

**The United Kingdom and Ireland experience of the Hemodialysis
Reliable Outflow (HeRO) Graft for Vascular Access**

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Abstract

Objectives

To describe the UK and Ireland experience of the Haemodialysis Reliable Outflow (HeRO) graft in complex vascular access.

Design

Observational, multi-centre case series

Methods

Data from any patient undergoing HeRO graft were collected from eight UK and one Irish centre. Any HeRO procedure between July 2013 and May 2016 was included. Demographics, primary and secondary patency rates and complications were analysed.

Results

52 patients underwent HeRO graft insertion. Median age was 55 (20-86), 24 (46%) were male and 66% were Caucasian. Median follow up was 290 (10-966) days and patient survival was 41/52 (79%). 48 procedures were in the upper limb with 39 using the brachial artery as inflow (75%). The IJV and SCV were most frequently used as access for outflow insertion Primary patency rates at 6, 12 and 24 month were 51.2% (95% CI 38.8%-67.4%), 40.9% (95% CI 28.7%-58.2%;) and 33.4% (95% CI 21.3%-52.5%) respectively.

Secondary patency rates at 6, 12 and 24 months were 84.8% (95% CI 75%-95.9%), 76.5% (95% CI 64.5%-90.6%) and 70.6% (95% CI 56%-88.9%) respectively. There were 65 surgical and 49 radiological interventions resulting in 2.30 interventions per year to retain patency. Complications included 4 infections and 2 episodes of steal syndrome.

Conclusions

The HeRO graft provides acceptable 12-month secondary patency rates and acceptable complication rates in a UK and Ireland multicentre series of complex access patients. HeRO should be considered in patients with central pathology as a potential alternative to lower limb grafts and long-term central venous catheters.

Key words: Vascular access; hemodialysis; arteriovenous graft; central venous occlusion; complex vascular access

Introduction

The provision of definitive vascular access (VA) for dialysis is crucial in offering patients' the best long-term outcome from haemodialysis. The Fistula First Campaign has stimulated a drive to ensure patients have surgically created VA on initiation of dialysis(1). However, with improved survival rates and an expanding population of dialysis patients there is an increasing cohort in whom upper limb vascular access options are exhausted due to multiple failed arteriovenous fistulas (AVF) or grafts (AVG). These patients frequently have central venous stenoses and are left with the option of a long-term central venous catheter (CVC) or lower limb VA. Central venous catheters, in particular, carry a high risk of infection and increased overall mortality and morbidity(2-4). In addition, in 2014 64% of patients in the UK initiated dialysis via a CVC and over 20% remain reliant on a tunnelled CVC for dialysis access long-term(5). These patients are at particularly high risk of central venous stenosis and early exhaustion of upper limb venous access.

The Haemodialysis Reliable Outflow (HeRO®) graft (Merit Medical Systems, Inc., South Jordan, UT, USA) is an innovative device that allows use of the upper limb in the presence of a central stenosis. The FDA licenced it in the US in 2008 for use in patients' dependent upon a CVC with a concurrent central venous stenosis or occlusion. The device provides reliable outflow directly into the right atrium (RA) whilst still utilising native arterial inflow via a prosthetic graft. All components of the HeRO are tunnelled subcutaneously minimising infection rates. A recent review combining evidence from US case

series shows favourable 12-month primary and secondary patency rates of 21% and 59% respectively(6). The HeRO has also been shown to be superior to repeat venoplasty or stenting in recurrent central venous stenosis(7) and complications such as steal syndrome and bacteraemia rates are comparable to those in arteriovenous grafts (6,8,9).

Reports on the outcome of HeRO grafts are, at present, restricted to US data and herein we describe the United Kingdom HeRO experience to date.

Methods

Study Design and Setting

A Retrospective review of all National Health Service (NHS) patients who underwent a HeRO graft procedure in a UK or Irish hospital from July 2013 to May 2016. Any HeRO graft in UK and Ireland centres performing the procedure for dialysis access, which includes Belfast, Dundee, Galway, Glasgow, Liverpool, Oxford, Birmingham, Manchester and London were included. Data were collected retrospectively to include relevant demographics and co-morbidities. Procedure-specific details, including site of inflow and outflow, complications and outcomes were collected and analysed. The number of surgical and radiological interventions to retain patency were also collected and analysed.

