Prospective multicenter study with a 1-year analysis of a new vascular graft used for early cannulation in patients undergoing hemodialysis

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Objective: **More than 85% of patients with end-stage renal disease start dialysis through a tunneled dialysis catheter (TDC) for long periods while their arteriovenous fistula or vascular access graft (arteriovenous graft [AVG]) matures. Because TDCs are associated with a high risk of complications, including death and infection, use of an AVG that can be cannulated safely immediately after implantation may reduce morbidity in these patients by allowing earlier TDC removal. We report a prospective multicenter study of a new early-cannulation AVG (Gore ACUSEAL Vascular Graft; W. L. Gore & Associates, Flagstaff, Ariz).**

Methods: **Patients requiring creation of a prosthetic vascular access for hemodialysis were enrolled between July 2010 and February 2012 and observed for 12 months. Data were collected on the patients' baseline characteristics; location, position, loss of patency, and revisions of prior AVGs; dialysis sessions using the AVG; and major adverse events related to graft implantation or cannulation. Cumulative and primary unassisted graft patency rates were calculated. A subgroup analysis compared outcomes in patients in whom the AVG was first cannulated within 72 hours after implantation with outcomes in patients in whom the initial cannulation was performed >21 days postoperatively.**

Results: **The population of this study was formed by 138 patients who received an ACUSEAL graft. During follow-up, 17 patients died and the AVG was abandoned in 27. The median value for follow-up was 360 days for all patients (variance 15,387). The overall mean time to initial cannulation was 15 days, with 54 grafts (40%) first cannulated within 72 hours after graft implantation and 33 grafts first cannulated >21 days afterward. The reason for late cannulation in some patients was dependent on the implanting surgeon's decision and the surgeon's personal experience with early cannulating grafts. The 1-year overall cumulative patency rate was 79% (95% confidence interval, 71%-85%); the primary unassisted patency rate was 35% (95% confidence interval, 27%-44%). Adverse events included 6 hematomas (two of which were related to cannulation and occurred 107 and 169 days, respectively, after AVG implantation), 15 graft infections, and 15 cases of steal syndrome requiring intervention. Patients in the early- and later-cannulation groups had similar characteristics and no significant differences in rates of cumulative or primary unassisted patency or adverse events.**

Conclusions: **This study demonstrated that the new, early-cannulation AVG graft can be cannulated soon after implantation without a significant difference in patency and complication rates compared with rates associated with standard cannulation of expanded polytetrafluoroethylene grafts in the literature. This new AVG may allow early removal or avoidance of TDC use in patients undergoing hemodialysis, potentially reducing or eliminating the number of days of catheter-dependent dialysis, but further studies will be needed to demonstrate this potential. (J Vasc Surg 2015;62:434-41.)**

In patients with end-stage renal disease (ESRD), the number of new hemodialysis patients starting their first treatment through a tunneled dialysis catheter (TDC) has not changed appreciably during the past decade. The percentage of incident hemodialysis patients with a TDC ranges from 78% to 81%.[1-3] Possible reasons for this continued high rate of TDC use include a lack of early referral, the patient's noncompliance, and an inability to obtain appropriate, timely surgical intervention. Efforts have been made to decrease the use of TDCs in the United States, but the incidence rate remains high. TDCs have been observed to be associated with high rates of morbidity and mortality within the first 90 days of starting hemodialysis.[4] Infection, a frequent adverse effect of TDC use, is the second most common cause of death in patients undergoing hemodialysis, after cardiac events.[5,6] Therefore, introduction of an early-cannulation graft for hemodialysis is an attractive alternative because it may reduce TDC contact time or avoid TDC use entirely, either of which has the potential to decrease infections and, possibly, the occurrence of central venous stenosis.

