluating Patency Rates of an Ultralow-Porosity Expanded Polytetrafluoroethylene Covered Stent in the Treatment of Venous Stenosis in Arteriovenous Dialysis Circuits. J Vasc Intervent Radiol 2014;25:183–9¹

In this retrospective single institutional study, the authors evaluated the use of a nitinol ultralow porosity stent graft (VIABIL; W.L. Gore and Associates, Flagstaff, AZ) for venous

outflow stenoses in dialysis circuits. The stent graft that was evaluated is largely nonporous, which prevents cellular migration across the graft as well as impairing cellular adhesion.^{2–6} It was postulated that the VIABIL stent graft may have less restenosis than traditional medium porosity endografts for these stenoses.

In this study, 20 patients were treated for outflow stenoses in arteriovenous fistulae (AVF; $n = 11$) or grafts (AVG; $n = 9$). All of the venous accesses were being routinely used for dialysis, and had clinical indications for fistula interrogation and intervention, including four patients in each group who presented with acute circuit thrombosis. The primary endpoint was treatment area patency at two and 6 months. No comparisons, historical or contemporaneous, were made to other stent grafts.

Results from this study demonstrated technical success of stent graft placement in all patients. Results were reported for all 20 patients as one cohort, including both AVF and AVG groups. Primary patency rates at the treatment area were 85% at both 2 and 6 month follow-up, while primary circuit patency rates were 65% and 45% at 2 and 6 months, respectively. Secondary patency rates were 90% and 85% at 2 and 6 months, respectively. Importantly, on follow-up there were no documented stent edge stenosis.

Although the authors reported follow-up times between 162 and 782 days, they did not specifically report on the number of reinterventions necessary per patient during the follow-up period. As far as anatomic placement of the stent grafts, six were placed across joints (four elbow and two hip) without documented stent fracture or other specific complications. Due to the small sample sizes, advanced subgroup analyses comparing the graft versus fistula patients were not possible.

Conclusions from the study are that the ultralow porosity of the evaluated stent graft may be a viable alternative to other stent graft types in the treatment of venous stenoses in dialysis access circuits. Additionally, such stent grafts may lead to less in-stent or stent edge restenosis, potentially resulting in the need for fewer post-stenting reinterventions.

Kitrou PM, Spiliopoulos S, Katsanos K, Papachristou E, Siablis D, Karnabatidis D. Paclitaxel-Coated versus Plain Balloon Angioplasty for Dysfunctional Arteriovenous Fistulae: One-Year Results of a Prospective Randomized Controlled Trial. *J Vasc Interv Radiol* 2015;26:348–54⁷

In this prospective randomized controlled trial, the authors reported one-year results from a single institution comparing angioplasty with balloons coated with paclitaxel to standard high-pressure balloons in the treatment of AVF. Primary outcome measures included technical success (device and anatomic), clinical success, and target lesion revascularization-free survival. Inclusion criteria included single lesions with $>50\%$ stenosis compared with the reference vessel; patients who had prior treatments of the same lesion were not excluded.

There were a total of 20 patients in each arm. Device success was significantly greater in the high pressure balloon group than in the coated balloon cohort (100% versus 35%, respectively; $p < 0.001$). The patients in whom the coated balloon failed to achieve optimal success underwent post-paclitaxel balloon dilation with a standard high-pressure balloon; this resulted in angioplasty success in the remaining 65% of the patients. Anatomic success ($<30\%$ stenosis following final angioplasty) and clinical success (performance of at least one dialysis session after treatment, and improvement in any predisposing abnormal dialysis parameters) was 100% for both groups.

Target lesion revascularization-free survival was defined as a functional circuit that did not present for a secondary intervention based on clinical criteria. The paclitaxel-coated balloon group demonstrated higher success in this outcome parameter than the high-pressure balloon group (308 days versus 161 days, respectively; $p = 0.03$). Access circuit primary patency rates, a secondary outcome in this study, was also significantly better in the drug-coated balloon cohort (270 days versus 161 days, respectively; $p = 0.04$).

