Clinical and Doppler ultrasonography data of a polyurethane vascular access graft for haemodialysis: a prospective study

Patrick Wiese¹, Jochen Blume¹, Hans-Joachim Mueller¹, Hermann Renner² and Barbara Nonnast-Daniel¹

¹Department of Nephrology and ²Department of Vascular Surgery, Klinikum Nuernberg, Nuernberg, Germany

Abstract

Background. Absence of a permanent vascular access in most patients starting haemodialysis remains a cause of high morbidity and costs. This study obtained new clinical and colour Doppler ultrasound (CDU) data of a polyurethane vascular access graft (PVAG) proposing early post-operative cannulation.

Methods. Baseline characteristics were determined in 15 patients and the PVAGs were evaluated prospectively including first cannulation, patency and complications. CDU was used post-operatively and after 1 year for assessing graft morphology and access blood flow.

Results. PVAGs were cannulated at a median of 4 days post-operatively. The 1-year primary patency of the PVAG was 66.7%. During the 15 months observation three grafts thrombosed, one was replaced because of infection and one because of ischaemia. CDU measurements at the feeding brachial artery revealed a mean initial access volume flow of 773 ± 89 ml/min, being significantly higher in patients without thrombosis compared to patients with thrombotic events (930 ± 90 vs 375 ± 143 ml/min, P < 0.05). The initial inability to directly monitor PVAGs by CDU changed at sites of frequent centesis, where Doppler signals and luminal morphology could be evaluated in the follow up examination.

Conclusions. The PVAG offers early access for urgent haemodialysis. CDU for access volume flow measurement at the feeding brachial artery contributes to predict access thrombosis. Direct non-invasive graft imaging is limited and the ultrasonographical changes in the polyurethane material enabling graft monitoring after repeated cannulation might indicate an injury of the graft with increased risk for access failure.

Keywords: Doppler ultrasonography; early cannulation; haemodialysis; polyurethane graft; prospective study; vascular access

Introduction

The arteriovenous (AV) fistula is recognized as the vascular access of choice in haemodialysis patients because of its low complications and high patency rates [1]. In patients who are not suitable for a native AV fistula, the most common alternative is still an expanded polytetrafluoroethylene (ePTFE) graft with significantly lower survival rates [2]. As ePTFE grafts usually require a maturation period of 2–3 weeks for primary cannulation and the majority of patients with end-stage renal disease do not have a patent permanent access at the start of dialysis, the insertion of a central venous catheter is often needed. Both starting haemodialysis with a central venous catheter and premature cannulation of a permanent access have resulted in more frequent vascular access (VA) failure [3].

One of the latest attempts to create a VA for immediate use to avoid temporary catheters is a polyurethane vascular access graft (PVAG) (Vectra®, Thoratec Laboratories Corporation, Berkeley, CA, USA). The graft is made of Thoralon®, a three-layered polyurethane material. It is claimed that the solid non-permeable medial layer of the PVAG has self-sealing properties, allowing a cannulation within 24 h after implantation.

With very little data available on the long-term performance of this new material, two studies have demonstrated the advantage of early cannulation of the PVAG with similar patency rates compared with ePTFE grafts [4,5]. Although one letter reported an inability to monitor the PVAG by colour Doppler ultrasound (CDU) [6], it was the aim of our study to focus, besides clinical data, especially on the ultrasound evaluation of the new polyurethane material to assess changes in morphology and function of the graft, both early post-operation and after repeated cannulation.
Subjects and methods

Patients and study design

A prospective study was performed on 15 patients, who received a looped PVAG in the forearm. Indications for implantation of such a graft in this carefully selected group of patients were the absence of sufficient native vessels to create an AV fistula and the need of urgent dialysis. At the time of enrolment into the study, baseline demographics and clinical information were obtained and patients were followed up for a period of 15 months. End-points were graft failure or death.

The time to first cannulation of the PVAG with a 1.6 × 20 mm fistula needle was determined, as well as the primary patency rate after 12 and 15 months, and the major causes of graft failure.