The patients in this study were followed according to local protocols and all units employed surveillance of efficacy of dialysis. All units discussed complex patients and follow up at multidisciplinary team (MDT) meetings with radiology, nephrology, HD nurses and surgeons. Stenosis in the graft was treated when there was more than 50% narrowing or physiological evidence of poor function. Treatment was either endovascular or surgical and was based on the local expertise, experience and type of stenosis.

Population and Indications

The manufacturer guidelines and FDA license for HeRO insertion include central venous stenosis or occlusion with catheter-dependence or failing AVF or AVG. Relative contraindications include; ejection fraction $\leq 20\%$; hypercoagulability or history of access failure due to thrombosis; small brachial artery (e.g. $\leq 3\text{mm}$) and systolic blood pressure $\leq 100\text{mmHg}$ (10). HeRO grafts performed for any intervention in patients with central venous pathology were included. Lower limb HeRO deployment was indicated in patients whom there was no option to recannalise an occluded SVC and who had developed iliac vein or IVC stenosis as a result of lower limb access procedures.

Intervention and Description

HeRO comprises an outflow section and an expanded polytetrafluoroethylene (ePTFE) graft for arterial inflow (figure 1). The outflow component is a 5 mm nitinol-reinforced silicone single lumen device that is placed into the right atrium (RA) using image-guidance. Access to the central venous system is usually via the subclavian (SCV) or internal jugular vein (IJV) and a wire is passed through the central stenosis. Following venoplasty the outflow component can be passed through the stenosis and the distal tip positioned in the RA. The proximal end can then be tunnelled subcutaneously to a position convenient for connection to the inflow. The PTFE graft inflow component is anastomosed to an appropriate ipsilateral artery, usually the brachial artery, and joined via a subcutaneous tunnel to the outflow component using a titanium connector (figure 1).

A modification of the above technique to facilitate early graft cannulation can also be employed. An 'early cannulation graft (Flixene™, Maquet or Acuseal™, W.L. Gore®) can replace the section of the PTFE used for needling. This requires a small additional incision to anastomose the two grafts together.

Outcome and definitions

Primary patency is defined as the time from implant to first intervention (radiological or surgical) for loss of patency.

Secondary patency is defined as the time from implant until graft loss or abandonment.

HeRO days is the number of days from implant to graft loss or abandonment.

Infection was not formally defined for the purpose of the manuscript and the diagnosis of graft-related infection was at the discretion of individual centres. Infection was split into early (<30 days) or late (> 30 days).

Statistics

Statistics were performed using SPSS version 23 (IBM Corporation, New York 10504-1722, US) or R Core Team (2015). R: A language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>). Continuous data are detailed using descriptive statistics (mean \pm SD, median (range)). Categorical data are detailed as values and percentages. Kaplan-Meier survival curves were used to detail primary and secondary patency. All survival outcomes are reported with 95% confidence intervals.

Results

Demographics

A total of 52 patients underwent HeRO graft insertion from 8 UK and 1 Irish centre with a median age of 55 years (20-86). There were 28 female (54%) and 24 males, the median number of previous access procedures was 4 (0-9) and the median number of previous CVCs was 5 (1-21). Co-morbidity and demographic data can be found in table 1. The majority of procedures were performed in the upper limb (48/52) using the IJV or SCV as the cannulation vein for outflow component insertion. The brachial artery was used as inflow for the majority of procedures (39/52). Eight of the grafts were anastomosed

to existing upper limb AVF or AVG and 30 were early cannulation grafts (Flixene™, Acuseal™). Of the 4 grafts inserted in the lower limb one used the popliteal artery as inflow and 3 used either SFA or CFA (table 2).

Patient selection

Selection for HeRO graft insertion was based on manufacturer guidelines described above and included patients with central stenosis or occlusion that precluded other upper limb access procedures. Patient selection was at the discretion of the local access surgeon.

Follow up

Median follow up was 290 days (10-966) with a total of 591 HeRO months follow up. Eleven patients died (21%) and in these patients all HeRO grafts were functioning at the time of death. One patient was transplanted with a functioning HeRO.

