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Current Experience and Midterm Follow-up of Immediate-Access Arteriovenous Grafts

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Abstract

Background: No independent reviews, with midterm follow-up, of current experience with immediate-access arteriovenous grafts (IAAVGs) exist. The goal of this project was to assess the real-world performance of 2 different IAAVGs over a 2-year period at a large tertiary referral center.

Methods: Between January 2014 and April 2016, all consecutive patients who underwent placement of Acuseal (Gore) or Flixine (Maquet) IAAVGs were identified for retrospective analysis from the electronic medical record and Vascular Quality Initiative database. Primary, primary-assisted and secondary patency rates, time to first cannulation, time to tunneled catheter removal, and overall survival were recorded.

Results: Forty-three patients were identified to have undergone placement of IAAVG, 31 Acuseal (72%), and 12 Flixine (28%). Of the Acuseal cohort, 7 were implanted with outflow through a HeRO catheter system (Merit Medical). Mean follow-up time was 8.4 months. Overall survival was 57.4% at 18 months. Overall primary, primary assisted, and secondary patency at 18 months were 33.36%, 34.31%, and 51.03%, respectively. Eighty three percent of grafts were successfully cannulated, and 78% of preexisting catheters were removed. Mean time to successful graft cannulation and catheter removal were 14.85 and 32.26 days, respectively.

Conclusions: Real-world experience with novel arteriovenous access grafts is consistent with results from industry-sponsored studies. Early cannulation of immediate-access grafts can be successfully performed in a wide variety of patients. However, prolonged catheter dwell times persist despite increased rates of successful early-graft cannulation. Further study of methods for promoting catheter removal in this patient population is warranted.

INTRODUCTION

In the decade since the current National Kidney foundation's KDOQI guidelines were first released, with companion publication of synonymous clinical practice guidelines by the Society for Vascular Surgery, arteriovenous fistulas (AVFs) have predominated as the favored access modality for patients reliant upon hemodialysis (HD).^{1,2} Compared with AVF, arteriovenous grafts (AVGs) are considered second-line due to increased rates of reintervention and inferior patency rates in patients with good quality superficial veins. As a last-resort means of access are tunneled dialysis catheters (TDC), which account for more than 75% of incident HD cases in the US.³

Despite not being an ideal means of access, AVGs are gaining acceptance as an incident modality in some patients because of inadequate venous anatomy and/or short-life expectancy.⁴ Traditional clinical practice states that an AVF will, on average, be suitable for use 6 weeks after creation, with standard AVG being ready for cannulation in just 2 weeks. However, evaluation of United States Renal Data System (USRDS) data finds both intervals far briefer than what is experienced in widespread clinical practice, with median AVF maturation being 18 weeks and median AVG maturation being 9 weeks.⁵ Regardless of modality, if a patient is already HD-dependent, any period between access creation and successful cannulation will require peritoneal dialysis or a TDC, with all its inherent risks, namely infection and induction of central venous stenosis.

Since the advent of immediate-access arteriovenous grafts (IAAVGs) and their increasing commercial availability over the last decade, numerous industry-driven studies have shown patency rates similar to those of standard AVGs, with the added benefit of a shorter interval period of TDC dependence.⁶ These prospective single-arm clinical trials assessing the functionality and short-term outcomes of the current, commercially available IAAVGs do not represent independent experience with 12- to 18-month outcomes of these grafts' performance in the heterogeneous treatment setting of the United States.

The goal of this project was to provide a descriptive analysis of real-world performance and midterm outcomes of IAAVG utilization at a major tertiary center in the United States.

METHODS

This study is a single-institution, retrospective review of 42 patients who underwent 43 consecutive attempts at IAAVG implantation between January 2014 and April 2016. At our institution, 2 types of IAAVG have been incorporated into clinical practice: Acuseal (W. L. Gore & Associates, Newark, Del.) and Flixene (Atrium Medical Corporation, Hudson, NH). Both grafts are commercially available, and none of the procedures were performed as part of an industry-funded trial.

