Chapter 5

Hemodialysis arteriovenous fistula patency revisited; results of a prospective, multicenter initiative

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Abstract

The K/DOQI vascular access placement standards are predominantly based on older single center reports and exclude the maturation period. However, hemodialysis population characteristics have changed dramatically and primary AVF failure is a significant problem. In this prospective, multicenter study we used standardized definitions to analyze patency rates and risk factors for patency reduction.

Eleven centers participated in a guidelines implementation program. All new permanent vascular accesses during this follow up period were included. Patency rates were calculated using Kaplan Meier analysis and life table method. Risk factors for patency loss were determined using regression models.

A total of 491 AVFs (76% of all inclusions) were placed in 395 patients. Mean age was 65 years and 62% were men. Six, 12 and 18 months secondary patency and functional patency were 75 ± 2.0%, 70 ± 2.3%, 67 ± 2.7% and 90 ± 1.9%, 88 ± 2.2%, 86 ± 2.7%, respectively. Primary failure rate was 35%. Thrombosis rate was 0.14 per patientyear. Only diabetes was associated with primary functional patency loss (HR: 1.70 [95%CI: 1.07–2.68]). No factors were related to secondary failure (SF). The SF-rate per hospital varied from 0 to 38%. Compared to the hospitals with low secondary failure rates, three hospitals had higher risks of SF.

We showed a marked difference between patency and functional patency, likely to be explained by high primary failure rates. After adjustment for potential risk factors, secondary failure was more likely in 3 of the 11 hospitals suggesting an important role for practice patterns.

Introduction

The K/DOQI standards promote the increase of native vascular access use because of superior patency rates and lower complication rates than grafts once established [1]. These recommendations are predominantly based on single center studies from the 1980's and early 1990's, and on studies that have excluded the phase between AVF creation and cannulation from patency calculations [2]. However, current hemodialysis patients are older, more often have diabetes [3] and more often have cardiovascular co-morbidity [4, 5]. Moreover, fistulas have high primary failure rates [6] and maturation problems will increasingly challenge vascular access teams in meeting the K/DOQI goals [7]. In patients with compromised forearm vessels graft patency has been shown to be better than AVF patency [8]. Therefore, a renewed analysis of native vascular access patency rates is justified.

The Dialysis Outcomes and Practice Patterns Study (DOPPS), in which the Netherlands was not included, showed large differences in both national and regional vascular access placement policies [5, 9]. At the start of the new millennium prevalent AVF use in the Netherlands was approximately 60% with a wide range [31-91%] [10]. Therefore, a multicenter guidelines implementation program, CIMINO (Care Improvement by Multidisciplinary approach for Increase of Native vascular access Obtainment), was initiated to increase AVF use in a proportion of the Dutch hemodialysis population. In addition, this prospective multicenter observational study was designed to learn more about both early and late functionality of the AVF. Recently our group showed that hospital specific aspects predominantly determine primary AVF failure [11].

The purpose of the analysis in the present study was to compare AVF patency rates in 11 dialysis centers with K/DOQI standards using standardized definitions in a methodological favorable study setup. Furthermore, we aimed at obtaining insight in risk factors affecting patency rates and late AVF functionality.

Patients and Methods

At the start of our program in 2003, the Vascular Access Society (www.vascularaccesssociety.org) presented the most recently updated guidelines on vascular access care by means of 26 algorithms consisting of clearly structured flow charts supported by literature-based evidence and expert opinions [12]. The recommendations of these 'European guidelines' included 1) for nephrologists: vein preservation, patient referral to vascular surgeon at least 6 months prior to expected hemodialysis, performance of a standard preoperative duplex examination and referral to ultrasound technician, surgeon or radiologist in case of suspected inadequate maturation at 4-6 weeks; 2) for vascular surgeons: order of preference of access placement is i) distal arm AVF, ii) proximal arm AVF and iii) basilic vein transposition or graft insertion. Artery and vein internal diameters should both be at least 2.0 mm, and end-to-side anastomosis is preferred over side-to-side; 3) for radiologists: aggressive treatment of the failing and failed fistula; 4) for dialysis unit: a surveillance program including access flow measurements. Summaries of these guidelines (translated into Dutch) were provided to the centers and vascular access teams were encouraged to adhere to these guidelines during the CIMINO program. In each center a dedicated vascular access coordinator was appointed to register practice patterns in a newly developed internet-linked database. This database contained information on medical history, medication use, preoperative duplex examination, surgery and records of complications and interventions. In-center analysis of the database allowed participating physicians to evaluate their own practice patterns during the entire project. Aggregated data were only available to the coordinating center, the University Medical Center Utrecht. Newsletters went out regularly to update participants on progress of the CIMINO initiative.

