### MANAGEMENT OF VASCULAR ACCESS IN EUROPE: PART 2 - A MULTI CENTRE STUDY OF RELATED COMPLICATIONS

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#### SUMMARY

Introduction | The pilot project of the Research Board of EDTNA/ERCA handled the management of vascular accesses (VA) in European dialysis centres. In the first part of the study, centre policies related to VA management were investigated. This paper reports on the second part of the project, investigating VA related complications reported during an observational prospective study.

Methods | A cohort of 1380 adult patients, randomly selected in 47 centres out of 16 European countries were followed during one year using a computerised data collection system. Data were collected at baseline, after six and 12 months and each time a VA complication occurred.

**Results** At the start of the observation period, 77% had a native AV fistula, 10% had an AV graft and 13% a catheter. A total of 489 complications were noted. Most frequently observed were thrombosis, stenosis, infection, bleeding and flow problems. Hospitalisation (mean duration=6.2 days) was required in 39% of complications and 29% of complications resulted in a definitive loss of VA. Complications were more frequently observed in catheters (27%) and AV grafts (37%) compared to AV fistulae (15%). When compared with AV fistulae, the risk for thrombosis was more than four times higher and for bleeding more than six times higher if an AV graft was used. Catheters showed an eightfold increased risk to develop infections and flow problems.

**Conclusion** | This study revealed the high complication rate in VA and strengthened the actions to promote AV fistulae as first choice VA.

#### **KEY WORDS**

- Haemodialysis
- Vascular access
- AV fistula, graft
- Catheter
- Complication

**Complications of vascular access (VA)** remain a significant clinical problem in the chronic treatment of patients with end-stage renal disease. Recent literature suggests that access related complications account for at least 25% of all hospital stays (1). In addition to the financial burden, VA complications also reduce dialysis adequacy and lead to a significant reduction in the quality of life of dialysis patients (2).

In 1996, the Research Board of the European Dialysis and Transplant Nurses Association / European Renal Care Association (EDTNA/ERCA) selected the management of VA as their pilot research project. The first part of the project studied centrefocused policies for the management of VA in 103 European dialysis centres (3). Results showed that large differences were observed in VA care and hygienic procedures used. It was concluded that it would be extremely interesting to relate the large differences observed in the centre policies of VA management to individual patients outcome parameters. This paper reports on the second part of the research project and will present results of an observational prospective study in individual patients, investigating vascular access related complications. In this first article, observed complications will be described and their relation to the type of vascular access will be highlighted.

#### **MATERIAL AND METHODS**

In all participating European dialysis centres, a cohort of 30 chronic haemodialysis patients per centre was followed for one year. Data concerning the type of VA in use and related parameters were selected at the start of the study period and after six and 12 months. All VA related complications requiring intervention were registered at the time of occurrence using an electronic data collection system.

#### | SELECTION PROCEDURE |

All centres included in the first part of the study were invited to participate. Participating centres were asked to send a list of all

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Haemodialysis patients included	n=1380
Age median (range)	64 years (15-90)
Sex (% males)	56%
Duration of treatment for ESRD median (range)	37 months (6-370)
Age of vascular access in use median (range)	30 months (0-300)
Previous permanent VA used	
No previous	59.2%
One	22.9%
More than one	17.9%
One More than one	22.9% 17.9%

Table 1: Description of study population.

patients matching the inclusion criteria (see below) to the coordinating centre in Antwerp, Belgium. The list included patients' initials, birth date and sex. In the coordinating centre, a cohort of 30 patients was randomly selected from this list. If the total number of patients in a centre was below 30, all eligible patients were included.

#### | SELECTION CRITERIA |

All adult patients who started a chronic haemodialysis programme at least six months prior the start of the study were included for at random selection. Children of less than 15 years and patients on haemodialysis for less than six months were excluded.

#### | DATA COLLECTION |

Centres started the study in the period 1998-1999. For data



collection, a computer-based questionnaire developed by Figure 1: Types of vascular access at baseline. The category 'other' included 12 patients treated with a combination of an AV fistula and a catheter. MedIQal® was used. After random selection of patients, the project installation software was sent to the participating centre. For all selected patients a standard data set was filled in at baseline, after six months and after 12 months. The standard data set included information concerning the type of VA, puncture techniques used, function of the VA and medication used. Throughout the one-year study period, VA related complications requiring intervention were registered as well as details concerning related interventions and hospitalisation.

#### | STATISTICAL ANALYSIS |

Basic statistical techniques were used to describe the types of VA used, complications observed and hygienic handling applied. Students' t-test was used for comparison of continuous variables and chi-square test for comparison of percentages, considering a p-value of p < 0.05 as the significance level. For complications, in-depth analysis was only performed on complications occurring frequently: thrombosis, stenosis, infection, bleeding and flow problems. Per patient, each reported complication was only counted once, also when it occurred more than one time during the study period. Differences in complication rates were related to patient characteristics, type of VA and puncture techniques used. Complication rates were also related to centre characteristics and hygiene policies, questioned during the first, centre based part of the study. Risk ratios for complications were calculated using logistic regression analysis enabling control for confounding factors.