After obtaining institutional IRB approval, patient comorbidities, graft configuration, operative characteristics, and subsequent follow-up were collected and analyzed with respect to primary patency, primary-assisted patency, and secondary patency. Additional outcomes included graft-related complications, time to first cannulation, time to tunneled catheter removal, catheter-related complications, and overall survival.

Five surgeons, whose practices include a large proportion of hemodialysis access work, performed the procedures. At our institution, IAAVGs early were reserved for patients with an urgent need for a durable hemodialysis access and lack appropriate venous anatomy, which would warrant the creation of a fistula or placement of a standard AVG and simultaneous placement of an interval TDC. More recently, however, certain surgeons have begun to transition toward using IAAVGs as their default conduit for nonautogenous access.

Patency was defined per Society for Vascular Surgery recommended reporting standards and was determined from the time of the index procedure.² Follow-up information was obtained through review of inpatient and outpatient records as well as external dialysis center records, when available.

Statistical Analysis

Categorical data are described with counts and proportions and continuous data with means, ranges, and standard deviations. Patency rates were analyzed using life-table analysis, and patency rate comparisons were made with a 2-group proportion comparison calculator with the *P*-value set as significant at <0.05. All analyses were performed using Stata 14 software (StataCorp LP, College Station, TX).

RESULTS

Forty-two patients were identified to have undergone placement of 43 IAAVGs, 31 Acuseal (72%), and 12 Flixene (28%). Of the Acuseal cohort, 7 were implanted with outflow through a HeRO catheter system (Merit Medical, South Jordan, UT). Demographics and comorbidities were consistent with USRDS national sample characteristics during this study period (Table I). Most patients had diabetes mellitus, hypertension, and COPD. Notably, 26% (11) of the patients in this sample had history of central venous occlusions ipsilateral to the side of their graft, 9 of whom were diagnosed with bilateral central venous occlusions. Five (11.9%) of the subjects had a failed prior lower-extremity graft.

Although access histories were incomplete, a mean number of 1.55 ± 1.58 prior dialysis accesses were documented. At the time of IAAVG placement, 81% of patients had an indwelling TDC. All but one of the procedures was for upper-extremity access. The 1 patient who underwent placement of a femoral-loop Flixene graft had a prior failed upper-extremity Flixene graft, in addition to a history of 5 other upper-extremity accesses.

Regarding configuration, 59.5% of the upper-extremity grafts implanted were of a straight orientation, and all but the aforementioned femoral graft derived their inflow from the brachial artery (97.7%). For forearm loop grafts, the venous outflow was predominantly via the brachial vein (82.4%).

All patients tolerated their procedures well, and technical success for creation of a functioning access was 100%. Three (7.14%) of the patients died within a month of their index operation; all were from causes unrelated to their access surgery. These 3 patients all died with a patent access. There were no cases of steal syndrome requiring surgical intervention. The 1 femoral graft patient in this series suffered a complication of his surgical

would requiring a return to the operating room for debridement. One Acuseal-HeRO combination access patient developed a graft infection 6 months after creation, and 1 forearm-loop Acuseal patient developed a graft infection 2 months after creation. Both accesses were abandoned at the time of their operative debridement/resection.

Mean follow-up time was 8.4 ± 8.2 months. Overall survival was 57.4% at both 12 and 18 months. Overall primary, primary-assisted, and secondary patency were 40.0%, 41.2%, and 58.3% at 12 months, and 33.4%, 34.3%, and 51.0% at 18 months, respectively (Fig. 1). In the Flixene group, by 1 year, 4 of the 12 grafts had thrombosed, 7 patients had died with a patent graft, and 1 graft remained patent. In the Acuseal group, by 1 year, 7 of the 24 grafts had thrombosed or been abandoned, 6 patients had died with a patent graft, and 11 grafts remained patent.