The author's conclusions were that, although the majority required additional high-pressure balloon dilation, the use of paclitaxel-coated balloons resulted in superior target lesion revascularization-free survival than high-pressure balloon dilation performed in isolation.

Liang HL, Fu, JH, Wang PC, et al. Endovascular Salvage of Immature Autogenous Hemodialysis Fistulas. *Cardiovasc Intervent Radiol* 2014;37:671–8⁸

This retrospective study was performed at a single institution over a 9-year time frame. By chart review, all patients with nonmaturing AVF, as defined by fistulae that could not be used for dialysis within the first three months, were identified. By this method, a total of 58 patients were identified, all of which had a radiocephalic AVF.

Vascular abnormalities responsible for the nonmaturing fistula were categorized as either stenosed, thrombosed, or obliterated. For patients who had a stenosis of the arterial-venous fistula connection itself leading to AVF dysfunction, angioplasty was performed with a 5 mm balloon in fistulae >6 weeks old, but with only a 1–2 mm balloon in recently created AVF. Lesions in the outflow vein were treated with 6 mm to 8 mm balloons. For thrombosed AVF, balloon fragmentation of the thrombus was performed. For obliterated veins, if the diseased segment could not be crossed a collateral vessel was accessed and balloon dilated if stenotic. Although embolization of competitive collateral outflow veins was an option, in only one patient was an embolization procedure performed.

Results of the study, which were classified according to the Society of Interventional Radiology reporting standards,⁹ demonstrated stenosis at the anastomosis in 47% of patients, and in the outflow vein in the other 53%. By these authors definition, 50% of the dysfunctional AVF were stenotic, 21% were thrombosed, and 29% were obliterated. Technical success was achieved in all of the stenosed and thrombosed AVF,

and in 88.2% of obliterated accesses; clinical success was achieved in all patients in whom technical success was achieved. Complications were noted in 15.5% of cases, most of which were venous ruptures; complications were reported more commonly in obliterated lesions. The authors reported patency rates at 3, 6, 12, and 36 months. Primary patency rates for stenosed, thrombosed, and obliterated lesions at 12 months were 55.2%, 45.8%, and 29.4%, respectively; secondary patency rates were 92.8%, 90.9%, and 64.7%, respectively. Three, 6, and 36 month rates were also presented in the manuscript but are not reiterated here. No significant differences were noted between the three types of lesions in either the primary ($p = 0.082$) or secondary ($p = 0.061$) patency rates, although statistical significance was reached when comparing stenosed and obliterated types ($p = 0.033$). Primary patency was compromised for patients in whom a vascular rupture occurred.

The conclusions by the authors were that angioplasty can prolong the patency and lifetime of immature AVF, but that vessel rupture was predictive of shorter primary patency rates.

Prologo JD, Minwell G, Kent J, Pirasteh A, Corn D. Effect of the Time to Intervention on the Outcome of Thrombosed Dialysis Access Grafts Managed Percutaneously. *Diagn Interv Radiol* 2014;20:143–6¹⁰

The authors of this study reported on the influence of time to intervention on procedural success of treatment of thrombosed dialysis grafts. The study design was a retrospective review of 268 interventions in 139 patients from two academic institutions treated between 2006 and 2011. The procedure performed (mechanical, pharmacologic, or mechanical thrombolysis; angioplasty or stent placement) was left to the discretion of the operator. The time to intervention was defined as the time difference between request for the procedure and the time the procedure was performed. When reporting results, the authors arbitrarily grouped patients into 24-hour cohorts: those undergoing intervention between 0–24 hours, 25–48 hours, and 49–72 hours. Patients who underwent declotting procedures following >72 hour thrombosis were excluded from the analysis.

Results from the study demonstrated an overall success rate (defined as a patent graft at the end of the declotting procedure and a successful dialysis session following the intervention) of 83.5%; most of the technical failures were due to the inability to dialyze post-thrombolysis failures of dialysis. In the successful and unsuccessful cohorts, the time to intervention was 19.9 ± 30.1 versus 22 ± 35 hours, respectively ($p = 0.71$).

Overall success rate was 85.3%. Differences in success rates between the three time-to-intervention groups did not reach statistical significance ($p > 0.05$).