Most patients who require a permanent prosthetic vascular access for hemodialysis are given an expanded polytetrafluoroethylene (ePTFE) graft. Early cannulation of standard ePTFE grafts has been reported, but these devices

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were not designed for that purpose, and excessive bleeding and hematoma formation are possible when they are cannulated within hours or days after implantation.[7]

In April 2013, a new, multilayer ePTFE arteriovenous graft (AVG; Gore ACUSEAL Vascular Graft; W. L. Gore & Associates, Flagstaff, Ariz) was cleared for marketing by the U.S. Food and Drug Administration (FDA). The FDA-accepted instructions for use for this device state that it can be cannulated for hemodialysis within 24 hours of implantation. Early results with this AVG in small, single-center, early-cannulation series were encouraging with respect to patency and complication rates.[8,9] Tozzi's experience in Europe demonstrated good patency rates and low complication rates with early cannulation of this graft.[9] The FDA clearance of the AVG was based on some of the data from the FDA-authorized clinical study reported here.

The principal purpose of our multicenter study was to evaluate the safety and efficacy of the new AVG when cannulated in the early postoperative period (≤72 hours after implantation). We therefore determined the 1-year cumulative and primary unassisted patency rates for the AVG in a cohort of patients undergoing hemodialysis and documented any adverse events related to cannulation or dialysis. In addition, because the time to first cannulation of the graft was observed to vary considerably in our cohort, we elected to assess whether early cannulation might reduce the number of days of TDC-dependent dialysis by comparing outcomes in patients in whom cannulation of the AVG was first performed early after implantation (≤72 hours) with outcomes in those in whom the initial cannulation occurred at a time commonly used for standard hemodialysis grafts (>21 days).

METHODS

Patients. The study was approved by the Institutional Review Board for each of the 10 study centers, and all enrolled patients or their legally designated representative provided written consent to their participation. Patients with ESRD were considered for enrollment if they presented between July 29, 2010, and February 29, 2012; were currently undergoing hemodialysis or expected to begin hemodialysis within 30 days; were not considered candidates for creation of an arteriovenous fistula (AVF); and were able to have the AVG placed in an upper extremity. This determination was made by the surgeon and based on vein mapping at each institution.

Patients were excluded from the study if they had previously had more than two vascular accesses in the arm in which the AVG was to be implanted or they had a known or suspected systemic infection, a hypercoagulable or bleeding disorder, or a sensitivity to heparin. Also excluded were patients who were receiving maintenance immunosuppression therapy or extended-release dipyridamole plus aspirin.

Graft. The AVG used in this study is a 6-mm by 40-cm trilayer device (Fig 1). It has an inner layer of ePTFE bonded with heparin (CBAS Heparin Surface, W. L. Gore & Associates), a middle elastomeric layer, and an outer layer of ePTFE. The heparin is bound to the inner ePTFE surface by means of an end-point covalent attachment that allows it to remain bioactive for several months.[10] The middle layer of the graft is intended to act as a sealant, possibly reducing blood loss and the time to hemostasis at cannulation sites. The cost of this graft is around $200 more than a standard heparin-bonded ePTFE graft.

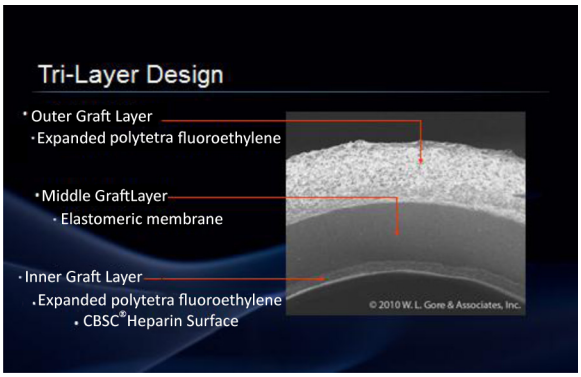

Fig 1. The vascular access graft used in the study (Gore ACUSEAL Vascular Graft; W. L. Gore & Associates, Flagstaff, Ariz) has inner and outer layers of expanded polytetrafluoroethylene (ePTFE) separated by a layer of medical-grade elastomer.

