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Outcome of GORE® ACUSEAL graft for brachial-axillary vascular access in chronic haemodialysis patients: Cohort retrospective single-centre study

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ABSTRACT

Background: The aim of this study was to evaluate the midterm results of a brachio-axillary arteriovenous graft (BA-AVG) for the provision of vascular access haemodialysis patients.

Materials and methods: A cohort retrospective consecutive single-centre study of 46 patients undergoing BA-AVG using the Gore Acuseal, from November 2015 to October 2019 was conducted. Data on patient demographics, comorbidities, medical therapy, and complications were collated for the initial endpoints of primary patency, primary assisted patency, and secondary patency. A subgroup analysis included outcomes in patients over 70 years old and events (complications) per AVG per year. Data were subjected to Kaplan-Meier survival estimator with log-rank analysis and test of probability.

Results: The mean age of the cohort was 63.5 years with male predominance (male, n = 27, 59%). A total of 37 (80%) patient procedures were conducted with elective settings as well as on an emergency basis with a 91.3% technical success rate. The most common complication was grade I steal syndrome (8.7%), followed by graft infections (4.3%), median nerve neuropraxia (4.3%), and postoperative bleeding (2%), demonstrating a 0.1 per AVG complication per 2 years. Median primary patency, primary assisted patency, and secondary patency over a mean follow-up period of 28 months was 5.5, 12.5, and 18 months, respectively, with no associated 30-day mortality.

Conclusion: BA-AVG with midterm longevity and low complications may serve as an alternative access type when a suitable site is not identified. The AVG patency rate in the elderly or patients with limited life expectancy is promising. However, more robust data are needed to confirm the benefit of AVG in this cohort.

1. Introduction

The number of patients with end-stage renal disease (ESRD) that require haemodialysis is constantly rising worldwide [1]. Arteriovenous fistulas created from native upper limb veins are the access site of choice as they provide superior patency and lower complication rates [2]. As the life expectancy of chronic haemodialysis patients rise, the use of a synthetic graft to create an arteriovenous brachial-axillary graft on the upper arm is recommended. This recommendation is for patients who have exhausted all autologous fistulas access options [3]. However, these grafts have lower patency rates and shorter lifetimes than autogenous arteriovenous fistulas [4].

Non-autogenous or prosthetic arteriovenous grafts AVG are considered secondary or tertiary access modalities as the surgery is more challenging. These access modalities are associated with a greater morbidity than with autogenous AV fistulas (AVF). They also have inferior primary and secondary patency compared to autogenous AVFs [5–7]. However, early failure of fistulas due to thrombosis and/or inadequate maturation is a barrier to increasing the prevalence of autogenous fistulas in patients who are being treated with haemodialysis [8].

The indications for prosthetic AVG include failed AVF/exhausted superficial veins, unsuitability of available veins particularly in elderly and diabetic patients, damaged vessels by careless repeated venipuncture, the need for prompt cannulation with avoidance of a central line insertion (relative indication), and for children who cannot tolerate multiple painful venipuncture associated with autogenous AVFs [9–11].

In the absence of randomised controlled trials, comparisons may be flawed by a selection bias, since AV graft patients are approximately 10 years older and have higher comorbidities (diabetes, cardiovascular disease, lupus) that are associated with poorer vascular anatomy [12]. AV grafts and other forms of vascular access should be delegated to a

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complementary role in the provision of vascular access.

The GORE® ACUSEAL Vascular Graft consists of a three-layer vascular graft, which includes an elastomer membrane between the inner and outer layers of expanded polytetrafluoroethylene (ePTFE). The lumen of the graft has a CBAS Heparin Surface, which provides a thromboresistant advantage to the vascular graft. The GORE® ACUSEAL Vascular Graft can be cannulated within 24 h after implantation [13, 14].

2. Material and methods

Research registry number: unique identifying number: researchregistry6235 [15].

This is a retrospective cohort data collection study. The data was collected from the medical records of NHS patients. As advised by the ethical committee in our institute, this study is exempt from ethical committee approval as it is a retrospective data analysis.

This is a retrospective cohort analysis of data collected from 46 patients on chronic haemodialysis who required vascular access in our department between January 2015 and October 2019.

These patients received a Gore® Acuseal Brachio-axillary vascular access graft as a permeant haemodialysis access site.

