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#### SUMMARY

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. In the second part of the study, individual patients were followed prospectively during one year. This paper reports on several topics of the second part of the project, investigating complications of the VA related to centre, patient characteristics and dialysis techniques. used.

Complications most frequently observed were thrombosis, stenosis, infection, bleeding and flow problems. Gradually more infections and flow problems were observed if the centre size and the patients/nurse ratio went up. Complication rate was not significantly influenced by age, gender, renal diagnosis, time on dialysis or medication used by the patient. In contrast, the number of vascular accesses in the past and interventions in the VA before first use resulted in an increased number of complications.

Nurses have a key role in the prevention, manipulation and outcome of vascular access related complications.

#### **KEY WORDS**

- Haemodialysis
- Vascular access
- AV fistula
- Graft, catheter
- Complication

## BIODATAS



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#### **INTRODUCTION**

Complications of vascular access (VA) remain a significant clinical problem in the chronic treatment of patients with end-stage renal disease. The Research Board of the European Dialysis and Transplant Nurses Association/European Renal Care Association (EDTNA/ERCA) selected the management and outcome of VA as their pilot research project.

The first part of the project studied centre-focused policies for the management of VA in 103 European dialysis centres (1). 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 patient's outcome parameters.

The second part of the project studied VA related complications in individual patients during a one-year observational prospective study. In a previous article in this journal, the population studied, types of VA used and complication rates observed in different types of VA, were described (2). At the start of the observation period, 77% of the patients had a native AV fistula, 10% had an AV graft and 13% a catheter. A total of 489 complications were noted documented. Most frequently observed were thrombosis, stenosis, infection, bleeding and flow problems. Hospitalisation

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

This second article of the European multi-centre study of the Research Board will focus on the observed complications in relation to the patient and centre characteristics and the dialysis techniques used.

## **MATERIAL AND METHODS**

In all participating European dialysis centres, 30 chronic haemodialysis patients were randomly selected and were followed for one year. All adult patients who started a chronic haemodialysis programme at least six months before the start of the study were included for random selection. Data concerning the type of VA in use and related parameters were selected at the start of the study period and after six and twelve months. All VA related complications requiring intervention were registered at the time of occurrence using an electronic data collection system. Methodological details of the study were described in the first article (2).

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. Risk ratios for complications were calculated using logistic regression analysis enabling control for confounding factors.

#### RESULTS

The questionnaire was distributed to 108 centres, 47 centres in 16 European countries completed the study. Participating centres were mainly from United Kingdom (n=11), Belgium (n=9) and Germany (n=6). A total of 1380 patients were included. Demographic and medical characteristics of the study population are summarised in table 1.

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)
Primary renal diagnosis:	
Glomerulonephritis	19.1%
Diabetic nephropathy	12.9%
Renal vascular disease	11.7%
Polycystic kidney disease	10.0%
Pyelo-interstitial nephritis	9.2%
Other systemic disease	8.7%
Other	20.4%
Unknown, undefined	8.0%
Medication used at baseline:	
Erythropoietin	84.5%
Anti-hypertensives	53.3%
Anti-coagulation	29.4%
Antibiotics	3.9%
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%

Table 1: Demographic and medical characteristics of study population.

## | CENTRE CHARACTERISTICS AND COMPLICATION RATE |

Complications were more frequently observed in hospital centres compared to satellite units. Additionally, centre size as well as patients/nurse per ratio influenced the complication rate. Gradually more infections and flow problems were observed if the centre size went up to more than 200 patients. The same trend was observed considering the patient/nurse ratio, with a significant increase in infection and flow problems if this ratio went up to more than seven patients per nurse (Figure 1).



Figure 1: Complications of vascular access related to characteristics of the centre: centre size and patient/nurse ratio.



Figure 2: Complications of vascular access related to number and type of previous vascular accesses.

## | PATIENT CHARACTERISTICS AND COMPLICATIONS |

Complication rate was not significantly influenced by age, gender, renal diagnosis or time on dialysis. No increased complication rate was observed in patients with more pronounced vascular pathology i.e. patients with renal vascular disease or diabetes. Neither the use of anti-hypertensives or oral anti-coagulation therapy was associated with a higher complication rate.

In patients with a higher number of vascular accesses in their medical history, a higher number of complications could be observed (Figure 2). Particularly, thrombosis and infections were more frequently noted in these patients. Moreover, patients with an AV fistula that required an intervention before first use showed a significantly increased complication rate of 25% compared to 15% in those without intervention.

## | COMPLICATIONS RELATED TO DIALYSIS TECHNIQUES USED IN AV FISTULAE AND AV GRAFTS |

AV fistulae and grafts, localised in the forearm, showed a lower complication rate compared to VA localised in the upper arm and particularly to those placed in the elbow. If only the first VA was considered, differences between forearm and upper arm disappeared. For the elbow localisation, thrombosis, infection, stenosis and flow problems were significantly increased. Controlled for patient/nurse ratio and previous number of VA, risk ratios for the elbow VA remained significantly increased for stenosis (OR=2.3) and flow problems (OR=5.2) compared to VA placed in the forearm (Table 2A).

