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ORIGINAL ARTICLE

Artificial Kidney / Dialysis

Maintaining lower limb access with the HeRO device

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Abstract
Central venous catheters (CVC) remain a mainstay of vascular access particularly for incident patients, but lead to central vein stenosis (CVS) in up to 1 in 6 patents. This often leads to establishing dialysis access in the groin which in turn may result in development of CVS in the lower body, although this is poorly reported. The HeRO device was designed to address CVS by bypassing the stenosed veins with a nitinol-reinforced silicone tube into the right atrium, which acts as an outflow conduit attached to an arterial inflow. The efficacy and safety of the HeRO device in the upper limb is well established, but there is no data on its use in the lower limb. We describe 2 cases of HeRO in the lower limb, one primary and one secondary, which remain in use. Lower limb HeRO is feasible in the lower limb and can work well either as de novo (to achieve vascular access) or as a salvage procedure (to maintain vascular access).

Keywords HeRO · Central vein stenosis · Central vein occlusion · Lower limb vascular access

Introduction

Central venous catheters (CVC) are used for vascular access for hemodialysis in 50–80% of incident and 20–50% of prevalent hemodialysis patients worldwide despite a sustained effort to reduce their use [1]. The complications of CVC are well recognized and include infection, occlusion, and central vein stenosis (CVS) [2]. It is increasingly recognized that CVS can have a catastrophic impact on obtaining and maintaining arteriovenous (AV) access in the affected limb [3]. Where CVS causes occlusion of the superior vena cava, urgent vascular access may only be obtained through non-tunnelled (NTCVC) or tunnelled (TCVC) central venous catheters in the groin vessels. Although less frequently reported, stenosis of the iliac veins can consequently develop in a similar fashion to what occurs in the upper limbs.

The treatment options for CVS are unsatisfactory with high rates of recurrence following venoplasty and stent-graft placement [4, 5]. To obtain and maintain upper limb arteriovenous access in patients with CVS, the Hemodialysis Reliable Outflow (HeRO) graft (Merit Medical Systems, Inc., South Jordan, UT, USA) has been developed. It is a novel device that bypasses venous stenosis by acting as an

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outflow conduit. The venous outflow component is a 5 mm nitinol-reinforced silicone, single lumen tube that is placed percutaneously across the venous occlusion into the right atrium under radiological guidance and then attached to an arteriovenous access (AV access)—usually a graft [6].

There is substantial observational data to support the utility and safety of the HeRO device since its FDA approval in 2008. In total, 409 cases are reported in the literature with patency rates comparable with AV access grafts (AVG) [7]. However, all published literature on the use of HeRO device is based on upper limb placement, and there is no data on the use of the HeRO device in the lower limb.

We describe the first of its kind use of the HeRO device in the lower limbs of two patients and further suggest a classification system for describing the use and outcomes of the HeRO device: one patient as a primary procedure to obtain AV access and the other as a secondary procedure to maintain established AV access.

Patients

Greater Glasgow and Clyde NHS Board is a tertiary service that supplies renal replacement therapy (RRT) to 650 prevalent patients, with 170 incident patients per year. We have previously published on the management of patients with CVS, their prevalence and associated factors [8]. Prior to introducing the use of HeRO, the mainstay of managing patients with symptomatic CVS consisted of lower limb AVG. Our 5-year experience includes placement of over 65 lower limb AVGs and 16 HeRO devices in the past 3 years. All patients involved in this study had given their informed consent. Ethical approval was not needed due to nature of the study being a case report.