Patients

Between May 2004 and July 2005, eleven vascular access centers in the middle part of the Netherlands, representing 1092 prevalent access sites, started participation in this prospective observational study. All hemodialysis

patients or patients with chronic renal failure (CRF) requiring a new permanent vascular access during this follow up period were included.

Definitions

Coronary artery disease (CAD) was defined as a history of coronary angioplasty, coronary bypass surgery, endovascular stenting or myocardial infarction. *Peripheral vascular disease* (PVD) was defined as a history of angioplasty, surgical endarterectomy, endovascular stenting or bypass surgery of the iliac and/or femoral arteries, but also amputation due to peripheral artery occlusive disease. *Cerebrovascular disease* was defined as the same interventions in the carotids, and also included previous cerebrovascular accidents (CVA). *Diabetes mellitus* (DM) was defined as current use of hypoglycemic medication or use of insulin, or when the diagnosis was recorded in a medical status.

Primary patency was defined as the interval from time of access placement to any intervention designed to maintain or reestablish patency, access thrombosis, or the time of measurement of patency [13]. *Assisted primary patency* was defined as the interval from time of access placement to access thrombosis or time of measurement of patency, including intervening manipulations (surgical or endovascular interventions) designed to maintain the functionality of a patent access [13]. *Secondary patency* was defined as the interval from time of access placement to access abandonment, access thrombosis or time of measurement of patency, including intervening manipulations (surgical or endovascular interventions) designed to reestablish the functionality of thrombosed access [13]. The word 'functional' was added to patency to indicate that patency interval started at date of first successful cannulation for hemodialysis treatment instead of date of placement.

A *functional AVF* is an access that is able to deliver a flow rate of 350-400 mL/min without recirculation for the total duration of dialysis. A *nonfunctional AVF* is an access that is not being successfully used for hemodialysis whether it is patent or not [13].

Inadequate maturation was defined as insufficient access flow to maintain dialysis or the unavailability to cannulate an AVF, if required, at 6 weeks after surgery.

Primary failure (PF) was defined as an AVF that did not develop to maintain dialysis or thrombosed before the first successful cannulation for hemodialysis treatment, regardless of eventual AVF abandonment or not. This definition includes 1) inadequate maturation, 2) early thrombosis, 3) failure of first cannulation, and 4) other complications such as ischemia or infection. *Secondary failure (SF)* was defined as permanent failure of the AVF, after it had achieved adequacy for hemodialysis.

Statistical analysis

Means are depicted ± SEM unless otherwise described. Kaplan–Meier survival analysis and the life table method were used to calculate patency rates, and the log-rank test was used to compare patency rates.

Only the first created AVF per patient in this dataset was used to determine relations between possible risk factors and AVF outcome. Risk factors for loss of primary functional patency and for secondary failure were determined using multivariate Cox proportional-hazards models. Hazard ratios (HR) are expressed with 95% confidence intervals (CI). Statistical significance was assumed when two-sided *P*-value was < 0.05. Analyses were carried out using SPSS 12.0 (SPSS Inc., Chicago, Ill) and SigmaStat 3.11 (Systat Software Inc., San Jose, CA) for Windows®.

Results

From 1 May 2004 to 1 May 2006, a total of 649 permanent vascular accesses, representing all inclusions of CIMINO, were recorded in the database. This included 491 AVFs (76%) in 395 patients. Of these patients, 80 received 2 AVFs during this observation period, 13 patients had 3 AVFs, and 3 patients had 4 AVFs. A total of 291 AVFs were created in the forearm, 198 in the upper arm and 2 in the leg. Mean age was 64.6 ± 14.2 years and 62% were males. Baseline characteristics are shown in table 1.