Additionally, frequency of thrombosis and stenosis increased significantly with increasing venous pressure. Comparing patients dialysed with venous pressure below 100mmHg with those of more than 180 mmHg, increased risk for thrombosis (OR=2.9) and stenosis (OR=4.4) was found in the latter group (Table 2B).

Using the rope ladder technique for puncturing the VA gave significantly less complications compared to other puncture techniques with 32% reduction of total complication rate and particularly 53% reduction of thrombosis (Table 2C).

## | COMPLICATIONS RELATED TO CATHETER CHARACTERISTICS |

Comparing catheters localised in the jugular vein and the sub-

A. Localisation of VA:	Forearm	Elbow	Upper arm	p-value (2)	<b>RR (95% CI)</b> <sup>(3)</sup>
	n=837	n=95	n=224		elbow vs. forearm:
Total complications	15.6%	29.5%	21.0%	0.001	1.75 (1.04–2.96)
Infection	1.8%	6.3%	0.9%	0.005	2.49 (0.80–7.73)
Stenosis	4.1%	9.5%	5.4%	0.056	2.32 (1.01–5.35)
Flow problems	0.7%	4.2%	0.4%	0.003	5.23 (1.23–22.2)
B. Venous pressure:	<100 mmHg	100-180 mmHg	>180 mmHg	p-value (2)	<b>RR (95% CI)</b> <sup>(3)</sup>
	n=230	n=723	n=227		>180 vs. <100 mmHg:
Total complications	16.1%	15.8%	27.3%	0.000	1.72 (1.03–2.87)
Thrombosis	3.9%	5.9%	12.3%	0.001	2.92 (1.30–6.52)
Stenosis	2.2%	4.3%	9.3%	0.001	4.37 (1.44–13.2)
C. Puncture technique:	Rope ladder		Other	p-value (2)	<b>RR</b> (95% CI) <sup>(3)</sup>
	n=334		n=868	P	rope ladder vs. other:
Total complications	14.1%		19.1%	0.040	0.68 (0.46–0.99)
Thrombosis	4.2%		7.6%	0.034	0.47 (0.25–0.89)

Table 2: Complications related to dialysis techniques used in AV fistulae and grafts<sup>(1)</sup>.

(1) Only complications showing significant differences are presented.

(2) P-values are based on univariate analysis and resulted from chi-square test or Fisher exact test.

(3) Relative risk (RR) and 95% confidence intervals (95% CI) are controlled for patient/nurse ratio and the number of previous vascular accesses.

clavian vein, no differences could be observed with a complication rate of 24% and 25% respectively. In contrast, the type of catheter was associated with the development of complications. In double lumen catheters, a complication rate of 38% was observed compared to 16% in single lumen catheters. Particularly infection rates doubled in double lumen catheters but also thrombosis, stenosis and flow problems were observed more frequently (Table 3A).

Additionally, results showed a higher complication rate in 12 french catheters compared to 10 french, also with an increased risk for infections. It has to be noted however, that two thirds of double lumen catheters had a diameter of 12 french explaining that comparable high complication rates were observed for both characteristics (Table 3B).

Further on, wearing nose/mouth protection when handling catheters, played an important role with only 4% of infections observed if nurses were wearing a mask compared to 27% if masks were not used (Table 3C).

#### DISCUSSION

During this one-year observation period, 489 VA related complications requiring intervention were observed in a cohort of 1380 patients. Particularly thrombosis, stenosis, infection, bleeding and flow problems were frequently noted.

Frequency of complications as well as the number of patients suffering a complication varied considerably among centres. Although the observed differences in complication rate per centre is suggestive of an underscoring in some centres, we could not observe centre differences in the quality of the other data collected at baseline, month six and month twelve. Differences can be partly explained by the expected differences in complication rate between hospital and satellite units with the latter showing a lower complication rate. Moreover, we have to take into account that patients are more or less selected for treatment in satellite units. One of the criteria is a good functional vascular access. In addition, the centre size and the patient/nurse ratio varied considerably among participants, resulting in higher complication rates in large centres and in centres with a high number of patients per nurse.

Age and vascular disease was not associated with complications in this study. It is a common experience in the elderly and in vascularly compromised patients that the creation of a VA is rather complicated (3,4). Since only patients on dialysis for more than six months were included, early failure of first VA, frequently occurring in the elderly, was not taken into account in this study.

We found no evidence to support the DOQI viewpoint (5) that VA is preferably placed in the forearm and in the elbow. Although we found the lowest complication rate for VA localised in the forearm, increased risk of complications, particularly infection, stenosis and flow problems were observed in elbow localisations. In contrast, we did not observe a higher risk of complications in VA localised in the upper arm if only first VA was considered.