Patient A: primary lower limb HeRO

A 43-year-old female with a complex background commenced regular hemodialysis in 2007 on a background of established renal failure due to lupus nephritis. Multiple interventions were required for vascular access over the next 2 years including: upper limb arteriovenous fistula (AVF) formation, 10 TCVCs, and following superior vena cava occlusion, a leg AVG. Shortly after this, she received a live unrelated transplant, but re-presented quickly thereafter with unsalvageable severe acute rejection necessitating a return to hemodialysis. Vascular access was problematic and eventually a translumbar TCVC was placed but did not allow an effective dialysis. Under a general anaesthetic, four-limb venography was performed and central venous access attempted. Eventually, a wire was fed through the right common femoral vein, which drained into a dilated obturator vein through pelvic collaterals, with the external and common iliac veins being occluded (Fig. 1). The wire was then fed into the IVC and a TCVC was placed to allow immediate dialysis rather than proceeding with an AVG, as the patient had received poor-quality hemodialysis for several days in the period leading up to the procedure, which in turn required a prolonged general anesthetic. Following several weeks of regular hemodialysis treatment through the TCVC, this was removed, a wire left in situ, the tract was dilated and a HeRO fed over the guidewire. This was attached to an early-cannulation graft and anastomosed to the common femoral artery in the leg (Fig. 2). The patient was anticoagulated. This HeRO device remains in use with ongoing patency 2 year later with excellent flow parameters. One episode of thrombosis occurred after 16 months in the context of intercurrent illness and sub-therapeutic anticoagulation; however, graft patency was immediately restored.

Patient B: secondary lower limb HeRO

A 44-year-old male with a complicated background (previous intravenous drug use, peripheral vascular disease) developed established renal failure due to diabetic nephropathy. The patient commenced regular hemodialysis through a CVC, and following failed upper limb AV access attempts,

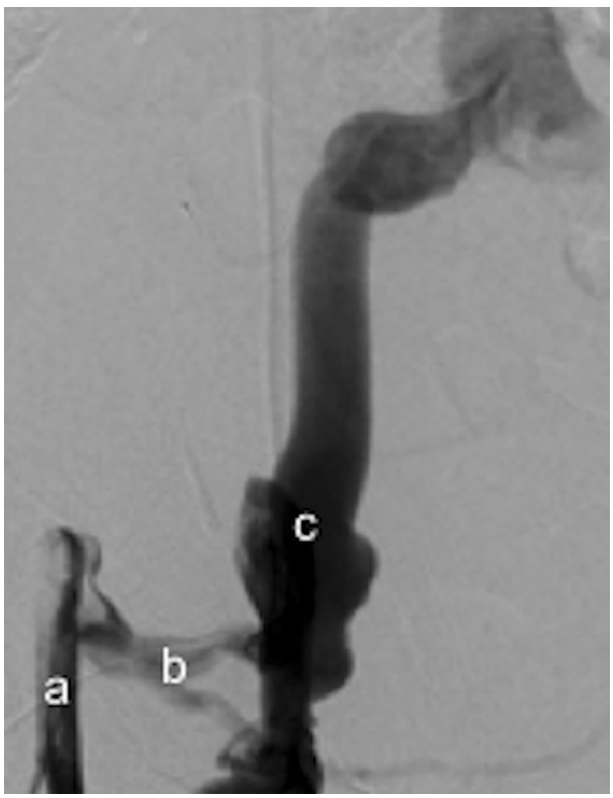

Fig. 1 Venogram of the lower limb showing contrast in the right common femoral vein (**a**) which drains into a dilated obturator vein (**c**) via pelvic collaterals (**b**)