Indication for the procedure was the absence of further autologous vascular access options for haemodialysis.

Patient risk factors included ischaemic heart disease (IHD), diabetes mellitus (DM), hypertension (HTN), peripheral vascular disease (PVD), hypercholesteremia, and smoking.

Preoperative assessment included a surgeons' clinical assessment in a dedicated vascular access clinic with a vascular access nurse, a duplex ultrasound scan for assessment of the axillary vein and brachial artery, and a central venogram for patients with previously failed access, previous central line, or a pacemaker on the same side as the procedure.

A preoperative anaesthesia assessment was also performed by a consulting anaesthetist prior to the intervention.

The follow-up protocol consisted of a monthly clinical assessment and an ultrasound with dilution method (transonic). A referral pathway to a vascular multidisciplinary team meeting was established to refer any patient with declining transonic surveillance velocity for discussion and prophylactic investigation or intervention.

The primary endpoints were defined as primary, primary assisted and secondary patency.

The secondary endpoints were graft-related mortality, as well as complications including bleeding, infection, steal syndrome and nerve injury.

The work has been reported in line with the STROCSS criteria [16].

3. Results

Forty-six patients (twenty-seven men and nineteen women) received a Gore® Acuseal vascular access graft as a result of ESRD. These patients, who were on chronic haemodialysis, had a technical success rate of 91.3% and included thirty-seven elective and nine emergency procedures.

The mean age was 63.5 years, and the mean follow-up time was 28 months (Range from four to fifty-two months).

Risk factors included IHD, 10 patients (21.7%); DM, 21 patients (45.6%); HTN, 34 patients (73.9%); PVD, 10 patients (21.7%); hypercholesteremia, 18 patients (39.1%); and smoking, 6 patients (13%); 13 patients were ex-smokers (28.2%) [Table 1].

Nine patients were on anticoagulation therapy (19.6%), eighteen were on single antiplatelet agents (39.1%), three were on dual antiplatelet agents (6.5%), and only twenty-two patients were on statins (47.8%).

We adopted the European Society of Vascular Surgery (ESVS) vascular access guideline definitions for primary, primary assisted, and secondary patency.

Table 1
Risk factors.

Risk factors	No of patients (%)
IHD	10 (21.7%)
DM	21 (45.6%)
HTN	34 (73.9%)
PVD	10 (21.7%)
Hypercholesteremia	18 (39.1%)
Current smoker	6 (13%)
Ex-smoker	13 (28.2%)

The median of primary patency was 5.5 months, with 37% at 12 months, 18% at 18 months, and 6.7% at 24 months. The median of primary assisted patency was 12.5 months, with 61% at 12 months, 47% at 18 months, and 31.25% at 24 months. The median of secondary patency was 18 months, with 81% at 12 months, 67% at 18 months, and 50% at 24 months [Fig. 1].

No postoperative or graft-related mortality was reported. Other complications were reported: two patients had graft infections (4.3%), one patient had postoperative bleeding (2%), four patients presented with symptoms of grade I steal syndrome (8.7%), and two patients had symptoms of median nerve neuropraxia (4.3%) [Table 2].

Subgroup analysis of patients over 70 years old (18 patients) showed that the median of primary patency was 9 months, with 53% at 12 months and 45% at 18 months. The median of secondary patency was 16 months, with 72% at 12 months and 59% at 18 months. Of these patients, there were eight (44%) that died between 18 months and 24 months.

4. Discussion

AVF is the first option for creating vascular access (VA) for patients with ESRF. AVG and central venous catheter are considered as the second and third options due to the higher incidence of postoperative complications and higher endovascular and surgical revisions for AVG failure in comparison to AVFs [17–19].

The durability of AVG grafts is one of the primary gaps in the field of VAs research [20]. One- and two-year primary patency varies between 40-50% and 20–30%, respectively. The secondary patency varies from 70 to 90% (at one year) and from 50% to 70% at 2 years, which is similar to our outcome [21–23].

Lazarides et al. published a meta-analysis in 2007 that revealed high primary autogenous AVF failure rates in elderly patients [24]. Despite these results, there is a lack of evidence in the guidelines of AVG in such a group of patients [20]. A subgroup analysis of patients aged >70 years showed high primary and secondary patency rates, which raises the question of whether we should offer AVG as a first option for dialysis to older patients or patients with limited life expectancy.