Total follow up time from access placement to lost-to-follow up, secondary AVF failure or study end was 343.3 patientyears. Follow up time from first successful cannulation to lost-to-follow up, secondary AVF failure or study end was 204.8 patientyears.

Baseline characteristics of CIMINO patients	
No. of AVFs	491
No. of patients	395
Age [yrs]	64.6 ± 14.2
Male sex [%]	62
RRT prior to AVF placement [%]	55
Coronary artery disease [%]	23
Peripheral vascular disease [%]	10
Cerebrovascular disease [%]	12
Caucasian ethnicity [%]	78
Current smoker [%]	21
BMI [kg/m^2]	25.1 ± 4.5
Body height [m]	1.70 (1.45 – 2.07)
Diabetes [%]	33
Diabetes as primary cause ESRD [%]	17

Table 1. Baseline characteristics

Values are depicted as percentages, as mean ± SD or as median with range. RRT = renal replacement therapy; BMI = body mass index; ESRD = end-stage renal disease.

Patency rate from surgical AVF creation

Patency	3 mo	95% CI	*N*	6 mo	95% CI	*N*	12 mo	95% CI	*N*	18 mo	95% CI	*N*
Primary	71%	[67 - 75]	319	57%	[52 - 62]	212	49%	[44 - 54]	102	39%	[32 - 46]	25
Assisted primary	77%	[73 - 81]	349	69%	[65 - 73]	262	64%	[59 - 69]	232	59%	[53 - 65]	38
Secondary	81%	[77 - 85]	366	75%	[71 - 79]	284	70%	[65 - 75]	147	67%	[62 - 72]	42

Patency rate from 1st cannulation

Patency	3 mo	95% CI	*N*	6 mo	95% CI	*N*	12 mo	95% CI	*N*	18 mo	95% CI	*N*
Primary functional	83%	[78 - 88]	212	70%	[64 - 76]	137	61%	[54 - 68]	54	57%	[49 - 65]	12
Assisted primary functional	92%	[89 - 95]	238	85%	[80 - 90]	171	83%	[78 - 88]	74	77%	[70 - 84]	15
Secondary functional	96%	[94 - 98]	248	90%	[86 - 94]	184	88%	[84 - 92]	80	86%	[81 - 91]	15

Table 2. Primary, assisted primary and secondary patency rates at 3, 6, 12 and 18 months (mo) with 95% confidence interval (CI) and number of patients at risk at the end of the interval (*N*).

Patency

Three, 6, 12 and 18 months patency rates and functional patency rates are depicted in table 2.

Primary AVF function

In the non-primary failure group (*N* = 321), a total of 258 AVFs (80%) had been successfully used for hemodialysis (Figure 1). Of these, 36 (16%) were not used until more than 120 days after placement; 34 (89%) of which were pre-dialysis patients.

Of the 63 patients whose AVF was not cannulated (20%), 16 patients had died, 3 were transplanted and 4 were lost-to-follow up before AVF use. The remaining 40 were preparing for dialysis at study end.

Median time to first cannulation was 49 days (interquartile range (IQR): 41 - 77 days). Of the salvaged AVFs (*N* = 44), median time to cannulation was 81 days (IQR: 51 - 115 days).

Before first cannulation, 205 complications occurred in 170 fistulas resulting in a primary failure rate of 35% and 1.2 complications per failing AVF. Forty-four fistulas (26%) were salvaged and successfully cannulated. In 26 (15%) patients, the AVF was not abandoned but cannulation was not performed yet at study end. Of these, 23 were preparing for dialysis, 1 patient died, 1 was transplanted and 1 was lost-to-follow up. Eventually, 100 (59%) AVFs were abandoned before first successful cannulation; primary AVF abandonment rate was 25% (lost-to-follow ups and predialysis patients excluded).