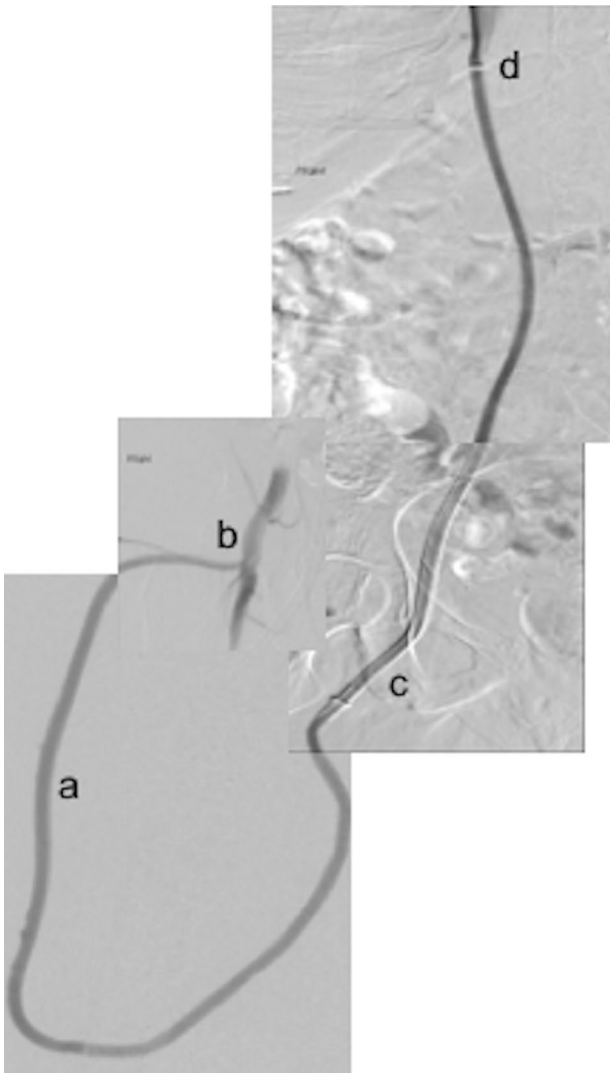

Fig. 2 Post-HeRO venogram images combined to represent the right AVG (**a**) with anastomosis at the right common femoral artery (**b**) draining into an HeRO (**c**) which runs via an obturator vein and eventually drains into the IVC (**d**)

imaging revealed bilateral CVS with no anatomical upper limb options. Over the next 3 years, several TCVCs and 3 femoral NTCVCs were placed for hemodialysis access. Recurrent CVC-related fungal septicemia and multiple extended hospital admissions related to CVC complications eventually led to placement of an early cannulation lower limb AVG. Prior to placement of the leg graft, ultrasound and venography had revealed normal venous and arterial anatomy. The patient dialysed successfully using this lower limb AVG for 3 years, during which he required a contralateral lower limb amputation for foot sepsis. After 3 years, the leg with the AVG developed edema and an angiogram revealed significant external iliac vein stenosis (Fig. 3). Given the efficacy of the patient's AVG and the limited alternative options for AV access, a decision was taken to place

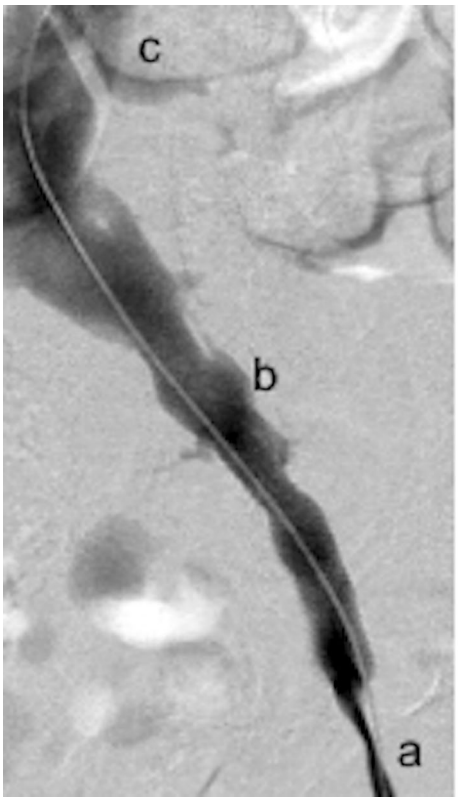

Fig. 3 Pre-HeRO Venogram showing a severely stenosed external iliac vein (**a**), draining into the common iliac vein (**b**), and IVC (**c**)

an HeRO device onto this established and functional access route (Fig. 4). This was performed under a general anesthetic with standard antibiotic prophylaxis. He dialyzed through this lower limb AVG—HeRO for a further 2 years without complications. Following the development of sepsis from his remaining foot that necessitated a further lower limb amputation, the HeRO occluded. An immediate thrombectomy was performed without need for alternative vascular access and the graft continues in use.