Mean number of reinterventions to maintain patency was 0.8 ± 1.7 procedures. Acuseal outflow via a HeRO catheter required significantly more reinterventions than those utilizing traditional venous outflow (2.3 ± 3.7 procedures vs. 0.3 ± 0.6 procedures, $P = 0.02$). The average number of reinterventions to maintain patency of a Flixene graft was 0.8 ± 1.0 procedures, and this did not differ significantly from the Acuseal grafts with standard venous outflow (0.3 ± 0.6 procedures, $P = 0.14$).

In this sample, 83.7% of grafts were successfully accessed, with a mean time to first cannulation of 14.9 ± 19.4 days. 41.2% of IAAVGs were accessed within 72 hr of placement. Catheter removal was achieved in 78% of those with an indwelling TDC at the time of the index procedure. The mean time to catheter removal was 32.3 ± 33.2 days. 30.3% of prevalent catheters were removed within 5 days of graft placement. All but one of the 7 Acuseal-HeRO patients had an indwelling TDC at the time of their procedure, and all were successfully converted to a functional access in the index operation. For this group, there was 100% success in immediate conversion from TDC dependence to a cannulated AVG within 24 hr. In the overall series, no grafts accessed within 10 days of placement developed any bleeding or infectious complications from early cannulation.

DISCUSSION

Our series serves as an independent descriptive analysis of real-world experience with currently available IAAVGs in a tertiary setting in the United States. In an independent setting, with a wide variety of patients, our study shows a consistent ability to successfully cannulate IAAVGs in the immediate perioperative setting with freedom from bleeding complications. Still, access was not achieved as early as possible, for the majority of patients. Overall, our outcomes, particularly the 1-year secondary-patency rate of 58.3%, are congruent with those published in industry-sponsored trials as well as in the more stringent European setting.^{7,8}

The earliest reported cases of early cannulation graft implantation were described in the 1980s, but this technology's entry into pervasive clinical practice has only really occurred in the past decade. The first widely used early-cannulation access was the Vectra trilayer graft (C. R. Bard Inc., Murray Hill, NJ). Early studies failed to identify any additional benefit

compared to standard expanded polytetrafluoroethylene grafts.¹ Later studies showed comparable long-term secondary patency rates compared to brachio basilic AVF; however, to achieve this outcome, there was a significantly greater need for reintervention with the Vectra graft.^{9,10} The Flixene vascular graft has been FDA approved and available for use since 2006 and can be accessed within 72 hr after implantation. The Gore Acuseal vascular graft is the most recent entry into the marketplace of IAAVGs (2013). The Acuseal, like the Vectra and Flixene grafts, is a trilayer design utilizing expanded polytetrafluoroethylene; however, the inner lumen is also coated with a layer of covalently bound heparin, and the graft can be accessed within 24 hr of implantation.

Aitken et al. recently reported on the use of IAAVGs in place of TDCs as an urgent access modality.¹¹ In this randomized trial, IAAVGs were associated with significantly fewer infectious complications compared to TDCs.⁹ Cost-equivalence occurred between the 2 accesses because costs associated with infectious complications in the TDC arm balanced initial surgical expenditures in the IAAVG arm.⁹ Though cost was not an end point in our present study, this series does have a significantly lower rate of infectious complications (4.7%) as compared to historical controls of TDC use, therein supporting the notion that such cost-equivalence could also apply in this patient population.^{12,13} In addition, in their series, the IAAVG cohort had a reported infectious complication of 3.3%, which is in line with the result of our series 4.7% (2/43).¹¹