In their conclusion, the authors stated that in patients presenting with thrombosed grafts, there was no association between procedure outcome and time to intervention up to 72 hours.

Rajan DK, Ebner A, Desai SB, Rios JM, Cohn WE. Percutaneous Creation of an Arteriovenous Fistula for Hemodialysis Access. *J Vasc Interv Radiol* 2015;26:484–90¹¹

In this study, the authors describe a technique used to create a dialysis access fistula using a completely percutaneous approach (pAVF). They appropriately state that there are still suboptimal results with surgical creations of AVF, including the need for catheter-based procedures to facilitate maturation of surgically-placed AVF as well as the treatment of thrombosed accesses. Their hypothesis was that creation of pAVF between arteries and veins in anatomic proximity to each other is possible, and perhaps provides better short term results compared with surgically-created accesses.

This study was a nonrandomized, prospective study. Inclusion and exclusion criteria paralleled those for patients undergoing surgical AVF creation, with the exception of the requirement that arteries and veins be within 2 mm of each other. Thirty-three patients were enrolled; an additional 28 patients were screened but were excluded from the study for various reasons, the most common being because of inappropriate anatomy. Four patients had undergone prior surgical AVF creation that had failed.

The authors described in great detail the procedure itself, which is beyond the scope of this review article. Briefly, the authors used a device specifically designed for the purpose of creating a pAVF. The pAVF was created between the ulnar artery and vein, as opposed to the more commonly performed radiocephalic vessels used in surgical AVF creation. The authors also embolized the outflow brachial vein in the upper arm to facilitate maturation of the fistula draining by the basilic and cephalic veins. As for the technique used, the device required catheter access into both the ulnar artery and vein. Strong magnets on the devices were used to approximate the vessels together, prior to vaporizing the tissue between the two magnets using a short burst (1 second) of a radiofrequency cutting current. Once the connection was achieved, all catheters were removed; no devices (i.e., grafts, stents) were left behind in the creation of these native fistulae.

Results of this study demonstrated a technical success rate of 97%, and evaluation of the pAVF by Doppler ultrasound at 24 hours showed patency of all pAVF that had been created. Four patients died of unrelated causes prior to the study endpoints, leaving 28 patients evaluated at 90 days post-pAVF creation; prior to 120 and 180 day follow-up, one patient was lost to follow-up and one patient withdrew from the study leaving 26 patients assessed at these time points.

In addition to the technical success rate, other primary endpoints included vein maturation at 3 months (96%), and serious device or procedure-related complications (3%). Secondary endpoints were also impressive, and included: 6 month patency (96%); dialysis initiated or ready AVF (96%); receiving dialysis via the pAVF (96%). Of note, the pAVF matured in an average of 58 days, however following minor revisions in the technique as well as increased

experience by the operators the average time to maturation decreased to 37 days. The authors reported that there was no evidence for arterial steal or peripheral neuropathy in any patient, although one patient did develop a pseudoaneurysm following the procedure that was treated by thrombin injection. The average rate of secondary catheter-based interventions was 0.6 per patient, which is significantly lower than the rate published for surgically placed fistulae (20–60%).¹²

The conclusion from this study was that preliminary data prove the feasibility of completely percutaneous creation of forearm AVF, as well as improved patency rates of these fistulae compared with those created surgically. Further studies are, of course, warranted.

Rajan DK, Falk A. A Randomized Prospective Study Comparing Outcomes of Angioplasty versus VIABAHN Stent-Graft Placement for Cephalic Arch Stenosis in Dysfunctional Hemodialysis Accesses. J Vasc Interv Radiol 2015; 26:1355–1361¹³

In 2015, Rajan and Falk reported on the results of a prospective randomized multicenter unblinded study comparing covered stent-graft placement versus percutaneous transluminal angioplasty (PTA) for treatment of cephalic arch stenoses in dysfunctional upper extremity hemodialysis accesses.