Patency

Primary patency rates at 6, 12 and 24 month were 51.2% (95% CI 38.8%-67.4%), 40.9% (95% CI 28.7%-58.2%;) and 33.4% (95% CI 21.3%-52.5%) respectively (figure 2). Secondary patency rates at 6, 12 and 24 months were 84.8% (95% CI 75%-95.9%), 76.5% (95% CI 64.5%-90.6%) and 70.6% (95% CI 56%-88.9%) respectively (figure 3). Of the 52 included grafts there was a total of 17988 HeRO days that required 114 interventions to retain patency.

This equates to 591.4 HeRO months follow up, with 114 interventions.

Therefore in order retain patency 2.30 interventions per graft per year were required.

Thrombosis

There were a total of 114 thromboses, requiring 65 surgical graft thrombectomy procedures and 49 radiological interventions to retain patency.

Complications

All complications are shown in table 3. Haematoma/seroma formation was the most frequently observed complication, which occurred 6 times in 4 patients of which three required surgical drainage. Surgical revision was required on 8 occasions in 6 grafts for a variety of indications. Two grafts were revised and re-tunnelled due to infection, two required anastomotic revision following thrombosis, one required patch-plasty of the arterial inflow and the three remaining were non-specified revisions. Four patients had infectious complications. One patient required multiple surgical thrombectomy procedures and the incision used to gain access to the graft became infected and failed to heal, resulting in an exposed graft. One patient developed an infected haematoma that resulted in graft infection. Two patients had steal syndrome, one required banding of the graft and the other was treated conservatively. One patient had an extensive ileofemoral deep vein thrombosis around the outflow component requiring warfarin therapy. One patient developed a pseudoaneurysm at a needling site, which was treated with a radiologically placed covered stent.

Graft failures

Eleven grafts failed (21%) during the study period and four were removed.

Two grafts were removed following failed graft salvage and one was removed due to infection. One was removed due to skin necrosis. The additional failures were following failed salvage and one graft was abandoned as it was infrequently used for dialysis due to difficulty cannulating the graft. Removal of a failed HeRO was left to the discretion of the clinician.

Discussion

We have described the first HeRO series outside the United States (US) and demonstrated 12 month primary and secondary patency rates of 40.9% and 76.5% respectively in a UK and Irish haemodialysis population.

The FDA (Food and Drug Administration) approved the HeRO graft in 2008 and the literature to date is limited to that based on North American centres. The first insertion in the UK was in July 2013 and at the time of data collection eight UK and one Irish centre had performed the procedure. A total of thirteen centres had performed the procedure at the time of manuscript submission showing a sustained uptake HeRO use over time. The 12-month primary and secondary patency rates of 40.9% and 76.5% respectively in this series are superior to the values of 21.9% (9.6-37.2%) and 59.4% (39.4-78%) from a recent systematic review of US data (6) and comparable to that of prosthetic grafts (8,11). However, our data have not quite reproduced the 24-month

secondary patency rate of 86% as reported by Gage *et al* in their multi-centre series of 164 patients, although the patient populations are different(9).

One perceived advantage of a HeRO graft is avoidance of a lower limb AVG, however the evidence is conflicting. There are three comparative studies that are all retrospective analyses comparing thigh loop grafts with HeRO grafts. Brownie *et al* compared 43 patients with thigh grafts with 33 upper limb HeRO grafts. The demographics were similar between the populations although the HeRO group had been on HD for a median of 95 versus 60 months and the thigh graft cohort had a central venous stenosis rate of 33% compared with 100% for the HeRO cohort. Secondary patency was superior in the thigh graft group with mean values of 53% versus 16%. Intervention rates were also lower in the thigh graft group with 0.6 versus 1.5 per graft per year required to maintain patency. Infection rates were comparable between the group with the thigh graft group having 26% versus 21% in the HeRO group, however 9 thigh grafts needed to be excised due to infection (12) . Steerman and colleagues compared 22 thigh grafts with 60 HeRO grafts in a population of patients well matched apart from in BMI. The HeRO group had a mean BMI of 32 compared with 26 in the thigh graft group. The 12 month secondary patency rate of 67% in the thigh graft group was higher than 57% in the HeRO cohort. The number of interventions was also higher in the HeRO group, requiring 2.21 compared with 1.17 per year to retain patency. Infection rates were similar with 0.71 per 1000 days in the thigh graft group compared with 0.61 in the HeRO group (13) . Finally, Kudlaty *et al* compared 35 leg grafts with 21 HeRO and statistically there was no difference in secondary patency,

infection rates or interventions needed to retain patency. Although numerically secondary patency and infection rates favoured HeRO and leg grafts required fewer interventions to retain patency (14) .

