Midterm Results with the Use of Polycarbonate Urethane Heterografts for Dialysis Access

BAYER ÇINAR, ONUR S. GÖKSEL and IBRAHIM YEKELER

Department of Cardiovascular Surgery, Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Center, Istanbul, Turkey

ÇINAR, B., GÖKSEL, O.S. and YEKELER, I. Midterm Results with the Use of Polycarbonate Urethane Heterografts for Dialysis Access. Tohoku J. Exp. Med., 2005, 207 (3), 233-238 —— Dialysis access surgery is currently one of the most common vascular operations as the dialysis patient population increases. Although autogenous arteriovenous fistulae (AVFs) and grafts (AVGs) are the primary methods of long-term hemodialysis access (Widmer et al. 2004). The role of vascular surgeons and the timing for those patients is better understood as 1-year complication rate of a primary prosthetic AV access for hemodialysis ranges from 33% to 99% and up to 35% of patients die within the first year of their initial hemodialysis (Sidawy et al. 2002). Although autogenous AVFs stand as the preferred method of access due to excellent patency and lower complication rates, AVGs provide alternative approaches when an autogenous AVF is impractical usually due to depleted veins (Palder et al. 1985; Kherlakian et al. 1986; Widmer et al. 2004).
In this prospective, non-randomized observational analysis, we present our midterm clinical results with polycarbonate urethane Expedial™ heterografts (LeMaitre Vascular Ltd., Wrexham, UK).

**MATERIALS AND METHODS**

Patients that received Expedial™ heterografts (LeMaitre Vascular Ltd.) for angioaccess at Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Center, Istanbul between October 2000 and December 2004 were prospectively followed. With the institutional review/ethics committee approval and informed consent from each patient, baseline data regarding the renal history, operative and perioperative course were recorded upon individual patient’s informed consent for the study and the procedure. First, 6th and 12th month outpatient controls consisted of physical examination and doppler ultrasound when needed. Outcome parameters were followed in accordance with the reporting standards for vascular grafts. Patency and complication rates are reported from implantation date to end-points as death, renal transplantation or as defined previously elsewhere (Sidawy et al. 2002). Primary patency is defined as the time from access creation to first graft occlusion or a reintervention. Secondary patency is the period from the first reintervention to graft renewal so as to be capable of providing blood flow sufficient to obtain an adequate dialysis dose within a maximum of 5 hour/session (Ravani et al. 2005). Maturation time is defined as the time required for a vascular access (AVG or AVF) to be able to provide an adequate dialysis dose as defined above.

Diabetic patients with infectious skin problems, immunosuppressive therapy, redo grafts in patients not enrolled in the study and those with insufficient arterial inflow or venous drainage (< 3 mm; stenosis/obstruction) upon preoperative doppler screening were to be excluded from the study. No patients, however, were excluded preoperatively due to distal venous obstruction/stenosis. For all patients, plexus/local anesthesia and atraumatic tunneling technique were used for preferably a forearm and straight graft implantation. Routine flushing of the graft lumen with 40 IU Na-heparinate/ml was applied in addition to 5,000 IU of systemic heparinization prior to vascular clamping and anastomoses with monofilament running suture (Prolene® 6/0). Primary intention was creation of an upper extremity dialysis access fistula so as to save lower extremities for future interventions.

Major indications for a femoral implantation were prior procedures in upper extremities or depletion of veins. Indications for a looped configuration in the forearm were mainly anatomical considerations as the extension of an adequate vein. All patients were given an instruction card for caretakers during hemodialysis in order to prevent puncture from the looped region as advised by the manufacturer. Three hundreds twenty five mg of aspirin *p.o.* was given routinely to all patients within 6 hours of the procedure.

Statistical procedures were done by using SPSS 10.0 (SPSS Inc., Chicago, IL, USA). Data are expressed as means ± standard deviation. A *p* value of less than 0.05 was considered to indicate statistical significance. “Binary Logistic Regression Analysis” and “Kaplan-Meier method” were used for the statistical evaluation of data. Significance and odds ratios for risk factors early and midterm failure for the grafts, was determined with “Binary Logistic Regression Analysis.” Analysis of patency curve for primary and secondary patencies was performed with the Kaplan-Meier estimation; difference between primary and secondary patencies were assessed with the log-rank test.

