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Early experience with a novel self-sealing nanofabric vascular graft for early hemodialysis access

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Abstract

Aim: To report initial experience regarding the use of novel self-sealing electrospun nanofabric graft.

Material and methods: A total of 21 patients aged between 22 and 64 (male:female ratio = 11:10) underwent AVflo vascular access graft implantation to forearm. Information for patency at 6 and 12 months after the operation was obtained. Cannulation for hemodialysis was allowed 8 h after the operation, as needed.

Results: Cannulation was performed before 12th hour of implantation in two patients, between 12th and 24th post-operative hours in 10 patients and between 12th and 24th postoperative hours in the remaining nine patients. Primary patency was 17/21 (80.9%) at 6th month and 15/21 (71.4%) at 12th month. Secondary patency was 19/21 (90.4%) at sixth month and 17/21 (80.9%) at 12th month.

Conclusion: AVflo self-sealing graft allows for early cannulation after implantation and thus may potentially eliminate the need for central venous catheters in selected patients.

Keywords

Vascular access, hemodialysis, arterivenous fistula graft, electrospun

Introduction

Hemodialysis access is an important issue in chronic renal failure (CRF) and success of creating a functional and durable access affects treatment outcomes. The incidence of CRF is increasing worldwide and an effective hemodialysis therapy is of crucial importance especially in patients waiting for future transplantation.[1] Creation of an autogenous arteriovenous fistula (AVF) initially is the most widely accepted way of access creation while use of central venous catheters (CVC) and arteriovenous fistula grafts (AVFG) being among the other options reserved for patients whom an adequately functioning AVF is not achievable.[2]

The age of onset dialysis is increasing in developed world and this brings about vascular access related problems that must be managed by vascular specialists.[3] Moreover, older patients may carry multiple comorbidities including uncontrolled blood sugar levels, obesity, coagulation disorders and various organ dysfunctions making them more susceptible against puncture-site related morbidities such as bleeding, wound infection or access failure.[4,5]

Placement of a tunneled CVC is easy and allows for early initiation of hemodialysis which is especially favorable in patients requiring hemodialysis imminently.[2] However, there has been increasing evidence indicating high infection and failure rates they produce within the first year of hemodialysis.[6] AVFGs have also been used as initial hemodialysis access. However, whether their use may potentially eliminate the need for central venous catheters is still controversial since still one-fifth of patients convert to CVC after being initiated on hemodialysis using AVF or AVFGs.[7] Success of cannulation during hemodialysis procedure is another important issue which should be optimized taking the advantage of novel developments targeting better outcomes.[8]

AVflo vascular access graft (Nicast, Lod, Israel) is a novel polyurethane vascular access graft featuring electrospun nanofabric which facilitates contraction of

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needle holes after decannulation and thus enables it to be used early after implantation. The graft has a four-layer design. The nanofiber microporous blood-contacting inner layer is designed to minimize platelet adhesion. The microporous middle layer contains a 40 μm thick barrier layer which prevents the diffusion of large molecules and provides strength and elasticity to the graft's structure. This report presents the authors' initial experience regarding the use of this newly commercial graft.

Material and methods

The study was approved by local ethics committee (Gaziosmanpasa University, Turkey). This was a retrospective study on patients undergoing AVF graft implantation between October 2011 and August 2014 in a tertiary hospital. Clinical records of a total of 21 patients aged between 22 and 64 (male:female ratio = 11:10) who underwent AVflo vascular access graft implantation to upper extremity were investigated. Patients were considered eligible if creation of an AVF is unachievable due to presence of one or more risk factors, including duplex confirmed poor vascular anatomy in upper arm vessels, failure of previous ipsilateral radio-cephalic AVF and unsuitable veins for AVF at contralateral arm, and high risk of creating a failing AVF because of multiple needle insertion sites over the ipsilateral arm. Patients with low platelet count (<30,000), coagulation abnormalities, ipsilateral upper extremity venous thrombosis, and those who were likely to benefit from endovascular angioplasty for AVF salvage were excluded. All of the operations were performed by the same surgeon. Patient demographics, surgery details and early postoperative data were obtained from archive records. Information for patency at 6 and 12 months after the operation was measured by dupplex ultrasound.

All of the operations were performed on the forearm but not on the upper arm. In this series, the surgeon used a center coiled (i.e. middle third segment of the graft is coiled, allowing make a complete U turn on the forearm without kinking) configuration of the AVflo, as recommended for forearm by the manufacturer. A local anesthetic solution was injected over antecubital fossa and then brachial artery and vein was exposed through a vertical incision. Specific instructions by the manufacturer were followed because the material of AVflo graft is softer than usual ePTFE grafts. The graft ends were anastomosed with 6.0 polyprolene rounded sutures to brachial artery and vein with the ringed middle segment of the graft looped at an adequate distance on forearm. After deairing and controlling for bleeding, incision is closed primarily.

Table 1. Baseline characteristics.

Variable	*n*
Male gender	11 (52.3%)
Mean age	56.61 ± 12.84
Diabetes mellitus	12 (57.1%)
Peripheral arterial disease	3 (14.2%)
Tobacco use	3 (14.2%)
Mean time from onset hemodialysis (years)	3.42 ± 1.56
Number of patients with previous AVFs	15 (71.4%)
Mean number of previous AVFs	2.04 ± 0.62
Patients with CVCs placed within last 6 months	17 (81.0%)

AVF, arteriovenous fistula; CVC: central venous catheter.