Graft implantation and cannulation. The patients' physicians made all decisions about preoperative assessment of veins in the upper extremity, the site of AVG implantation, the time of first cannulation of the AVG, the need for intervention to maintain or to restore AVG patency and the type of intervention performed, and the treatment of any adverse events. Patients were scheduled to be examined by their clinicians 1, 3, 6, and 12 months after graft implantation. Routine scanning was not part of the protocol. Clinicians examined the patient, looked at the wounds, and listened to the bruit of the graft. In accordance with the instructions for use for the graft, staff members at hemodialysis centers were encouraged to maintain pressure on needle exit sites for 10 to 15 minutes to achieve hemostasis after decannulation of grafts implanted <14 days earlier.

Data collection and definitions. Data included patients' baseline characteristics (demographic information, comorbid conditions, and vascular access history); location, position, loss of patency, and revisions of the AVG; time of first AVG cannulation; and major adverse events related to graft implantation or cannulation. Data were collected prospectively at each study site by using a web-based data-capture system. Data collection in the study ended on February 12, 2013.

Patients were referred for evaluation for a possible AVG thrombosis when neither a thrill nor a bruit was detected. Cumulative patency was defined as freedom from complete loss of the access regardless of whether interventions were done to restore or to maintain patency or to manage hematoma, infection, or steal syndrome during the 12-month study period. Primary unassisted patency

Table I. Patients' baseline demographic characteristics, comorbid conditions, and vascular access history (total N = 138)

Variable	*Value*[a]
Age, years, mean ± SD (range)	63 ± 14 (27-94)
Male/female	67 (49)/71 (551)
BMI, kg/m^2, mean ± SD (range)	30 ± 8 (17-56)
Race[b]	
African American	76 (55)
White	49 (35)
Other	14 (10)
Diabetes mellitus	83 (60)
Hypertension	134 (97)
Cardiovascular disease	70 (51)
Cerebrovascular disease	38 (27)
Peripheral arterial disease	24 (17)
Current tobacco use	32 (23)
Previous hemodialysis	114 (83)
Time receiving dialysis, years, mean ± SD (range)	2 ± 3 (0-19)
No. of previous permanent vascular accesses	
1	64 (46)
2	25 (18)
≥3	2 (1)
AVF or AVG currently in use	7 (6)
TDC currently in use	101 (89)
No. of previous TDCs	
1	40 (29)
2	12 (9)
≥3	3 (2)

AVF, Arteriovenous fistula; *AVG,* arteriovenous graft; *BMI,* body mass index; *SD,* standard deviation; *TDC,* tunneled dialysis catheter.
[a]Values are number (%) of patients unless otherwise indicated.
[b]As reported by patient.

was defined as freedom from complete loss of the access without thrombosis or an intervention during the 12-month period.

In accordance with the standard care of patients with a TDC who are switching to hemodialysis through a permanent access, the TDCs that were in place in our patients at enrollment were assumed to be eligible for removal after the third consecutive successful dialysis session through the AVG.[11,12] Thus, in the data analysis, the third consecutive cannulation was considered the marker for the end of catheter-dependent dialysis, even though some TDCs may have remained in place awaiting orders for or scheduling of removal.

Post hoc subgroup analysis. An initial assessment of our data showed that first cannulation of the AVG occurred over a wide range of times after implantation. We therefore conducted a post hoc subgroup analysis to compare basic characteristics and outcomes in the 54 patients in whom the AVG was first cannulated within 72 hours after implantation and the 33 patients in whom the initial cannulation occurred >21 days postoperatively. The times were chosen with reference to the 2006 Clinical Practice Guidelines for Vascular Access, which state that AVGs generally should not be cannulated for at least 2 weeks after placement and that, in most cases, AVGs should be placed 3 to 6 weeks before the expected start of hemodialysis.[13]

Table II. Graft implantation and cannulation data

Variable	*Value*[a]
Graft location	
Upper arm	103 (75)
Forearm	35 (25)
Graft position	
Loop	69 (50)
Straight	68 (49)
Reverse J	1 (1)
Graft cannulated at least once	135 (98)
Time of first graft cannulation after implantation	
≤24 hours	30 (22)
≤48 hours	48 (36)
≤72 hours	54 (40)
≤1 week	70 (52)
Time to first graft cannulation, days, mean ± SD (range)	15 ± 21 (0-116)
Time to third consecutive HD through graft, days, mean ± SD (range)[b]	21 ± 21 (3-123)

HD, Hemodialysis session; *SD,* standard deviation.
[a]Values are number (%) of patients unless otherwise indicated.
[b]In 134 patients.

