INITIAL EXPERIENCE WITH HEMASITE VASCULAR ACCESS DEVICE FOR MAINTENANCE HAEMODIALYSIS

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Summary

Thirteen uraemic patients having undergone chronic haemodialysis from a minimum of 16 months to a maximum of 15 years (mean 6.5 years) with unsuitable peripheral vessels for standard arteriovenous fistulae, received Hemasite®, a new vascular access device which provides vascular access without needle puncture.

Eight devices are still being used routinely with enthusiastic acceptance by the patients. Three subjects died because of unrelated causes, two of whom had a functioning device. Nine thromboses occurred in five patients. Thrombectomy was successful in three subjects. There were two cases of infection with loss of one device. In conclusion, the main advantage of Hemasite is the possibility of performing haemodialysis without needles, thus potentially maintaining the longevity of graft fistula. The only disadvantage of the device is its cost.

Introduction

The arteriovenous fistula (AVF) [1] is the method of choice for gaining vascular access in uraemic patients undergoing chronic haemodialysis. There is general agreement that the operation should be performed in the distal forearm in order to spare vessels which could be available for successive operations in case of failure of the first procedure. Provided the operation is performed with adequate vessels and the arterialised vein correctly punctured, the AVF could represent reliable and occasionally long-lasting angioaccess [2]. The vessels, nevertheless, are sometimes unsuitable for constructing an AVF because of different reasons: repeated operations with progressive exhaustion of the vascular surface; inadequate calibre and/or blood flow; or presence of abundant subcutaneous tissue. In these cases the surgeon can utilise prosthetic material of biological and synthetic origin in order to create a new vascular surface utilisable for venepuncture. However, the use of such grafts did not meet with complete success
due to complications such as thrombosis, infection, bleeding after needle extraction and true aneurysm or pseudo-aneurysm formation [3].

Recently a new device, namely Hemasite® (Renal System Inc, Minneapolis, MN, USA) has been introduced into clinical practice [4–6], its main advantage being the possibility of performing haemodialysis without needle puncture. The preliminary results utilising Hemasite are challenging. The aim of this paper is to report our experience with this type of vascular access.

**Materials and methods**

The Hemasite (Figure 1) consists of a carbon coated titanium T-shaped body with a silicone self-sealing septum inserted in the round side arm or ‘well’ which extends above skin level. The T configuration provides a permanent transcutaneous access through the well. Beneath skin level, the body is surrounded by a Dacron velour which is incorporated into the subcutaneous tissue by fibrous ingrowth thus providing a barrier to bacterial invasion. The body is supplied with or without 6mm venous PTFE and tapered 4mm arterial PTFE grafts. At dialysis, the blunt double cannula access set is inserted in the septum. The cannulae have three holes on opposite sides to allow the blood to flow in and out.

![Figure 1. Schematic representation of Hemasite with the septum assembly and the access set](image-url)
Between January 1983 and April 1984 13 Hemasites were implanted in 13 uraemic patients having undergone chronic haemodialysis for a minimum of 16 months to a maximum of 15 years (mean 6.5 years). The patients numbered 10 females and three males, ranging from 44 to 73 years of age (mean 58 years). Mean follow-up was nine months. Causes of renal failure were chronic glomerulonephritis (6 patients), hypertensive nephropathy (4 patients), polycystic disease (2 patients) and SLE (1 patient). Before undergoing insertion of Hemasites the patients had been submitted to numerous vascular access procedures, ranging from a minimum of two to a maximum of 11 (mean 8.0±3.0). All the devices were implanted in a straight fashion in the upper arm interposed between the brachial artery and the brachial vein. Our operative technique is very similar to the one described very accurately by McIntyre and Putnam [7]. Under local anaesthesia two separate skin incisions are made in order to isolate the vessels. Hemasite is introduced after tunnelling the subcutaneous tissue between the two incisions and a small round segment of the skin is removed at a predetermined exit point and the device is passed through. End-to-side anastomoses are performed in a continuous fashion with 6/0 monofilament suture between graft and vein first and then between graft and artery. Prophylactic antibiotics and antiplatelet drugs are not administered routinely. Fistulae are not used for a period of 10–15 days after operation. Blood flow through the device is measured at operation and four and seven months post-operatively by means of an instrument provided by the manufacturer on the basis of a method suggested by Collins [8].