Our study showed that in order to retain patency 2.30 interventions per graft per year were required. This value is comparable to the previously published HeRO series that ranges from 1.5-3 interventions per year (6) and to that of standard AVGs which range from 1.7-3.5 (6,16) . The current series has been compared with data from the North American experience although the dialysis populations in each series are different. The UK population is primarily Caucasian and Asian (Indian), compared to the primarily black African-American of that in the United States (US). In addition, the rates of diabetes are from 53-65% in the US population, compared to 23% in this series, so a direct comparison is not possible.

The most interesting finding from this study was that the median number of days to first use for dialysis was 1 day. This demonstrates that the HeRO graft can be successfully used as a rescue procedure in patients with access failure due to central venous pathology. Immediate access can be achieved by utilising inflow from a pre-existing AVF (8 patients) or replacing the PTFE graft with an instant needling graft (30 patients). This requires an additional incision but negates the need for a bridging dialysis catheter thereby reducing the infection risk, poor flows and need for replacement. A recent analysis has shown that the overall cost of using a bridging dialysis catheter is greater than the use of instant cannulation graft (18) . This current series has also shown

that lower limb HeRO insertion is feasible, with 4 lower limb grafts performed in 4 different centres. One patient suffered an ileofemoral DVT that required warfarin therapy and one patient had calciphylaxis over the graft but there were no infection-related complications recorded.

Four patients from 52 suffered an infectious complication with an overall rate of 7.7%. This rate is difficult to compare with some of the other HeRO series as they are described as bacteraemia rate per 1000 days, although Steerman (13) and Hart (19) describe infection rates of 22% and 19% in their respective series. One graft was removed due to infection and the others were all superficial infections. Rates of surgical intervention for thrombosis in our HeRO series are relatively high in comparison with AVF and AVGs and with other HeRO data, although the details on thrombectomy are not defined in many of the HeRO series to date. Gebhard *et al* describe successful percutaneous intervention on 71 separate occasions to retain patency in their HeRO series (20) . It appears that despite the length of the outflow component and the prosthetic graft percutaneous intervention is effective in the HeRO graft. However in the UK centre with the largest number of patients all thrombectomy procedures were carried out surgically which explains the higher surgical versus percutaneous intervention rate in this series.

The incidence of steal syndrome from the systematic review of North American data was 6.3% (1-14.7%)(6), In our series 2 patients were affected (4%). Both patients had inflow from the brachial artery and one patient was treated conservatively and one patient had their graft banded, which

successfully treated the steal symptoms and no further intervention was required. The relatively low incidence of steal syndrome is likely to be due to a combination of factors. First, inflow in eight patients was from a pre-existing AVF or AVG in which there would have already been arterial remodeling and accommodation. Second, the outflow segment is 5mm in diameter, which is less than standard prosthetic grafts and certainly less than native central veins. This will result in reduced flow and therefore greater resistance, which reduces the chance of steal syndrome.

A recent analysis has shown that a HeRO graft has a marginal net positive cost compared with a tunnelled CVC (21) . The large upfront cost of a HeRO insertion is offset over time by the savings in number of device failures, infectious and thrombotic complications compared to tunnelled CVCs but this does not quite reach cost neutrality. The study that modelled this used NHS tariffs and data from UK dialysis populations reliant on a CVC and compared it with HeRO outcomes from North America. A Cost analysis from a North American study suggested that conversion from a CVC to a HeRO should result in an overall cost saving (22) . There is an immeasurable difference between the US and UK health systems in terms of treatment cost and it is difficult to draw unbiased conclusions from the published literature on the cost benefit of the HeRO graft in a UK population. The financial implication of the HeRO does not appear to be significant but data on patient reported quality of life outcomes in comparison to those using a CVC are lacking and combining that with a long term cost analysis of UK patients would be an interesting and informative area of study. The authors acknowledge that a limitation of this

manuscript is the absence of a cost analysis, particularly given the increased number of interventions to retain patency the HeRO requires compared to lower limb grafts. However the data presented demonstrate that based on the cost-analysis by Shakarchi and despite the lack of evidence outside North America there has still been a sustained uptake across the UK in HeRO graft use.