Statistical analysis. Kaplan-Meier analysis was used to prepare the patency curves. Comparisons between the early-cannulation (≤72 hours after graft implantation) and the later-cannulation (>21 days) groups were done by using least square means, Fisher exact, or log-rank testing. A P value of $< .05$ was considered to represent a significant difference between groups. All statistical analyses used SAS version 9.2 software (SAS Institute, Cary, NC). Sample size of 138 subjects was determined to be necessary to obtain a 90% power to statistical 6-month cumulative patency rate >60% using a one-sided binomial exact test and a type I error rate of 2.5%.

RESULTS

Patients. A total of 138 patients with ESRD underwent implantation of the AVG during the study period. Table I shows their baseline demographic characteristics, comorbid conditions, and vascular access history. At enrollment, almost 90% of the patients were undergoing hemodialysis through a TDC. The AVG was the first permanent access for 34% of the patient cohort. The locations and positions of the implanted AVGs are shown in Table II. No patients were lost to follow-up. Sixteen implanting surgeons were involved with this study. Implantation by site included Burgess (30), Glickman (24), Shuman (20), Cull (19), Gable (14), Kinter (10), Hurwitz (7), Morrissey (6), Greene (6), and Ross (2).

Seventeen of the 138 patients enrolled in the study died within a year of AVG implantation. The causes of death were cardiac disease or cardiopulmonary arrest (n = 8), renal failure (n = 2), respiratory failure (n = 2), multiple-organ failure (n = 1), sepsis (n = 1), bacterial

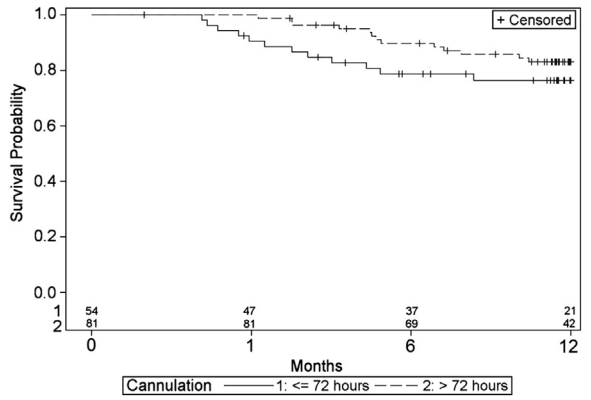

Fig 2. Kaplan-Meier curve showing cumulative graft patency in the whole cohort for up to 12 months after graft implantation. Patients who attended their 12-month follow-up visit earlier than 365 days after implantation were considered to have completed the study and were therefore censored from the 12-month number at risk. The standard error does not exceed 8%.

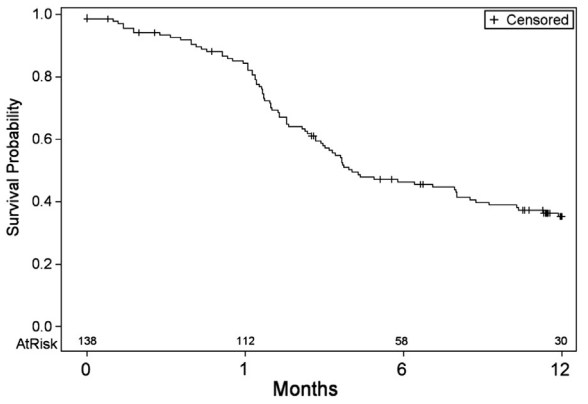

Fig 3. Kaplan-Meier curve showing primary unassisted graft patency in the whole cohort for up to 12 months after graft implantation. Patients who attended their 12-month follow-up visit earlier than 365 days after implantation were considered to have completed the study and were therefore censored from the 12-month number at risk. The standard error does not exceed 8%.