It is difficult to formulate clear conclusions concerning the occurrence of VA complications in relation to the puncture technique used in AV fistulae. In this study, the complication rate varied between less than 15% using the rope ladder technique (= planned insertion of the needles at fixed intervals along the entire puncturable length of the VA) to more than 20% using the button hole technique (= use of a single site with two to three places for puncturing) or selecting a puncture site at each puncture time. Although a decreased risk of complications was demonstrated using the rope ladder technique, it can be argued that this tech-

A. Lumen: Total complications Infection	<b>Single lumen</b> n=80 16.3% 7.5%	Double lumen n=94 38.3% 18.1%	p-value (2) 0.001 0.045	RR (95% Cl) (3) double vs. single lumen: 3.34 (1.54–7.24) 2.10 (0.68–6.39)
B. Size:	<b>10 french</b> n=54	<b>12 french</b> n=67	p-value (2)	RR (95% Cl) (3) 12 french vs. 10 french:
Infection	1.9%	16.4%	0.030	5.83 (0.58–58.8)
C. Nurse wearing nose/mouth protection:	<b>Yes</b> n=84	<b>No</b> n=41	p-value (2)	<b>RR</b> (95% Cl) (3) no protection vs. yes:
Infection	3.6%	26.8%	0.000	3.21 (0.64–16.1)

Table 3: Complications related to dialysis techniques used in catheters (1).

(1) Only complications showing significant differences are presented.

(2) P-values are based on univariate analysis and resulted from chi-square test or Fisher exact test.

(3) Relative risk (RR) and 95% confidence intervals (95% CI) are controlled for patient/nurse ratio and the number of previous vascular accesses.

nique can only be used in well-developed and functioning VA. In patients dialysed with catheters, the use of a single lumen catheter showed a markedly lower complication rate of 16% compared to 38% in double lumen catheters. In Europe, single lumen catheters were used in about half of the patients whereas this type of catheter was not promoted and seldom used in the US (5, 6). One of the reasons may be that in some European countries, e.g. Belgium, the use of an arterio-venous blood pump is quite popular. As shown in table 3, complication rates related to dialysis techniques used in catheters revealed less conclusive results. Although p-values for differences between complication rates were significant, risk ratios lost significance mainly due to the small sample sizes and the high influence of confounding factors such as patient/nurse ratio and previous VA.

Hygienic precautions showed no positive results for preventing VA related infections, except for nurses wearing nose/mouth protection when handling catheters. This was the normal practice in 40 to 50% of centres when handling respectively fistulae/grafts and catheters (1). From the first part of this study, we learned that in all centres gloves were used when handling VA, that these gloves were always changed between patients and that they were sterile when puncturing VA in half of the centres. Unfortunately, we did not collect any information on handwashing practices of the nurses before handling VA or the patients' practice of wearing masks if they were dialysed with a catheter. Positive results of these hygienic measures were shown in other publications (7).

#### CONCLUSIONS

This study demonstrated once more that complication rates of VA are unacceptably high. In view of prevention, it can be concluded that common actions of the multidisciplinary team includ-

ing nephrologists, surgeons, radiologists and nurses are needed to avoid VA complications. Primary prevention will consist of making the exact choice of type and localisation of VA well in advance and using dialysis techniques with a low risk for complications. Moreover, nurses have a key role in the prevention of VA infections, respecting strict hygienic precautions when handling fistulae/grafts and catheters.

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# REFERENCES

- 1. Van Waeleghem JP, Elseviers MM, Lindley EJ. Management of vascular access in Europe. Part I: A study of centre based policies. EDTNA/ERCA Journal 2000; 4: 8-34
- Elseviers MM, Van Waeleghem JP. Management of vascular access in Europe. Part 2: A multi centre study of related complications. EDTNA/ERCA Journal 2003 1: 45-50
- Windus DW, Jendrisak MD, Delmez JA. Prosthetic fistula survival and complications in haemodialysis patients: effects of diabetes and age.
  American Journal of Kidney Diseases 1992; XIX (5): 448-452
- 4. Lin S-L, Huang C-H, Chen H-S, Hsu W-A, Yen C-J, Yen TS. Effects of age and diabetes on blood flow rate and primary outcome of newly created haemodialysis arteriovenous fistulas. **American Journal of Nephrology** 1998; 18: 96-100
- National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Vascular Access, 2000. American Journal of Kidney Diseases 2000; 37 (1, suppl 1): \$137-\$181
- 6. Marr KA, Sexton DJ, Conlon PJ, Corey GR, Schwab SJ, Kirkland KB. Catheter-related bacteremia and outcome of attempted catheter salvage in patients undergoing haemodialysis. **Annals of International Medicine** 1997; 127: 275-280
- 7. Kirkland KB, Sexton DJ: Dialysis-access infection, in Conlon PJ, Nicholson ML, Schwab S (eds.): Haemodialysis vascular access: practice and problems, chap 6. **Oxford, England, Oxford University Press,** 2000, pp 85-100.