The main limitation of the current series is the observational nature of the data collection, which is not as strong as that gathered in a prospective trial. The authors also acknowledge that patient selection across the different centres was not standardised and may give rise to selection bias such that individuals deemed low-risk may have been selected for initiation of the procedure. However, this report is not a selected case-series and describes the initial experience of employing a new device in many centres, with all patients included. That said, the complexity of the patient population in this series is illustrated by a median number of 4 previous access procedures, high rates of IHD and cardiac failure and should not be underestimated. These data, in conjunction with the US HeRO experience, show that the HeRO graft can be used to prolong the use of upper limb access and delay the need for lower limb grafts. In order to confirm the cost effectiveness of HeRO grafts in a UK and Irish population further investigation is required.

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Disclosures

N Inston, D Kingsmore and J Gilbert have all received honoraria from Cryolife or Merit Medical and the rest of the authors have no conflict of interest

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Tables

Demographic	N
Age (median, range)	55 (20-86)
Male (%)	24 (46)
Ethnicity (%)	
White	35 (67)
Asian	12 (23)
Black	5 (10)
Number of previous access procedures (median (range)) ^{\$}	4 (0-9)
Number of previous CVC median (range) ^{\$}	5 (1-21)
Diabetes (%)	12(23)
IHD (%)	14 (27)
Cardiac failure (%)	5 (10)
Centre	
St Bartholomew's, London	8
City Hospital, Belfast	5
Queen Elizabeth Hospital, Birmingham	7
Ninewells Hospital, Dundee	3
University College Hospital, Galway	4
Western Infirmary, Glasgow	5
Royal Liverpool, Liverpool	2
Churchill Hospital, Oxford	13
Royal Infirmary, Manchester	5
Follow up (days)	290 (10-966)
Patient Survival (%)	41 (79)

Table 1. Demographic details of the study population. \$ = Data incomplete.

HeRO location	N (%)
Outflow insertion	
IJV	25 (48)
SCV	10 (19)
CFV	4 (8)
Upper limb - other	13 (25)
Site of inflow	
Brachial artery	39 (75)
Axillary artery	1 (2)
Pre-existing AVF/AVG	8(15)
SFA/CFA	3 (6)
Popliteal artery	1 (2)

Table 2. Location of outflow and inflow sites used for HeRO graft. IJV = internal jugular vein, SCV = subclavian vein, CFV = common femoral vein, SFA = superficial femoral artery and CFA = common femoral artery. Upper

limb 'other' refers to cannulation of an upper limb vein that may be a collateral, an unnamed vessel or unavailable data.

Outcomes	N
First use for dialysis (days) median (range)	1 (1-56)
Total thrombosis events	114
Median (range)	1 (1-26)
Radiological	49
thrombectomy	65
Surgical thrombectomy	16
Surgical interventions	8
Revision	3
Evacuation haematoma	1
Banding for steal	4
Graft Excision	
Complications	
Infection	
Early (<30d)	4
Late (>30d)	0
Steal	2
Seroma/haematoma	6
DVT	1
Pseudoaneurysm	1

Table 3. Outcomes and complications following HeRO graft insertion. *

Outcome	N	Median Secondary patency (days)	Graft failure N (%)
Upper limb	48	290	10 (91)
IJV	25	284	5 (45)
SCV	10	483	2 (18)
Other	13	119	3 (28)
Lower Limb	4	266	1 (9)
Overall	52	290	11 (100)

Table 4. Outcomes of HeRo grafts split into insertion location and by cannulation vein. (IJV = internal jugular vein, SCV = subclavian vein.

Legends for illustrations

Figure 1. Illustration of the anatomy and location of the HeRO device. The venous outflow is depicted in the right atrium through insertion via the internal jugular vein. The outflow is tunnelled subcutaneously and connected to the arterial graft which is anastomosed to the brachial artery.

Figure 2. Kaplan-Meier plot illustrating primary patency in the UK HeRO series. Each 'event' is an episode of thrombosis or graft loss and patients are censored by death with a functioning graft or transplantation. Number of patients at risk is shown below the x-axis.

Figure 3. Kaplan-Meier plot illustrating secondary patency in the UK HeRO series. Each 'event' is a graft loss and patients are censored by death with a functioning graft or transplantation. Number of patients at risk is shown below the x-axis.