endocarditis (n = 1), multiple myeloma (n = 1), and liver failure (n = 1). None of the deaths were considered by the patients' clinicians to be related to either the AVG implantation procedure or use of the AVG for dialysis. The 17 patients who died during follow-up were included in the calculation of primary unassisted graft patency until their death but were censored from the 1-year cumulative patency assessment because they were not alive at the 1-year time period for follow-up. In 27 of the enrolled patients, the AVG was eventually abandoned. These patients were included in the assessment of loss of cumulative patency, but they were not otherwise followed up after graft abandonment. Abandonment was determined at each site and consisted of repeated thrombosis or infection.

Cannulation variables. Graft cannulation data are shown in Table II. Three of the AVGs were never cannulated because the patient died before cannulation could be performed (n = 1), the graft was removed during the implantation procedure because of inadequate arterial inflow (n = 1), or the graft was abandoned before cannulation because of repeated clotting during implantation (n = 1). The mean time to first cannulation of the remaining 135 grafts was 15 days (range, 0-116 days); the median time was 5 days. The mean time to the third consecutive successful hemodialysis session using the graft was 21 days (range, 3-123 days; median, 15 days).

Graft patency. During the follow-up period, 80 of the 138 patients had a total of 220 graft revisions or interventions, primarily percutaneous transluminal angioplasty or thrombectomy. The majority of stenoses (62%) developed at the venous anastomosis. On Kaplan-Meier analysis, the cumulative graft patency rate at 1 year was 79% (95% confidence interval [CI], 71%-85%; Fig 2). The 1-year primary unassisted patency rate was 35% (95% CI, 27%-44%; Fig 3). No pre-emptive angioplasties were performed in this study; 67% of the thrombosed grafts were treated by percutaneous methods and the remainder by surgical intervention.

Adverse events. Major adverse events related to graft implantation and cannulation, including those that occurred in patients who subsequently died or had graft abandonment during the follow-up period, are shown in Table III. No patient had a pseudoaneurysm or seroma formation. The two hematomas that were related to cannulation occurred 107 and 169 days, respectively, after AVG implantation. One of the hematomas resolved without treatment, whereas the other resolved after partial graft revision and administration of amoxicillin. Of the two procedure-related hematomas, one (at the incision site) resolved during prophylactic antibiotic treatment; the other required explantation of the AVG. Of the two disease-related hematomas, one was caused by extravasation during a percutaneous transluminal angioplasty procedure at the venous anastomosis and resolved after insertion of a stent graft. The other resolved after treatment with protamine, a heparin-reversing agent.

None of the 15 graft infections (Table III) were considered by the patients' clinicians to be related to the AVG itself. All 11 infections related to the cannulation procedure developed between 45 and 351 days after the AVG was implanted. Seven of the infections were treated successfully with either antibiotic therapy alone (n = 3) or both antibiotics and partial graft revision (n = 4). In the other four patients, the grafts were abandoned and explanted. Two of the three procedure-related infections occurred 8 days after implantation and resolved after antibiotic therapy. The third reported infection was discovered 20 days postoperatively during a revision for thrombosis. The AVG was explanted and a histologic analysis was performed, but no bacteria were detected on either culture or Gram staining. One wound infection considered to be related to the patient's underlying ESRD was observed

Table III. Major adverse events related to graft implantation or cannulation

Event	*No. (%) of patients or events*[a]
Any hematoma	6 (4)
Hematoma related to cannulation	2 (1)
Hematoma related to implantation procedure	2 (1)
Hematoma related to disease	2 (1)
Bleeding at incision or suture site	6 (4)
Any graft infection	15 (11)
Graft infection related to cannulation	11 (8)
Graft infection related to implantation procedure	3 (2)
Graft infection related to ESRD	1 (1)
Steal syndrome requiring intervention	15 (11)
Pseudoaneurysm	0
Graft infiltration or seroma	0

ESRD, End-stage renal disease.
[a]Two patients had both a hematoma and bleeding at the incision or suture site. The 15 cases of infection occurred in 13 patients, with two patients having two infections.