**RESULTS**

Between October 2000 and December 2004, 234 de novo AVFs were created and 34 Expedial™ heterografts were implanted in 30 patients (22 males, 8 females; median age 60.6 years, range 32 - 70). Seven patients were diabetic and 3 had medically treated coronary artery disease.

| Table 1. Preoperative characteristics of 30 patients |
|-----------------------------|-----------------|
| Patients                    | (n = 30)        |
| Age (Years)                 | 60.6            |
| Gender                      | 8               |
| (n, Female)                 |                 |
| Followup duration (Months)   | 16.3 ± 6.1      |
| DM (n)                      | 7               |
| CAD (n)                     | 3               |
| Previous abondoned access   | 3.4 ± 0.5       |
| (n/patient)                 |                 |
| Hypoalbuminemia (n)         | 6               |

Data are shown as the mean ± s.d. except for age given as median values; DM, diabetes Mellitus; CAD, coronary artery disease.
disease (Table 1). A 6-mm Expedial™ heterograft was implanted in all patients except that a 4-mm graft was used in one patient due to distal obstructive arterial disease for anticipation of a possible steal phenomenon. Twenty eight grafts (82.4%) were placed in forearm position (20 straight, 8 looped; brachial artery and cephalic vein) and 6 grafts were placed in the groin region (all looped-superficial femoral artery and the greater saphenous vein). The mean followup for 30 patients were 16.3 ± 6.1 (range 4 - 30) months. Only one patient expired (22nd month) and one patient was lost during the followup (after 14th month). The most common cause for re-intervention was thrombosis at the venous anastomotic site (6 thrombotic events; one being an early thrombosis within 24 hours of surgery). No patients received percutaneous interventional measures for patency maintainance. One patient was re-explored for progressive hematoma in the groin region. In another patient with a femoral graft, ligation of the graft was performed 1 week after implantation due to paleness, paresthesias and pain of the lower extremity (steal). Further investigation of this patient yielded moderate obstructive arterial disease at the popliteal region. As mentioned above, a patient with mild popliteal stenosis received a smaller-sized graft and no steal phenomenon was observed. One patient had a prosthetic *Staphylococcus aureus* infection with a pseudoaneurysm formation and was explanted. In three patients, repeat thrombectomies were performed.

![Fig. 1. Kaplan-Meier analysis for primary patency.](image1)

In all patients through followup, the median censored primary patency was found as 27 ± 1.7 months (95% CI, 23.38 to 30.67). Note that the events affecting primary patency rates of the grafts are shown on the curve.

![Fig. 2. Kaplan-Meier analysis for secondary.](image2)

The median censored secondary patency was 30.42 ± 1.1 months (95% CI, 28.30 to 32.54). Note that the events affecting secondary patency rates of the grafts are shown on the curve.
Midterm Results with Expedial TM Grafts during the followup. The most common causes of graft removal were recurrent thrombosis and stenosis due to intimal hyperplasia (4 patients).

Primary patency was found as 81% (Fig. 1). In all patients through followup, the median censored primary patency was found as 27 ± 1.7 months (95% CI, 23.38 to 30.67). Secondary patency for all patients was 94%. The median censored secondary patency (Fig. 2) was 30.42 ± 1.1 months (95% CI, 28.30 to 32.54). Primary and secondary patencies (Fig. 3) were not significantly different ($p = 0.15$).

Several potential risk factors as age, diabetes mellitus, hyperlipidemia, coronary artery disease and hypoalbuminemia were investigated for graft patency. Among those, only presence of diabetes was found as a significant risk factor in the regression model ($p = 0.01$). Table 2 shows risk factor analysis for impaired patency.