Results

No per-operative complications were observed. Dialysis personnel quickly became familiarised with the device. Eight fistulae are functioning and routinely utilised for dialysis. Three patients died from causes unrelated to the presence of the device. The Hemasite was functioning in two of them but not in the third. Cardiac disease was the cause of this patient’s death and was also responsible for the repeated failure of the device (3 thrombosis episodes). Thrombosis and infection were the only complications observed. A total of nine thromboses, due probably to acute hypotension, distributed over a period of 10 days to eight months, occurred three times, twice and once in one, two and two patients, respectively. Thrombectomy was successful in three subjects. Most of the declotting procedures were carried out by surgery, making a small longitudinal incision on the arterial graft close to the anastomosis. Thrombectomy through the well was successful once but failed four times. Symptomatic infections were noted at exit sites in two patients. Culture was positive for Pseudomonas aeruginosa and Staphylococcus aureus respectively. In the latter case infection developed prior to the first thrombotic episode. After successful thrombectomy, infection, associated with bacteriæmia, extended to the incision site of the arterial graft and the functioning device was removed. The second patient was treated successfully with antibiotics and by keeping the area around the well dry through absorbent swabs.
Mean blood flow through the Hemasite was: 650±240ml/min (11 subjects), 1157±364ml/min (7 subjects) and 1103±235ml/min (7 subjects) at operation, and four and seven months later, respectively. The difference between per-operative and post-operative values was statistically significant (p<0.001). Distal ischaemic complications and/or congestive heart failure never occurred.

Discussion

These preliminary results in a small number of cases, are encouraging and suggest that Hemasite might be a reliable device for providing durable vascular access for haemodialysis. Eight devices have been and are being used routinely. A retrospective comparison between cumulative survival of Hemasite group and cumulative survival of PTFE and bovine grafts showed no significant difference [9]. Patient acceptance has been enthusiastic because of the opportunity of undergoing haemodialysis by means of a needleless device thus eliminating pain when starting the treatment. In our experience, indeed, the reason for utilising the Hemasite in all the subjects was the lack of peripheral vessels and not patient fear of receiving venepuncture at every dialysis. According to Nissenson’s classification all the subjects were classified as ‘high risk patients’ except one ranking at ‘moderate risk’ [10]. Thrombosis and infection were the only complications noted. Thrombosis was a major concern. Five devices clotted nine times because of hypotensive episodes. The incidence of thrombosis was similar to that reported by Kaplan but much higher if compared with other larger series [4,6]. The cause of the difference cannot be easily discerned. The presence of almost all of our patients in the high risk group might be a plausible explanation. Declotting by the use of a small Fogarty catheter through the well was unsatisfactory because of a high chance of leaving a clot remnant in the conduit close to the arterial anastomotic line.

Contrary to our expectations only one device was lost because of persistent infection which started at the exit site and spread through the arterial graft. The infection rate (15%) was very close to those in Collins’s and Dienst’s observations [4,6]. As stated by other authors [5] it is very important to maintain the integrity of the skin around the well and take all precautions such as accurate cleaning and preventing any trauma to this area in order to avoid infectious complications.

Blood flow measurements revealed a statistically significant increase in flow four and seven months after operation, but provided no predictability of imminent thrombosis of the device by early detection of a decrease as observed in a few cases by Kaplan.

In conclusion, the main advantages of the Hemasite vascular access device are:

1. Elimination of needles used for cannulation, involving no pain for patients, no trauma of the skin and graft, no bleeding after dialysis, no true aneurysm or pseudo-aneurysm formation.

2. High blood flow, useful for haemofiltration and ultrafiltration procedures.

3. The theoretical possibility of performing a declotting procedure through the well without operation.
We would finally state that the high cost of the device, the only drawback found so far, may be largely offset by its many proven advantages.

References

10. Nissenson AR. *Trans ASAIO 1983; 29*: 784