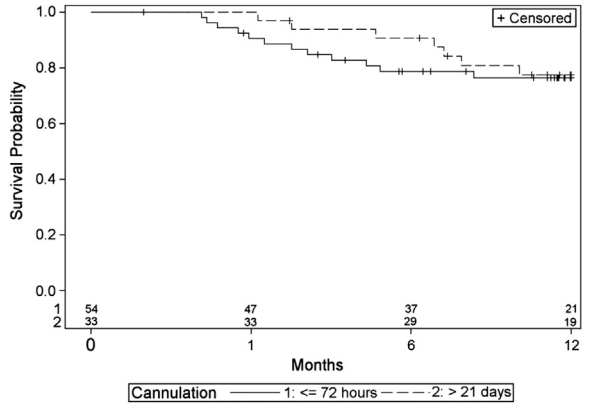

Fig 4. Kaplan-Meier curve showing cumulative graft patency for up to 12 months in patients in whom the graft was first cannulated either ≤72 hours or >21 days after implantation. Patients who attended their 12-month follow-up visit earlier than 365 days after implantation were considered to have completed the study and were therefore censored from the 12-month numbers at risk. The difference between the groups was not significant on log-rank testing ($P = .70$). The standard error does not exceed 8%.

near a revision site 64 days after AVG implantation; it resolved after antibiotic treatment. Symptoms of steal syndrome developed in 20 patients, 15 (11%) of whom required a surgical intervention. In 10 of the 15 patients, the symptoms resolved after treatment. Another patient underwent graft ligation, and the remaining four patients continued to have mild symptoms during the follow-up period.

Post hoc subgroup analysis. The analysis comparing patients in whom the AVG was first cannulated within 72 hours after implantation (n = 54) and those in whom the initial cannulation was >21 days postoperatively

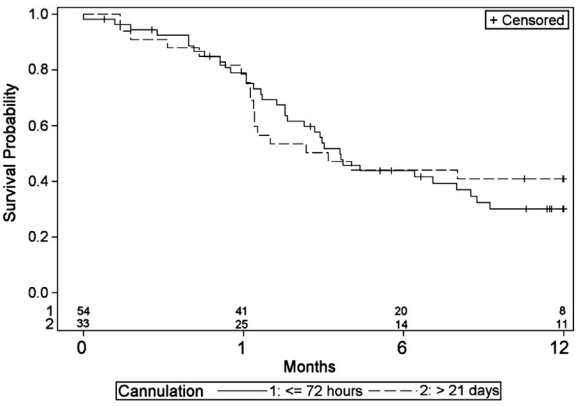

Fig 5. Kaplan-Meier curve showing primary unassisted graft patency for up to 12 months in patients in whom the graft was first cannulated either ≤72 hours or >21 days after implantation. Patients who attended their 12-month follow-up visit earlier than 365 days after implantation were considered to have completed the study and were therefore censored from the 12-month numbers at risk. The difference between the groups was not significant on log-rank testing ($P = .60$). The standard error does not exceed 8%.

(n = 33) found no significant difference between the groups in body mass index, race, comorbid conditions, vascular access history, or AVG location or position. However, there were statistically significant differences in the two groups in regard to both gender and age. Patients in the early-cannulation group were significantly younger than those in the later-cannulation group (mean age, 61 years [range, 30-88 years] vs 68 years [range, 43-94 years]; $P < .0001$). There was also a significant difference between the two groups with respect to gender; 57% of patients in the early-cannulation group but only 30% of those in the later-cannulation group were men ($P = .016$).