Our study involved a wide range of demographics, risk factors, and anticoagulants/antiplatelet regimes in our patients. These are not included in many other studies as well as a mid - to long-term follow-up (up to 52 months with an average follow-up of 28 months). We believe this has not been shown in previous studies [25–28].

The high prevalence of diabetes, hypertension, and hypercholesteremia in our cohort played a major role in reducing the primary, primary assisted, and secondary patency rates in these patients. A further sub-analysis is required to confirm this correlation.

Our study reflects a single-centre experience. In the future, this could be part of a further systematic review or metanalysis investigating AVG durability and its role in elderly chronic haemodialysis patients or patients with limited life expectancy.

A limitation to our study could be the lack of longer follow-up data and the sample size. On the other hand, the study showed no graft-related mortality, low complication rates and reasonable technical success rates.

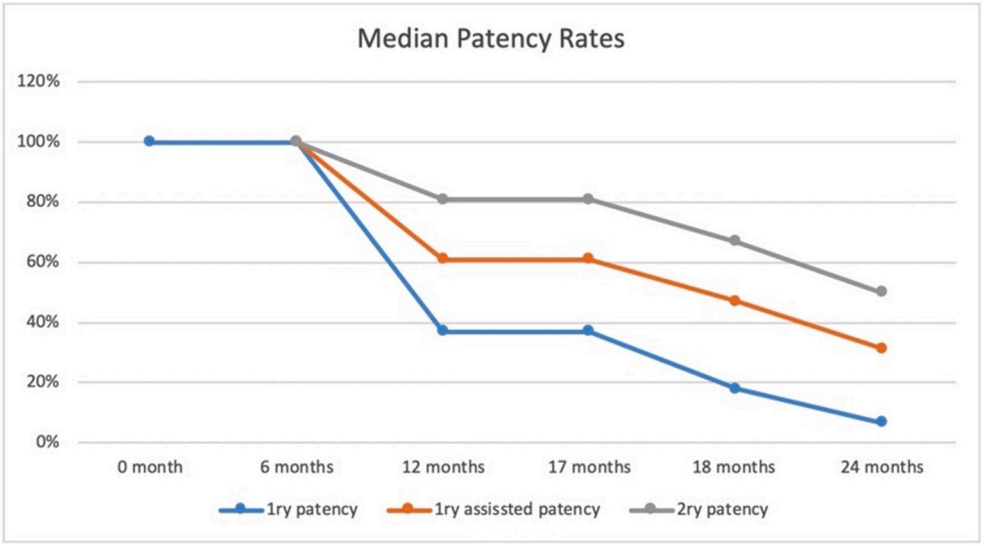

Fig. 1. Kaplan-Meier curve showing primary, primary assisted and secondary patency median rates for the Gore® Acuseal vascular access graft in 46 patients between January 2015 and October 2019 in our centre.

Table 2
Complications.

Complications	No of patients (%)
Bleeding	1 ((2%)
Infection	2 (4.3%)
Steal Syndrome	4 (8.7%)
Median nerve injury	2 (4.3%)

5. Conclusion

This series showed that the Gore® Acuseal graft can be used as a VAs option in ESRD patients on chronic haemodialysis with no other autologous fistula options. It had a reasonable technical success rate that was comparable to other synthetic access grafts and low complication rates in mid-to long-term follow-up. The AVG patency rate in the elderly or patients with limited life expectancy is promising. However, additional robust data are essential to confirm the benefit of AVG in this cohort.

Statement of ethics

Not applicable, retrograde data collection from hospital registry.

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Author's contribution

Study Conception: TS.
Data Collection: MM, YA, AD, WW, DM, AS.
Analysis: TS.
Investigation: TS, AS, MM.
Writing: TS.
Critical review and revision: all authors.
Final approval of the article: all authors.
Accountability for all aspects of the work: all authors.
Provenance and peer review were not commissioned, the paper was externally peer-reviewed.

Registration of research studies

1. Name of the registry: Research Registry
2. Unique Identifying number or registration ID: researchregistry6235
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/browse-the-.registry#home/registrationdetails/5fa7eb1d65bcac00159ee538/.

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Consent

Not applicable

Declaration of competing interest

The authors have no conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amsu.2020.11.042.

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