The patient population included individuals with mature forearm or upper arm hemodialysis accesses created more than 2 months prior to study enrollment who were expected to remain on hemodialysis for 12 months. Angiographic criteria for inclusion were stenotic lesions located ≤ 30 mm from the cephalic arch, measuring < 30 mm in length, and showing $> 50\%$ narrowing; secondary sites of stenosis were allowed if specific conditions were met, most notably resolution with $< 30\%$ residual narrowing after treatment with conventional PTA prior to randomization. Selected pertinent study exclusion criteria were access thrombosis, presence of indwelling catheters, incomplete PTA (residual balloon waist), complication of PTA, symptomatic central venous stenosis, active infection, contrast allergy, and heparin induced thrombocytopenia. Of note, prior bare metal stent placement in the cephalic arch did not constitute an exclusion criterion. Patients recruited into the study were randomized in a 1:1 fashion to receive PTA with or without stent-graft placement (VIABAHN; W. L. Gore & Associates, Flagstaff AZ).

From a procedural standpoint, PTA involved use of a balloon sized 0–1 mm larger than adjacent normal cephalic vein, and balloons were left inflated for a minimum of 45 seconds. In cases randomized to stent-graft deployment, the device diameter was the same as the dilating PTA balloon, and the stent-graft was extended across the genu of the cephalic arch to allow a smooth transition from the cephalic vein. After treatment, patients were followed with angiography and/or transonic measurements at 3-, 6-, and 12-months post-procedure. Repeat interventions were also performed in cases of access dysfunction. Power analysis indicated a need

for 34 patients (17 per study group). Measured primary outcomes included anatomic success ($< 30\%$ residual stenosis following treatment), clinical success (resumption of normal dialysis for at least one session), and circuit primary patency.

A total of 14 patients were enrolled over a 4-year period, of which 5 underwent PTA while 9 received stent-grafts. All patients had mature brachiocephalic arteriovenous fistulae. There were no statistical differences in patient and lesion characteristics, and no patients were lost to follow-up. Mean patency in the PTA and stent-graft groups were 100 days and 300 days, respectively. A significant difference in primary access circuit patency favored the stent-graft group: 100%, 67%, and 22% versus 20%, 0%, and 0% at 3-, 6-, and 12-months, respectively ($p < 0.01$). Target lesion patency was also superior in the stent-graft group: 100%, 100%, and 29% versus 60%, 0%, and 0% at 3-, 6-, and 12-months, respectively ($p < 0.01$). There were no complications in either group.

The major study limitation was poor patient recruitment over prolonged study period, with failure to achieve sufficient subject enrollment to adequately power assessment of secondary outcomes measures such as variables associated with patency and assisted/secondary patency. Nonetheless, the authors concluded that stent-graft treatment of cephalic arch stenoses provided statistically superior primary patency rates up to 1-year post-treatment as compared with balloon PTA. While this management approach for cephalic arch lesions should be considered, corroborative studies are necessary.

Rasuli P, Chennur VS, Connolly MJ, Hadziomerovic A, Pomerleau FE, Ryan SE, French GJ, O'Kelly K, Aina R, Champagne P, Petrcich W. Randomized Trial Comparing the Primary Patency following Cutting Versus High-Pressure Balloon Angioplasty for Treatment of de Novo Venous Stenoses in Hemodialysis Arteriovenous Fistulae. J Vasc Interv Radiol. 2015;26:1840–1846¹⁴

In this single-center prospective randomized clinical trial, postinterventional primary patency rates by cutting balloon angioplasty and high-pressure balloon angioplasty in the treatment of de novo stenoses within autogenous arteriovenous (AV) fistulae for hemodialysis were compared in 48 patients.