The cumulative graft patency rates at 1 year in the two subgroups were similar (76% [95% CI, 62%-86%] in the ≤72 hours group vs 77.5% [95% CI, 58%-89%] in the >21 days group; $P = .70$; Fig 4), as were the 1-year primary unassisted patency rates (30% [95% CI, 18%-43%] vs 41% [95% CI, 24%-57%]; $P = .60$; Fig 5). There was also no significant difference between the groups in freedom from hematoma (90.5% in the ≤72 hours group [95% CI, 76%-96%] vs 97% [95% CI, 80%-100%] in the >21 days group; $P = .34$) or freedom from graft infection (93% [95% CI, 82%-98%] vs 94% [95% CI, 80%-99%]; $P = .33$) during follow-up.

The mean time to the third consecutive successful dialysis session using the AVG was significantly shorter in patients in whom the AVG was first cannulated within 72 hours after implantation compared with patients in whom the initial cannulation occurred >21 days postoperatively (7 days vs 47 days; $P < .0001$). Thus, on average, patients in the early-cannulation group were eligible to become catheter independent within a week of implantation of the AVG, whereas those in the later-cannulation group

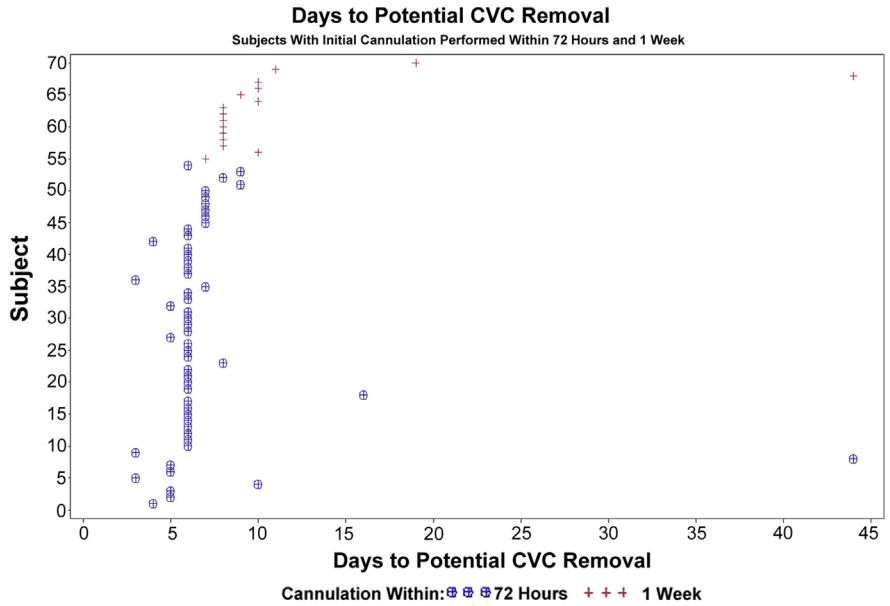

Fig 6. Chart demonstrating number of patients who had successful early cannulation and the potential for catheter removal. *CVC,* Central venous catheter.

could not have become catheter independent for almost 7 weeks. The potential for catheter removal is demonstrated in Fig 6. This demonstrates the number of patients cannulated within 72 hours, successfully for three straight dialysis times, and the potential for early catheter removal.

DISCUSSION

Vascular access-related infection and sepsis remain major causes of morbidity and mortality in patients undergoing hemodialysis. Rates of hospitalization in such patients have increased 43% since 1993 and appear to be associated with their high incidence of catheter use.[1] Patients who have ever had a TDC in place are seven times more likely to have had an infection than those who had only an AVF or AVG.[14] Shingarev et al[15] reported that 45% of all failures of TDCs were due to catheter-related bacteremia, with 35% of patients having an infection at 3 months after catheter insertion, 54% at 6 months, and 79% at 12 months. Moreover, central vein thrombosis has been reported to occur in 26% of patients with a history of TDC use.[16] Ravani et al[17] showed that patients undergoing hemodialysis through a catheter had a higher risk of death, infection, and cardiovascular events than patients who did not have catheters and had functioning AVFs or AVGs. Avoidance of catheter use or substantially reducing the number of days of catheter-dependent dialysis seems to be paramount if changes in positive outcomes in hemodialysis-dependent patients are to occur. This ideal could be achieved by having an AVG with such characteristics that would allow safe cannulation early after implantation, thus avoiding the need of a TDC. In 1986, Schanzer et al[18] reported favorable results with a first generation of a three-layer PTFE/silicone graft. This graft did not get wide clinical use because of no FDA approval. Further, early cannulation of AVGs to address this issue has had variable results and is not widely accepted.[19-21]