Discussion

The universal exposure to TCVC in most renal patients at some stage in their renal replacement treatment has led to the emergence of CVS as a leading cause of cost in patients [9]. The natural history of CVS remains elusive for several reasons: it is rarely attributable to a single TCVC, there is often considerable temporal delay from the exposure to TCVC to the presentation of symptoms, and, in addition, the competing risks of changes in modality in RRT, as well as death, may limit its identification. Perhaps most importantly, the changes of CVS are largely irreversible and all therapeutic measures to address the stenosis are associated

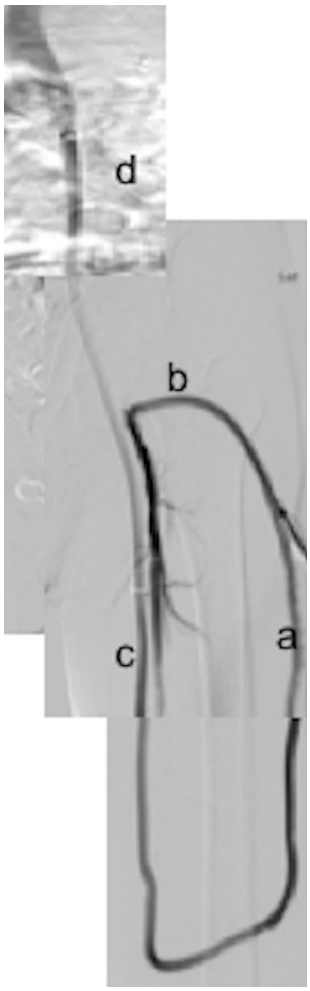

Fig. 4 Post-HeRO venogram images combined to show left lower limb AVG (**a**) with inflow at the common femoral artery (**b**), connected to a HeRO (**c**) which drains into the left common iliac vein (**d**)

with ongoing poor outcomes [4, 5]. Until recently, patients with occlusion of the superior vena cava or bilateral central vein occlusions have had no way to obtain urgent vascular access other than the use of groin TCVCs, which in turn will lead to stenosis of the central veins draining the lower limbs. This is much less frequently reported.

For patients with CVS, the HeRO device essentially provides a long-term venous outflow onto which can be attached an arteriovenous access. A systematic review of 409 HeRO grafts showed encouraging results with 1 year secondary patency of 59.4% [7] and low rates of bacteremia—0.13–0.7 per 1000 days [10, 11]. HeRO grafts require more maintenance to keep them patent: 1.5 interventions per year vs 0.6 for AVGs [12, 13]; however, this cost must be balanced against access longevity, quality of dialysis and reduced risk of bacteremia to the alternative methods of vascular access.

The current literature only describes the use of the HeRO device in the upper limb, other than one case reported by Wallace and colleagues. They describe a cohort of 19 HeRO patients and mention one who had a lower limb device placed via collaterals draining into the IVC [14], but no further information was given on this case.

This paper serves two purposes: firstly, it gives a classification of how the device can be used (primary or secondary HeRO); secondly, it describes in detail two cases of HeRO device placed in the lower limb. Patient A had no direct access to central vessels despite many attempts at placing an upper limb HeRO device. The lower limb HeRO was integral to achieving a successful arteriovenous access (primary HeRO). In contrast, patient B had a HeRO placed in his lower limb to save an already working AVG (secondary HeRO).

There has been some criticism of reports in which the use of the HeRO device in the lower limb has been included (unpublished data). However, there is no logical reason to believe that the HeRO device cannot be used in the lower limb, given that blood flows from a higher pressure to lower pressure against gravity in returning to the heart, irrespective of the location of the arteriovenous access. Our cases support this position with both devices remaining patent at 2 years and support the viability of this option in patients in whom upper limb access has failed completely and who have un-navigable upper limb vasculature preventing successful upper limb HeRO placement. These cases have been included in an accepted, unpublished publication of overall outcome rates in the UK. No data on specific techniques or classification are part of this publication. Future reports of outcomes of HeRO should sub-classify into primary and secondary HeRO, in addition to including instances where these devices have been placed in the lower limb.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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