Implant procedure of the PVAG

The implantation was performed by one of two surgeons. The graft was soaked in sterile saline and compressed to remove air bubbles from the microstructure to avoid skin inflammation. Incisions were made below the elbow and above the wrist to expose the vessels. Two tunnellers were introduced subcutaneously from both angles of the distal incision to the proximal one, creating an oval shape. Both ends of the graft were introduced into the distal ends of the tunneller sheaths and advanced until the stiffer middle part of the graft was taut between the tunnellers at the distal wound. Graft and tunneller were kept wet to facilitate the sliding process. While removing the tunnellers through the proximal incision, care was taken about the position of the graft, as it cannot be repositioned afterwards. Arterial and venous anastomoses were created by standard techniques and before finishing the venous anastomosis, the graft was flushed. Despite the rubber-like polyurethane material, trimming and suturing was not more difficult than with PTFE and there is no suture-line bleeding.

Colour Doppler ultrasound

CDU is a non-invasive technique for the assessment of vascular accesses, as previously described by us [7]. Early post-operative PVAGs were evaluated from the arterial anastomosis, through the entire access and into the draining vein, with an Accuson 128/XP4 (5.0 MHz and 7.0 MHz transducer) or a Philips HDI 5000 (12.0 MHz and 15.0 MHz transducer) CDU unit. Access blood flow was calculated by equipment software from the diameter of the feeding brachial artery in the distal one-third of the upper arm in transverse plane and from the time velocity integral of a mid-stream spectrum obtained from a normal, non-turbulent area of the brachial artery in the longitudinal plane. The Doppler angle was held below 60°. Three cycles of flow measurement were averaged. The complete CDU examination was repeated after a follow-up period of 12 months to evaluate ultrasonographic changes in graft morphology and function.

Statistical analysis

Access volume flow data are expressed as means ± SEM and two-sided P-values <0.05 were considered significant. Primary patency rates at 12 and 15 months were evaluated for patients with a primary patent PVAG compared with all patients who were still living and followed-up.

Results

Baseline patient characteristics

The 15 patients (10 male, 5 female) had a mean age of 66.3 years (range 39–85) and an average time of dialysis treatment of 5 months (range 0–31) before implantation of the PVAG. Seven patients had one or more previous permanent vascular accesses that had failed. Further baseline patient characteristics are summarized in Table 1.

Time of first use of PVAG for haemodialysis

After complication-free implantation, 13 of 15 PVAGs (86.7%) were cannulated within 4 days (median at 4 days, range 1–19 days), with three grafts already in use on the first post-operative day.

Patient outcome and patency rate

At the end of the 15 months follow-up period, six of 15 patients were still being dialysed with a primary patent PVAG. Three patients had died with patent grafts. Graft failure with the necessity of an operative revision had occurred in five patients, predominantly due to thrombosis. One patient was lost to follow-up (Table 2).

The 1-year primary patency rate of the PVAGs was 66.7% with eight primary patent grafts in those 12 patients who were living and were successfully followed up. Primary patency decreased to 54.5% after 15 months with six patent grafts in those 11 patients still living and followed-up.

Colour Doppler ultrasound

The mean Doppler ultrasound access volume flow in the feeding brachial artery early post-operatively was 773 ± 89 ml/min

Table 1. Baseline characteristics of the patient population (n = 15)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>6</td>
<td>40.0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>13</td>
<td>86.7</td>
</tr>
<tr>
<td>Hyperparathyroidism</td>
<td>12</td>
<td>80.0</td>
</tr>
<tr>
<td>Obesity</td>
<td>5</td>
<td>33.3</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>12</td>
<td>80.0</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>7</td>
<td>46.7</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>8</td>
<td>53.3</td>
</tr>
<tr>
<td>Smoking</td>
<td>8</td>
<td>53.3</td>
</tr>
</tbody>
</table>

Table 2. Outcome of the PVAG (n = 15) at the end of the follow up period (15 months)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living with patent graft</td>
<td>6 (40.0)</td>
</tr>
<tr>
<td>Died with patent graft</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>Graft failure</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>Revision for peripheral ischaemia</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Revision for graft infection</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>1 (6.7)</td>
</tr>
</tbody>
</table>
In those six patients with patent PVAGs until the end of the observation period, the mean initial flow was $930 \pm 90$ ml/min without significant changes in the 12-month follow-up examination ($841 \pm 154$ ml/min). The mean initial access volume flow in those three patients with a thrombotic event was significantly lower ($375 \pm 143$ ml/min, $P < 0.05$) compared to patients without complications until the end of the study.