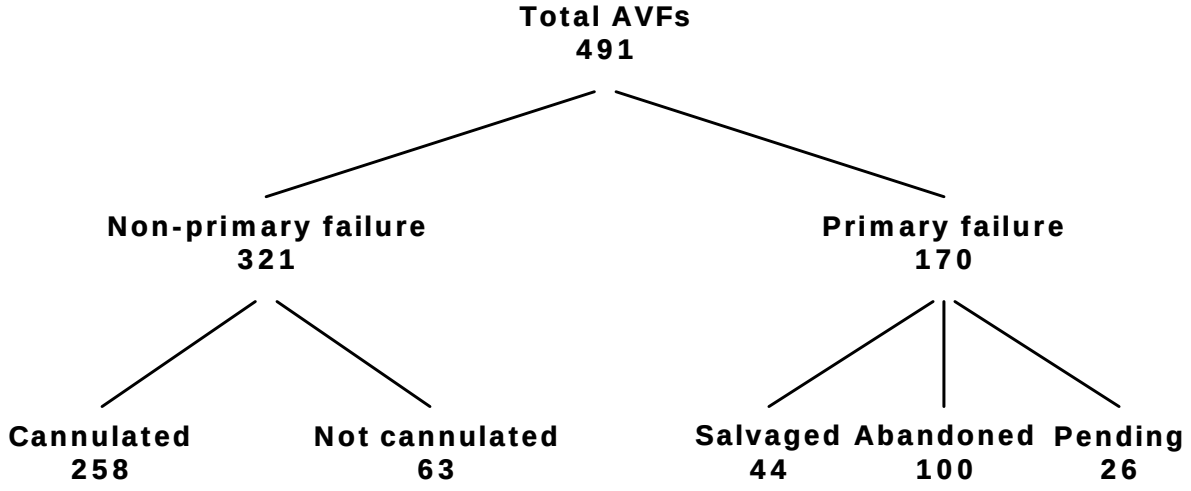

Figure 1. Diagram of primary AVF function

Complications

At the end of the follow up period, 302 AVFs had been used in 285 patients. Thrombosis occurred 29 times (0.14 per patientyear). Eight patients received antibiotics for AVF infection. Two ischemic events required surgical intervention, 1 in a forearm AVF and 1 in an upper arm AVF. A total of 49 PTA-procedures and 40 surgical revisions (including the 2 procedures for ischemia) were performed in order to salvage fistulas. Eventually, 31 AVFs were abandoned in 27 patients.