**DISCUSSION**

Vascular access remains the lifeline for end-stage renal failure patients treated with chronic intermittent dialysis. The most widely accepted access-related care today is presented as DOQI guidelines (Saran et al. 2001). If an AVF is impractical for dialysis access, AVGs provide an alternative approach with their large surface areas, simple cannulation, short maturation period and easy surgical handling. The present study summarizes intermediate outcome of single center experience with polycarbonate urethane Expedial TM heterografts, which have been advised for immediate access after implantation and lower hemostatic problems after hemodialysis by the manufacturer. Since none of the patients in this series required emergency hemodialysis, it should be noted that the mean interval between angioaccess and implantation was 5.3 ± 2.15 days, a period shorter than the widely accepted maturation period of 10 to 14 days.

AVGs are considered as a second choice for hemodialysis for their disadvantages as reduced patency rates, infections and pseudoaneurysms (Palder et al. 1985; Kherlakian et al. 1986; Widmer et al. 2004). One-year patency for pros-

![Fig. 3. Comparison of primary and secondary patencies. Log-rank test showed that the difference between primary and secondary patencies is not significant ($p = 0.15$).](image)

<table>
<thead>
<tr>
<th>Table 2. Logistic regression analysis for graft failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>p</td>
</tr>
<tr>
<td>----</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>DM</td>
</tr>
<tr>
<td>CAD</td>
</tr>
<tr>
<td>Hypoalbuminemia</td>
</tr>
</tbody>
</table>

*p $< 0.05$.

DM, diabetes mellitus; CAD, coronary artery disease.
thetic angioaccess grafts ranges from 43% to 86% at different anatomical locations and configurations (Hodges et al. 1997; Kao and Chang 2004; Hazinedaroglu et al. 2004; Ko et al. 2004; Tordoir et al. 2004). Our cumulative primary patency rate was 81% for both femoral and forearm positions.

Besides thrombosis and occlusion, another major drawback regarding AVGs is infection, which has been reported as 2.5 - 10% within 1 year of implantation (Mennes et al. 1978). In the followup of 30 patients with 34 graft implantations, we observed one case of deep infection with pseudoaneurysm of the graft.

Steal phenomenon is another anticipated problem in angioaccess surgery especially in diabetic and elderly population (Tordoir et al. 2004). Hazinedaroglu et al. (2004) reported a 30% rate of steal requiring closure of the graft. In our series, we observed only one case of steal phenomenon and the femoral loop graft of that patient was ligated. He was not diabetic, nor had he initially presented with any symptoms or signs of obstructive arterial disease.

It is of note that none of our patients received percutaneous intervention to improve patency during the followup in accordance with previous published data (Huber et al. 2004). Rather, a direct surgical approach was preferred upon diagnosis with color doppler ultrasound. Surgical procedure regarding thrombectomy or graft renewal depends on the pathology anticipated. Postoperative monitoring is also managed with doppler ultrasound.

Dense mesh of the polycarbonate urethane supposedly prevents hemostatic problems during/after hemodialysis. Patients with already deranged hemostatic system may experience pseudoaneurysm formation after puncture. We did not observe such a case in any of the patients.

Various medications as calcium channel blockers, angiotensin converting enzyme inhibitors in addition to antiplatelet agents have been suggested to increase patency (Saran et al. 2002; Widmer et al. 2004). We did not routinely prescribe any specific medication besides low dose aspirin (125 mg/day) for these patients. In accordance with previous data (Gibson et al. 2001; Widmer et al. 2004), presence of diabetes was found as a significant risk factor for graft thrombosis/occlusion within first year according to the regression model (p = 0.01). Previous venous catheterizations were not included in the analysis due to strict preoperative confirmation of outflow patency with doppler ultrasound.

Being a prospective, non-randomized observational study, this report has some limitations. Particularly, followup of intra-access pressure measurements at particular time points would provide a better insight to characteristics to this relatively newer heterograft. Also, presentation of longer followup with larger sample size may provide with a detailed demonstration to patency and complication rates regarding the graft.

In our series, polycarbonate urethane Expedial™ heterografts implanted for dialysis vascular access have shown relatively lower complications. Short maturation times and hemostatic characteristics remain to be tested in future studies.

References