Angioplasty was performed using cutting balloon or high-pressure balloon 4–8 mm in diameter (because cutting balloons larger than 8 mm were not available). Nine patients were excluded after angiography, with seven requiring balloons larger than 8 mm. In the remaining 39 patients, there were 42 stenoses in the following regions: juxtaanastomotic (38%), perianastomotic (38%), midcephalic (9%), and cephalic arch (14%). Patients in the cutting balloon group were younger (mean age difference, 9 years; $p = 0.04$), but other demographic variables were comparable (range, $p = 0.08$ –.89). The mean follow-up period was 8.5 months (range, 24 days to 32 months). Kaplan–Meier analysis was used to compare duration of patency

Table 1 Patency rates for reported each anatomic region

Anatomic region	6-month assisted primary patency rate: cutting balloon	6-month assisted primary patency rate: PTA	12-month assisted primary patency rate: cutting balloon	12-month assisted primary patency rate: PTA	p-value
Graft-venous anastomosis	86%	56%	63%	37%	$p = 0.37$
Intragraft	67%	62%	39%	49%	$p = 0.371$
Venous	84%	70%	55%	46%	$p = 0.360$
Arterial anastomosis	70%	75%	30%	33%	$p = 0.921$

Technical success was 100%. At 3, 6, and 12 months, the postinterventional primary patency rates for the cutting balloon group were 61.1% (95% confidence interval [CI], 35.75–82.70%), 27.7% (95% CI, 9.69–53.48%), and 11.1% (95% CI, 1.38–34.71%), respectively, compared with 70.0% (95% CI, 45.72–88.11%), 42.1% (95% CI, 20.25–66.50%), and 26.3% (95% CI, 9.15–51.20%), respectively, for the high-pressure balloon group ($p < 0.3$ at each interval).

Authors concluded that high-pressure balloon angioplasty and cutting balloon angioplasty are equivalent for de novo stenosis in autogenous arteriovenous fistulae.

Saleh JM, Gabr AK, Tawfik MM, Abouellail H. Prospective, Randomized Study of Cutting Balloon Angioplasty versus Conventional Balloon Angioplasty for the Treatment of Hemodialysis Access Stenoses. J Vasc Surg 2014;60:735–40¹⁵

In this multi-institutional study at three referral institutions, 623 patients were randomized to receive either cutting balloon angioplasty or PTA without microtomes. Inclusion and exclusion criteria were similar to other angioplasty trials, but patients with previous PTA for the same lesion or PTA combined with stenting were excluded. Significant stenoses were defined as >50% narrowing in one angiographic plane. For the sake of analysis, stenoses were divided into native outflow vein, graft-to-vein anastomosis, intragraft, or arterial anastomosis. Patients with AVF and arteriovenous grafts (AVG) were enrolled in the study. Endpoints included clinical success of the primary procedure, defined as one successful dialysis session post-intervention; hemodynamic success, defined as restoration of normal blood flow through the treated region; and anatomic success, defined as residual stenosis <30%.

In this study, patients were followed for a mean of 15 months post-intervention. 316 patients underwent cutting balloon angioplasty, and 307 patients underwent PTA. Anatomic location of the stenoses were nearly equivalent in within groups and in comparing both of the groups (between 70 and 95 patients at each anatomic location, in all groups with the exception of intragraft stenoses in the cutting balloon group ($n = 61$)).

The results were separated into anatomic regions, however overall group results were also reported. These overall results demonstrated high clinical success rates of 89% in the cutting balloon group and 86% in the PTA cohort ($p = 0.637$). In the subgroup analyses, assisted primary patency rates were equivalent at 6- and 12-months for the treatment of intragraft, venous, and arterial anastomotic stenoses. ▶**Table 1** shows the results for each subgroup.

Complications were equivalent in both groups (3 in the cutting balloon group, 2 in the PTA group), although the authors did not perform formal statistical analysis of the complication rates.

The author's conclusions from this study were that cutting balloon angioplasty was safe at all locations, and that it was more effective than standard PTA at the graft-venous anastomosis.

Summary

The treatment of dialysis access stenosis continues to be an important component of most interventional radiology practices, as well as vascular surgery and interventional nephrology practices. While it may appear provincial, seven of the eight articles presented here were from primary authors from radiology practices (one was from a vascular surgery department). The articles, however, were chosen prior to identification of the primary researcher departments. This result reinforces the notion that interventional radiology continues to produce high value dialysis access research.

The articles presented here represent a wide cross-section of dialysis access advancements. Technical advances such as the optimal way to perform angioplasty, advancements in endovascular techniques or devices, and the clinical management of dialysis access. Future advancements in these areas as well as others are anticipated in the next several years.

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