In our series, the Acuseal graft was implanted in the majority of patients. Few studies focusing on Acuseal grafts exist in the peer-reviewed literature. In those identified, there is great heterogeneity of results regarding the number of grafts implanted, indications for placement, patency rates, and duration of follow-up.^{7,14,15} In Maytham's independent European series of 55 Acuseal grafts, 1-year results were notable for 12 month primary patency of 46% and secondary patency of 61%, with 73% of patients being cannulated within 24 hr of graft placement.⁸ The largest prospective series (138 grafts) was published by Glickman in 2015 and reported a primary patency and secondary patency at 12 months of 33% and 78%, respectively.⁸ When comparing our findings to the independent European series, there is congruity; however, when compared to Glickman's industry-supported trial's 1-year results, the primary patency results are comparable, yet there was a significant disparity in the cumulative patency and the total number of reinterventions. The Glickman study describes a cumulative patency rate of 79%, but with a larger number of reinterventions (1.6 per-access) to achieve this outcome. By comparison, the 24 patients in our series with Acuseal grafts utilizing a standard venous outflow underwent an average of 0.3 ± 0.6 procedures per access.

Twelve Flixene grafts were used in our series and represent the earliest immediate-access graft placements at our center. Recent studies have demonstrated 1-year primary patency rates ranging from 30 to 66% and secondary patency rates of 63–84%.^{8,16–18} Several of these studies showed consistent success at cannulation within 72 hr of graft placement and with low rates of infection (0–11%), consistent with the experience reported in our series.^{6,15,16}

Though capable of being accessed shortly after placement, our experience also demonstrates the nonoperative limitations of leveraging the perceived benefits of such new technology. Respectively, despite 41.2% and 61.7% of all grafts being accessed within 3 and 14 days of placement, an overall mean catheter dwell time around 1 month is indicative of a disconnect in the outpatient setting during the postoperative period. Early on in this series, before knowledge of, and experience with these novel trilayer grafts became more common, HD unit nurses and their supervising nephrologists were treating these grafts no differently than the standard AVGs to which they had become accustomed. Recently, and in large part because of this analysis, our practice is directly contacting HD units at the time of postoperative discharge to notify them that an incident IAAVG is ready for cannulation at the time of their next HD session. This, in coordination with a targeted postoperative management plan involving early clinical follow-up with a goal of clinic-based TDC removal should lead to a dramatic reduction in the catheter dwell times for those with functional IAAVGs. We hope to evaluate and report on the success of this intervention in the future.

When reviewing our series in the setting of similar studies, there is a notable difference in the 1-year survival. At 12 months, the overall survival of 57.4% in our series is significantly lower than that reported by the Glickman Acuseal series (87.7%) but is comparable to outcomes identified in the USRDS.¹⁹ This is likely the result of our heterogeneous mix of patients, many of whom were “end-stage dialysis patients” and not just suffering from end-stage renal disease.

This project does have its limitations, namely given its relatively small size and retrospective nature, combined with a heterogeneous patient sample, any comparisons between graft types or generalizations of experience might not be translatable to a larger population. Further study of the performance of IAAVGs in the real-world setting, with comparison to a cohort of standard AVGs from the same center(s) would further discern any advantages or pitfalls of this novel technology in the creation of durable hemodialysis accesses.

CONCLUSION

Real-world experience with novel arteriovenous access grafts is consistent with results from industry-sponsored studies. Early cannulation of immediate-access grafts can be successfully performed in a wide variety of patients. However, prolonged catheter dwell times persist despite increased rates of successful early graft cannulation. Further study of methods for promoting catheter removal in this patient population is warranted.

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Fig. 1.

Primary, primary-assisted, and secondary patency (all standard error <10%).

Table I.

Patient characteristics

Variable	Mean (range) or no. (%) (<i>n</i> = 42)
Demographics	
Age, years	61.2 (23.5–89.8)
Male	24 (57.1)
White	21 (50)
Black	21 (50)
Body mass index	28.4 (18.0–51.9)
Comorbidities	
Diabetes	24 (57.1)
Hypertension	38 (90.5)
Tobacco use	25 (59.5)
COPD	15 (35.7)
Central venous occlusion	11 (26.2)