Active hand and forearm movements were encouraged early after the operation and the patients were suggested to keep their arm slightly elevated. Cannulation for hemodialysis was allowed 8 h after the operation, as needed. Patients were given acetylsaliyclic acid to prevent graft failure in long term if they were not receiving for other purposes.

Results

Baseline patient characteristics were given in Table 1. There were no patients with a past history of AVFG implantation. The operation took within a range of 45–96 minutes (mean 61.62 ± 14.40). AVflo implantation was performed on the left side in 16 patients and on the right side in five patients.

Early, surgery-related complications rarely occurred. Bleeding and subsequent hematoma occurred in one patient and the patient underwent a revision 2 h after the operation. Source of the bleeding was a small tributary vein; anastomoses were patent and not bleeding. Graft thrombosis, wound infection and pseudoaneurysm did not occur. In two patients, cannulation of the graft was allowed before 12th hour of operation because they needed hemodialysis imminently due to high potassium levels. Hemodialysis via the newly implanted graft was allowed between 12th and 24th postoperative hours in 10 patients and between 24th and 48th postoperative hours in the remaining nine patients. Dialysis was performed uneventfully in all patients.

Primary patency was 17/21 (80.9%) at 6th month and 15/21 (71.4%) at 12th month. Within 12 months, 6 patients had graft failure, all of which were due to graft thrombosis. Two out of these patients presented within three months after the operation and achieved patency after thrombus evacuation, whereas the

remaining four patients were those presenting relatively later (six to nine months after surgery) and did not benefit from thrombectomy. Thrombectomy interventions were made using open surgical technique. Thus, secondary patency was 19/21 (90.4%) at 6th month and 17/21 (80.9%) at 12th month. All of the patients with a patent graft were receiving routine hemodialysis via their graft. Graft infection did not occur during follow-up period.

Discussion

This report describes the author's initial experiences using AVflo synthetic graft in patients unsuitable for AVF fistula creation. The graft actually allowed for early cannulation as early as 9 and 11 hours after the operation, within a shorter time than proposed by the manufacturer. Both these patients were those requiring dialysis imminently within the day of surgery and were among last five patients operated on by the surgeon. Thus, upon confirming that there was no actual bleeding and depending on the initial successful experiences with the graft, punctioning of the graft was allowed under surgeon's supervision rather than inserting an additional temporary dialysis catheter. All of the patients in this series received hemodialysis within 48 h after the operation where more than half could succesfully be performed within 24 h, indicating the potential of this self-sealing, electrospun nanofabric material in eliminating the need for CVCs in incidental hemodialysis in selected cases.

All of the patients in this series were permanently on hemodialysis therapy and more than half had either an AVF or tunelled CVC implanted previously. None of the AVFs were patent and a second AVF had been attempted in 13 patients. Seventeen patients were those having a CVC in the last six months and the catheter was not functioning properly in seven patients and was totally dysfunctioning in three patients; catheters were functioning in the remaining seven patients, but these patients were dissatisfied with the outsided tips of the catheter. Thus, AVflo grafts were used as a last resort in this series and produced acceptable 6 and 12 month patency.

This is not the first report regarding the use of AVflo graft, but to date there have been three previous studies. Wijeyaratne et al.[9] were the first using the graft in man and reported that primary and secondary patency rates were 72.7% and 81.8% at 6 months and 54.5% and 72.7 at 12 months, respectively. The authors reported that postimplantation access could be achieved in all 17 patients, emphasizing the prevention of need for catheters. However, although all grafts were cannulated within eight days, which still seems more advantageous than other type of grafts, the earliest time of cannulation was not earlier than 48 h in that study.

In another study by Ferraresso et al.,[10] the AVflo graft was used in 10 patients but implanted in the upper arm in seven patients and in thigh in three patients. Primary and secondary patency rates were still acceptable in these locations. Karatepe et al.[11] used the graft in 24 patients and reported that cannulation was performed within 24 hours of implantation without increasing complication rates. They reported 50.0% and 70.8% primary and secondary patency rates at 12-month follow-up including early failures.

In line with those above, more than two-thirds of our patients had primarily patent AVFs in the 12th month. Graft thrombosis could be fixed when the presentation was not later than three months after the operation, whereas patients presenting later than six months no longer had benefit from the graft. I think that potential causes of these should be analysed individually for each patient as there were multiple variables affecting the graft survival. One most important cause is that technique for cannulating the grafts has not yet been well optimized as even adequately experienced hemodialysis staff is quite unfamiliar with their use.

The present study had several limitations including retrospective design, lack of any control group and single surgeon experience. Therefore, results presented here await confirmation by further study.

In conclusion, use of AVflo self-sealing graft provided an effective hemodialysis as early as 12 h after the implantation, indicating a potential role of eliminating the need for CVC in certain occasions. Use of the graft is recommended especially in patients with high AVF failure risk and requiring hemodialysis imminently and permanently thereafter.

Declaration of conflicting interests

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