Most infections in functioning grafts occur after puncture for hemodialysis or reoperation.[22] The national combined local and systemic infection rates for permanent accesses, as calculated by the Vascular Access 2006 Work Group, range from 1% to 4% for primary AVFs and from 11% to 20% for grafts during their expected periods of use.[13] The infection rate in our study (11%; n = 5) was therefore equivalent to the low end of the range for grafts. Moreover, because the earliest cannulation-related infection occurred 45 days after AVG implantation, neither of the two cannulation-related infections in our study could have resulted from early cannulation.

Several risk factors for steal have been identified, including diabetes, female sex, and brachial artery anastomoses.[23,24] Symptoms of steal occur in 75% of patients with an AVF and 90% of those with an AVG.[25,26] The reported rate at which steal in patients with a graft requires intervention ranges from 5% to 15%.[21,27,28] The rate in our study was about 11%. This higher than expected rate may have been related to the considerable proportion of patients with diabetes in our cohort (60%). The findings suggest that patients who are at high risk of steal may benefit from a more proximal arterial placement of the AVG. Another possible cause of steal in our patients may have been undetected proximal arterial stenoses, which have been found to cause access dysfunction in >10% of patients undergoing hemodialysis[29] and to be present in 25% to 50% of those with access-related ischemia.[30,31] Use of tapered grafts may reduce the occurrence of steal in high-risk patients.[32,33]

In our post hoc analysis comparing patients who underwent cannulation within 72 hours after AVG implantation with those who had cannulation after the conventional 21-day period, there was no significant difference between the two groups in comorbid conditions, access history, body mass index, race, hematoma formation, or infection rate. Patients in the early-cannulation group were, however, significantly more likely to be men and were significantly younger than those in the 21-day group. We do not think that these differences affected outcomes because neither gender nor age has been associated with improved patency or a lower risk of complications in patients undergoing dialysis.

The time to the third consecutive dialysis session through the AVG was significantly shorter in the early-cannulation group, indicating that earlier TDC removal may be possible in patients given this graft, without an increase in complications or a decrease in patency rate. Early removal of TDCs may reduce septic complications in patients undergoing hemodialysis.

Our study had the usual limitations of a nonrandomized investigation. However, we think that the results indicate that early cannulation of the new AVG is safe and feasible, that use of the device may allow a reduction in TDC use, and that additional investigations of the possible benefits of early cannulation of the AVG are warranted.

CONCLUSIONS

In a multicenter trial of the safety and efficacy of a new graft in 138 patients requiring a prosthetic vascular access for hemodialysis, 30 patients underwent cannulation within 24 hours after graft implantation, 48 within 48 hours, and 54 within 72 hours. There were no differences in patency or complication rates between patients in the early-cannulation group (≤72 hours) and those in whom the AVG was first cannulated 21 days after implantation. Use of this AVG may provide patients with the opportunity to reduce their number of days of catheter-dependent dialysis or to avoid TDC use entirely, without a compromise in safety.

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AUTHOR CONTRIBUTIONS

Conception and design: MG, JB, DC, PR, HS
Analysis and interpretation: MG, DC, PR, HS
Data collection: MG, JB, DC, PR, HS
Writing the article: MG, PR
Critical revision of the article: MG
Final approval of the article: MG, PR, HS, JB
Statistical analysis: MG, PR
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