#### RESULTS

The questionnaire was distributed to 108 centres and 81 of them sent their patients' list to the coordinating centre enabling a random selection of 30 patients. Finally, 47 centres out of 16 European countries completed the study. Participating centres were mainly from United Kingdom (n=11), Belgium (n=9) and Germany (n=6). In the remaining countries (Austria, Cyprus, Denmark, Finland, France, Greece, Italy, Malta, the Netherlands, Norway, Slovenia, Spain and Switzerland) less than four centres participated.

#### | PATIENT CHARACTERISTICS |

A total of 1380 patients were included. Median age was 64 with 56% male. Patients were on chronic haemodialysis therapy for a median of 37 months (Table 1). During the one year study period 15.5% of patients died, 6.4% were transplanted, 0.7% switched to PD and 4.5% were lost to follow-up.

#### | DESCRIPTION OF VA IN USE AT BASELINE |

At start of the observation period, 77% of patients had a native AV fistula, 10% had an AV graft and 13% a catheter. AV grafts

were predominantly synthetic grafts (89%). Twelve patients were treated with a combination of an AV fistula and a catheter (Figure 1).

At baseline, 59% of patients were dialysed with their first VA and 23% with their second (Table 1). The remaining patients had between three and ten permanent vascular accesses. Considering only patients dialysed with their first VA (n=792), 88% had an AV fistula and only 4% an AV graft.

Median age of patients with a first permanent VA was respectively 56, 57 and 66 for those with an AV fistula, an AV graft and a catheter. Patients had their baseline VA for a median of 30 months. AV fistulae had a median maturation time of 43 days and one out of ten AV fistulae required a surgical intervention before first use.

#### | VA COMPLICATIONS |

During the one-year observation period, 19% of patients had a VA complication requiring intervention, varying from one to 18 patients per centre (3 to 60%). A total of 489 complications were noted, ranging from one to 20 complications per patient (mean 1.8).

Complications most frequently observed were thrombosis (25%), stenosis (15%), infection (14%), bleeding (13%) and flow problems (12%) (Figure 2). The category of 'other' complications included pain, haematoma and high cardiac output. Balloon dilatation was used in one third of stenosis/thrombosis. A thrombolyser (usually a chemical one) was used in one fourth. Bleeding, most frequently occurring post-dialysis was mainly treated with medication all or not combined with compression. Surgical intervention was required in 39% of complications.

Hospitalisation was required in 39% of complications for a period from one to 64 days (mean 6.2). Particularly for thrombosis, stenosis and aneurisma, more than half of the patients were hospitalised. The longest hospitalisation period however, was noted for infections (mean 12 days).

Additionally, 26% of complications required the use of a temporary catheter, 3% resulted in a change of therapy and 29% resulted in a definitive loss of VA. Definitive loss was most frequently observed as a result of thrombosis (46%), steal syndrome (42%) and infection (36%).

#### | COMPLICATIONS AND TYPE OF ACCESS |

During the observation period of one year, complication rate

was 15% in AV fistulae, increasing to 27% in catheters and to 37% in grafts. Taking into account only patients with first VA (n=792), complication rates showed even more pronounced differences between the different types of VA with 12% in AV fistulae, 23% in catheters and 47% in AV grafts. In AV fistulae and AV grafts, thrombosis and stenosis were most frequently observed. In catheters, about half of complications reported were infections (Figure 3).

In table 2, risk ratios for developing VA complications comparing different types of VA were presented. Since it was found that complication rates were highly influenced by the size of the treating dialysis centre and a first or a subsequent VA, presented risk ratios were corrected for these factors. As shown in the last column of the table, the risk of developing a complication almost doubled for patients with catheters and tripled for patients with grafts compared to patients with AV fistulae. Additionally, comparing AV grafts with AV fistulae, the risk for thrombosis was more than four times and the risk for bleeding more than six times higher if an AV graft was used. When catheters were compared with AV fistulae, the risk of developing infections and flow problems both showed an eightfold increase in catheters.

#### DISCUSSION

During this one-year observation period, 489 VA related complications requiring intervention were observed in a cohort of 1380



Figure 2: Vascular access related complications reported during the observation period of one year. The category 'other' included pain, haematoma and high cardiac output. patients. Particularly thrombosis, stenosis, infection, bleeding and flow problems were frequently noted. VA complications required hospitalisation in 39% and resulted in a definitive loss of VA in 29% of patients.