Examining the PVAG from the feeding artery through the entire loop into the draining vein, no colour duplex signal or Doppler spectrum could be monitored within the graft lumen distal to the arterial anastomosis early after operation. There was only a strong reflection from the superficial surface of the graft with acoustic shadowing below (Figure 1A). At the 12-month follow-up examination, the same phenomenon could be observed in those parts of the graft that had not been cannulated, including especially the site of the arterial and venous anastomosis. In areas of the PVAG that had repeatedly been cannulated, the strong reflection from the surface of the graft was clearly diminished. Through acoustic windows varying in size from holes with the diameter of single fistula needles (Figure 1B and C) to a length of some centimetres at sites of frequent centesis (Figure 1D), intraluminal colour Doppler signals could be recorded. This allowed both flow measurement and the assessment of morphological changes in these graft segments.

**Discussion**

This study shows that decreased blood flow, especially below 650 ml/min, is associated with a high probability of thrombotic events in PVAGs. This emphasizes the role of flow measurements by CDU as a predictor of access thrombosis in this specific type of access, as already described for PTFE grafts [8].

The early post-operative cannulation of the polyurethane graft at a median of 4 days and 86.7% of all PVAGs in use at that time is supported by two reports in the literature describing experiences of an early use of the PVAG [4,5]. One study determined the initial cannulation of the graft at a median of 3 days [5]. The other evaluation compared the time to first dialysis...
access between PVAG and ePTFE grafts, revealing that 53.9% of all PVAGs were cannulated before 9 days vs none of the ePTFE grafts [4]. Although there are studies showing that ePTFE grafts can also be accessed early without compromising long-term patency [9], the general recommendation for puncture of ePTFE grafts is still 2-3 weeks after implantation to allow endothelialization of the internal wall [10]. However, a study assessing the outcome of early cannulation of the PVAG compared to early cannulation of ePTFE grafts is pending.

To a large extent, patients have no functional permanent access at the start of haemodialysis [10]. For those selected patients who are not suitable for an AV fistula and therefore do need an AV graft, early access is of vital importance to decrease the requirement of a central venous catheter for initial haemodialysis. This can help to reduce the more frequent access failures and the higher associated risk of death seen in patients who start dialysis using central catheters [3,11]. Furthermore, early access can minimize hospitalization and its associated costs.

There is a wide variation in the 1-year primary patency of AV grafts with recent data of 36% [1] and 49.9% [2]. In our study the primary patency of the PVAG was 66.7% at 12 months, an acceptable survival rate for AV grafts. The previously mentioned studies with PVAGs revealed 1-year primary patency rates of 44% [5] and 44.9% with no significant differences in patency compared to ePTFE grafts [4]. The major cause for graft loss in our study was thrombosis, as is also reported by other authors [5]. The other two complications needing removal of the access were distal limb ischaemia and severe graft infection. Both complications are not unexpected, taking into account a population of elderly patients with immunodeficiency due to their end-stage renal disease and extensive co-morbidity, including peripheral vascular disease.

Recently it was reported that there is an inability to monitor the polyurethane graft by Doppler ultrasound, limiting the possibility for non-invasive graft patency monitoring [6]. In our study this disadvantage was only seen in those segments of the PVAG that were not used for cannulation, including both areas close to the anastomosis. However at sites of frequent centesis, CDU imaging could be performed, with the ability to assess Doppler spectrum, flow and morphology. Despite the claim that the Thoralon® polyurethane material has excellent biodurability and self-sealing haemostatic properties [12], these ultrasonographical results suggest cannulation induced changes in the graft material. These changes may point to increased interaction of blood and biomaterial, with an increase in the clotting cascade effect. This would agree with the angiographic observation of more frequent stenosis of the PVAG lumen and intimal hyperplasia at the site of repeated cannulation [12]. There might also be a component of biodegradation of the graft material, which is known to be mediated predominantly by neutrophils and macrophages during the inflammatory response after exposure to the surface of an implanted polyurethane medical device [13].

In conclusion, the PVAG offers an alternative for patients in need of prosthetic graft material with the advantage of early access. Colour Doppler ultrasound assessment of the PVAG is restricted to indirect measurements at the feeding artery and draining vein as well as direct monitoring of the graft at sites of repeated cannulation. The definitive pathophysiological mechanisms for the changes in the polyurethane material, allowing CDU imaging after frequent centesis, as well as the question of whether this represents an injury to the PVAG with increased risk for access failure, are still to be determined.

Conflict of interest statement. None declared.

References


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