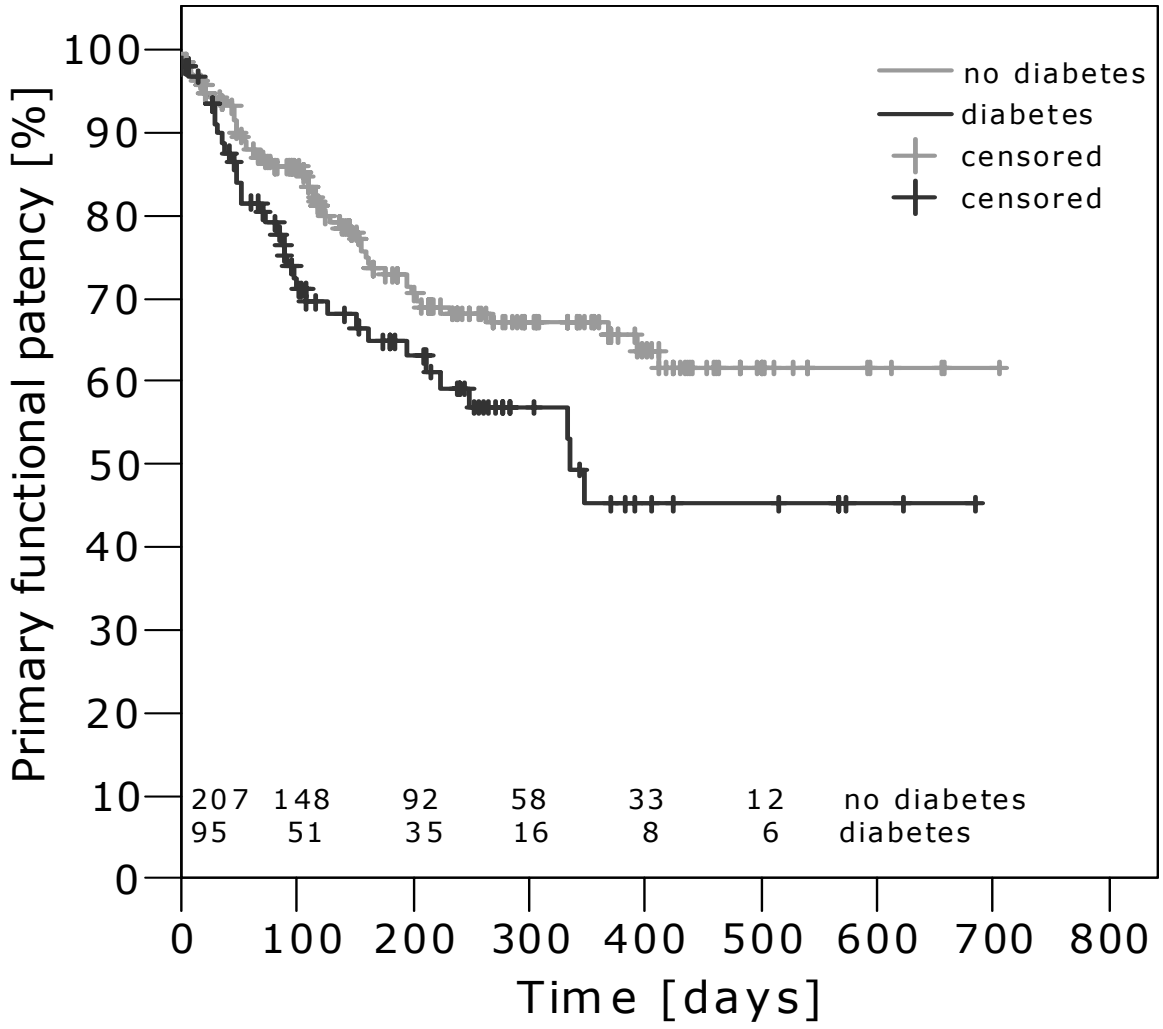

Figure 2. Primary functional patency in diabetics (black line) and non-diabetics (grey line) with numbers of patients at risk

Primary functional patency rates are significantly different (Log rank test: P = 0.03). After adjustment for age ≥ 65 yrs, gender, coronary artery disease, peripheral vascular disease, renal replacement therapy prior to access cannulation, BMI ≥ 30 kg/m^2 and AVF location in the forearm, diabetics had a higher risk of loss of primary functional patency then non-diabetics (HR: 1.70 [95% CI: 1.07 to 2.68]).

Risk factors for loss of patency

In univariate analyses male gender (HR: 0.72, *P* = 0.14), age ≥ 65 years (HR: 1.53, *P* = 0.06), presence of peripheral vascular disease (HR: 0.39, *P* = 0.07) and diabetes (HR: 1.69, *P* = 0.02) were related to loss of primary functional patency. No characteristics were associated with secondary failure.

On multivariable survival analysis with age ≥ 65 yrs, gender, coronary artery disease, peripheral vascular disease, fistula location, BMI ≥ 30 kg/m^2 and RRT prior to access cannulation, diabetes was the only factor significantly associated with loss of primary functional patency (HR: 1.70 [CI: 1.07 – 2.68]) (Figure 2). None of these factors were significantly related to secondary failure (Table 3).

Characteristic	Loss PFP (*N* = 87)		Secondary failure (*N* = 27)	
	HR	95% CI	HR	95% CI
Male gender (yes vs no)	0.69	0.44 – 1.09	1.11	0.48 – 2.57
Age ≥ 65 yrs (yes vs no)	1.52	0.97 – 2.39	1.00	0.45 – 2.21
CAD (yes vs no)	1.07	0.63 – 1.84	0.84	0.32 – 2.25
PVD (yes vs no)	0.38	0.14 – 1.10	1.54	0.42 – 5.63
Diabetes mellitus (yes vs no)	1.70	1.07 – 2.68	0.94	0.38 – 2.30
BMI ≥ 30 kg/m^2 (yes vs no)	1.03	0.53 – 1.98	1.38	0.45 – 4.26
RRT prior to cannulation (yes vs no)	1.08	0.66 – 1.77	1.74	0.64 – 4.73
Forearm AVF (vs upper arm)	1.19	0.75 – 1.89	1.37	0.59 – 3.18

Table 3. Results of a multivariate Cox proportional hazard model for loss of primary functional patency and for secondary AVF failure.