The observed hospitalisation rate due to vascular access related complications seems to be rather high. A total of 186 hospitalisations with a mean duration of 6.2 days was registered resulting in a hospitalisation rate of 0.84 days per patient year. This means that each patient of this European cohort had a chance of spending one day in hospital per year for a vascular access related complication. Since we did not ask for the total number of hospitalisation days, we cannot compare our European observation with the observation of PJ. Held et al (1) that in the US more than one fourth of all hospitalisations were due to vascular access related complications.

In this random sample of 30 patients per unit, it was demonstrated once more that the European dialysis patient is dialysed predominantly with a native AV fistula with 88% of first permanent VA being an AV fistula. This is in sharp contrast with US practice where only approximately 20% of patients have a native AV fistula (4,5,6). On the other hand, AV grafts were used in only 10% of European patients. Taking into account only first permanent VA, this percentage decreased to 4%. These frequencies are far below the US practice where about half of patients were dialysed with an AV graft (4,6).

It is clear that clinical practice in first choice VA widely differs between Europe and the US. While native AV fistulae are preferentially used in European countries, AV grafts are most commonly used in the US (6). The DOQI clinical practice guidelines for vascular access (7) are appreciated worldwide as reasonable,



Figure 3: Frequency of complications in AV fistula, AV graft and catheter and distribution of main complications per type of vascular access.

	Fistula	Graft	Catheter	p-value <sup>(2</sup>	<b>RR</b> (95% CI) <sup>(3)</sup>
	n=1049	n=131	n=178		
Total complications					graft vs. fistula:
	15.5%	37.4%	—	0.000	2.77 (1.75–4.40)
					catheter vs. fistula:
	15.5%	-	27.5%	0.000	1.86 (1.23–2.81)
Thrombosis					graft vs. fistula:
	5.2%	18.3%	-	0.000	4.10 (2.22–7.56)
Bleeding					graft vs. fistula:
	2.1%	8.4%	-	0.000	6.68 (2.28–19.5)
Infection					catheter vs. fistula:
	2.1%	-	12.9%	0.000	8.19 (3.85–17.4)
Flow problems					catheter vs. fistula:
	1.0%	-	5.1%	0.001	8.56 (2.87–25.5)

(1) Only complications showing significant differences are presented.

 P-values are based on univariate analysis and resulted from chi-square test or Fisher exact test.
Relative risk (RR) and 95% confidence intervals (95% CI) are controlled for patient/nurse ratio and the number of previous vascular accesses.

Table 2: Complications related to type of vascular access <sup>(1)</sup>.

maintenance of vascular access survival. Since these guidelines are developed in the US however, it can be asked if additional European guidelines are appropriate in view of wide differences in practice.

In their 2000 update, the DOQI guidelines (7), stressed once more their preference for a native AV fistula as first choice VA. They suggest the AV graft as second choice and advise avoidance of dialysis with a permanent catheter. In support of this viewpoint, we could demonstrate that the risk of complications tripled for grafts and doubled for catheters compared to native AV fistulae. Of course, these results were obtained in the European situation where AV fistulae are preferred and grafts are mostly used as second choice. It is clearly shown that preferences and experience with a particular VA type have an important influence on outcome (5,8). Compared to the US experience, we have the impression that in this European study AV grafts scored lower compared to US results and that catheters showed better results as expected.

#### CONCLUSION

This study demonstrated once more that complication rates of VA are unacceptably high. Results corroborated the opinion that AV fistulae need to be promoted as first choice VA for chronic haemodialysis. In view of prevention, it can be concluded that a common action of nephrologist, surgeon, radiologist and nurse is needed to avoid VA complications. Primary prevention will include the correct choice of type and localisation of VA and the use of dialysis techniques with a low risk for complications. Within this framework, nurses have a key role and can be considered as the gatekeepers of well-functioning VA. In daily clinical practice they need to handle VA correctly and to be aware of all the signs of possible complications.

#### ACKNOWLEDGEMENT

The project questionnaire was developed with the help of all members of the Research Board. Technical and administrative help was provided by Colin Aldridge, Jan Aldridge and Jago Taylor (MedIQal, Stevenage, United Kingdom) and by Dirk De Weerdt and Eddy Van Hout (Department of Nephrology, University of Antwerp, Belgium). We would like to thank all the participants of this study. Without their sustained effort of data collection during a whole year, this study could never have been realised.

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# **STATISTICS CORNER**

## Invitation

- Are you involved in scientific research in your renal unit?
- Do you have questions about the best method to choose for your research project?
- Are you confronted with some specific questions about the statistical analysis of the data that you collected?
- Did you read a scientific article and do you have questions about the statistical methods presented?

We kindly invite you to send your methodological and statistical questions to the journal editor, via email preferably 106111.2270@compuserve.com. In the following issues of this journal, we will try to handle your question(s). Your input will contribute to make this statistical corner a useful forum for all kind of research problems. And yes you can send your questions in the same language you receive the Journal.

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