AVF = arteriovenous fistula, CAD = coronary artery disease, PVD = peripheral vascular disease, BMI = body mass index, RRT = renal replacement therapy.

PFP = primary functional patency, HR = hazard ratio, CI = confidence interval.

Hospital specific aspects

The secondary failure rate per hospital varied from 0 to 38% (Table 4), and secondary functional patency rates were different among the 11 hospitals (*P* < 0.01).

Because of the relatively small number of events that occurred, the hospitals were divided in 2 subgroups; secondary failure rate greater (*N* = 3) and less (*N* = 8) than the mean (9.5%). The risk of secondary failure was

significantly greater in the 3 high rate hospitals in comparison to the low rate group: HR: 3.03 [95% CI: 1.12 – 8.24], HR: 6.80 [95% CI: 2.36 – 19.57] and HR: 4.86 [95% CI: 1.68 – 14.10] for hospitals 1, 4 and 11, respectively.

Characteristic	**Hospital**											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**Total**
No. of patients	35	53	27	13	22	37	10	34	21	11	22	285
Male gender [%]	69	59	63	69	59	68	50	77	57	82	59	65
Age ≥ 65 yrs [%]	51	55	59	54	73	62	70	56	52	27	41	55
CAD [%]	33	23	15	31	14	22	40	29	33	27	18	25
PVD [%]	6	8	7	23	9	3	30	9	10	18	5	9
Diabetes [%]	20	43	44	46	36	27	50	21	33	9	14	31
BMI ≥ 30 kg/m^2 [%]	3	17	8	0	19	11	20	24	15	0	14	13
RRT prior to cannulation [%]	69	74	82	69	59	51	80	85	76	91	73	72
Forearm AVF [%]	66	42	33	85	46	76	50	62	62	36	64	56
SF-rate per hospital [%] [*N*=27]	17.1	5.7	7.4	38.5	4.5	2.7	0	8.8	0	9.1	22.7	9.5

Table 4. Patient characteristics and secondary failure rate per hospital

Results are presented as percentages.

CAD = coronary artery disease, PVD = peripheral vascular disease, BMI = body mass index, RRT = renal replacement therapy, AVF = arteriovenous fistula, SF-rate = secondary failure rate.

Discussion

In the present prospective multicenter study we have shown that AVF patency and functional patency are markedly different. This difference appears to be caused by high primary failure rates. After adjustment for potential risk factors, primary functional patency was only decreased in diabetics. Secondary failure rate among participating hospitals varied from 0-38% and was not related to patient characteristics or cardiovascular risk factors. Compared to the hospitals with a low secondary failure rate combined, 3 hospitals had a significantly higher risk for secondary AVF failure.

The thrombosis rate at 0.14 episodes per patientyear at risk was well below current outcome goals (0.25 per py) [1]. Regarding the multicenter character of this study, the K/DOQI goal seems to be more than reasonable.

Patency rates

A significant proportion of the AVFs suffer from primary failure during the first weeks after surgery [6, 11, 14]. However, when patency rates are calculated starting at the day of first cannulation, primary failed AVFs are not included. In order to prevent confusion and incorrect comparisons we discriminated patency from functional patency as reported by Sidawy *et al.* [13]. Functional patency started when a vascular access had been successfully used for hemodialysis treatment for the first time; patency started at the day of surgical AVF creation. Whereas primary AVF failure was extensively studied and reported earlier by our group [11], we focused on aspects of functional patency in the present study.

Primary functional patency was similar to rates in current literature [15]. Our 18-months secondary functional patency was somewhat higher at 86% (median: 690+ days). The difference may be explained by the fact that more than half of the reports used in Huber's review were published before the appearance of the first K/DOQI guidelines [15], and surveillance programs and preventative stenosis correction were not common practice yet. In contrast, 18-months secondary patency (from creation date) was 67%. The long-term difference of approximately 20% appears to be caused by a

significant primary failure rate. Thus, after adequate maturation resulting in successful initiation of HD treatment, only little fistulas are abandoned (table 2). Consequently, reduction of primary failures is likely to result in greatest patency improvements.

Diabetes was identified as risk factor associated with loss of primary functional patency (HR: 1.70), but not with secondary failure [16]. These results indicate that diabetics may encounter more complications during fistula life but if treated adequately, functionality can be maintained as long as in non-diabetics, regardless of the anatomical location of the anastomosis [17]. Similar results were observed for primary functional patency in elderly, albeit that the hazard ratios did not reach significance [18]. In contrast to a report by Kats *et al.*, we did not observe any effects of obesity on secondary failure [19]. Similarly, BMI was not related to an increased risk of primary failure either [11]. All other factors including gender, coronary artery disease, peripheral vascular disease, fistula location and renal replacement therapy prior to cannulation did not reduce AVF survival [20].

Hospital specific aspects

Secondary failure rate varied from 0-38% between the hospitals participating in CIMINO resulting in significant difference of secondary functional patency rates (log rank test: $P < 0.01$). The limited number of patients and secondary failures hindered analysis of individual hospital effects. However, the 3 hospitals in the high secondary failure-rate subgroup each had a significant higher risk of secondary failure compared to the other hospitals combined. Since none of the cardiovascular risk factors were related to secondary failure, local practice patterns may have played an important role. Similarly, practice patterns have been shown to be involved in vascular access placement [21-23] and in the risk of primary failure [11]. Although this study was not designed to identify aspects of secondary failure in detail, surgical aspects are less likely to be involved. Indeed, Prischl *et al.* suggested that the surgeon creating the fistula was involved in patency but these differences were predominantly generated during the first months after fistula creation [24]. In the present study, only successfully used AVFs were analyzed.

Practice aspects such as negligent shunt surveillance (dialysis unit), delayed action to detected stenoses (nephrologists) or inadequate PTA / surgery procedures (radiologist / vascular surgeon) may have contributed to the current findings. Further in-center analysis can be useful to improve secondary functional patency rates but obviously the multidisciplinary character of complication handling requires a well functioning vascular access team [25].

Patient selection and future improvements

The greatest improvements in fistula patency are to be achieved during the peri-operative period [6, 11]. Diabetics in particular, bus also elderly and women can be expected to encounter early complications and require extra attention. In these risk groups, upper arm AVFs may be more appropriate resulting in less complications [17]. Next to careful physical examination and pre-operative duplex scanning, additional 'vascular wall-quality' tests such as the arterial resistance index at reactive hyperemia [26] may be useful in determining the best location for creation of the anastomosis. Optimal anastomosing techniques [27], alternative locations for anastomosing [28, 29], and aggressive treatment of primary failing fistulas [30, 31] should also further increase the proportion of functional AVFs.

The clear relation between the hospital of access placement and AVF survival in 3 participating hospitals further support the idea that the most important prerequisite for optimal vascular access care is a motivated vascular access team that is willing to meet current standards and adjusts practice patterns to AVF outcomes [25].

Limitations

Fistulae are preferred over grafts because of superior long-term patency. Follow up time in our study was limited to 18 months. In ePTFE grafts, six, 12 and 18 month secondary functional patencies are approximately 76%, 65% and 55% [15]. When primary graft failures (approximately 10%) are also included, secondary graft patency from date of creation is likely to decrease slightly, expecting fistula survival to be superior from 12 month on (Table 2).

However, extra follow up time is required to obtain further insight in long-term AVF patency.

Conclusion

A total of 76% of the vascular accesses in our prospective database were native AVFs. Using recently suggested standardized definitions we showed a marked difference between patency and functional patency that can be explained by high primary failure rates. Furthermore, after adjustment for potential risk factors, secondary AVF failure was more likely in 3 of the 11 participating hospitals suggesting an important role for local practice patterns.

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