

The importance of guidelines and quality of care on outcome in patients with chronic kidney disease

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Preface

Despite significant improvements in treating patients with chronic kidney disease (CKD) in recent years, the morbidity and mortality rate in these patients is still considerably higher than in the general population. The Kidney Disease Outcomes Quality Initiative (KDOQI) practice guidelines and European Best Practice Guidelines (EBPG) were

published in an effort to improve clinical outcomes. The subject of this “*Dialysis Update*” deals with publications describing the implementation of these guidelines in different study centres and countries and evaluating the clinical outcome.

The study of Richards et al. shows that differences in care of haemodialysis (HD) patients between countries still exist. A continuous quality improvement programme allowed to diminish these differences and to improve the quality of the delivered treatment. The importance of the implementation of the guidelines in patients on HD was demonstrated in the studies of van Loon et al. and Tentori et al. as well. The former were able to reveal an increasing number of arterio-venous fistulas in new and prevalent HD patients when implementing the vascular access guidelines; the latter found a significant reduction in mortality when several targets of KDOQI guidelines were met simultaneously. However, targeting the blood pressure guidelines, an increase of mortality was shown. Craver et al. describe the course of mineral metabolism parameters throughout chronic kidney disease in stages 1 – 5 under consideration of the KDOQI target ranges. They were able to demonstrate an early start of mineral metabolism disturbances in the course of CKD. *KB*

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1. Assessment of quality guidelines implementation using a continuous quality improvement programme

The quality of the dialysis care delivered to the patient with chronic kidney disease is more and more focused. In June 2002 Fresenius Medical Care (FME), the leading provider of products and services for individuals undergoing dialysis because of chronic kidney failure, officially adopted the European Best Practice Guidelines (EBPG) within its clinic network located across Europe. The main aim of this study by **Richards et al.** was to describe the level of implementation of the EBPG in the European FME clinic network.

For this study, patient data from four countries - i.e. France, Italy, Spain, Great Britain (GB) - were chosen and were assessed through the FME EuCLiD® database. This electronic, multilingual, fully codified, anonymised clinical database is used as part of the

Quality Management System of FME and its Continuous Quality Improvement (CQI) Programme. The parameters selected for this study were haemodialysis (HD) adequacy, high-flux dialysis, anaemia control and serum phosphate control which are surrogate indicators for quality of care and whose targets were taken directly from the EBPG [EBPG for haemodialysis, part 1, *Nephrol Dial Transplant* 2002, 17, Suppl 7; EBPG for the management of anaemia in patients with chronic renal failure, *Nephrol Dial Transplant* 1999, 14, Suppl 5 and revised EBPG for the management of anaemia in patients with chronic renal failure, *Nephrol Dial Transplant* 2004, 19, Suppl 2]. The indicators were compared, by country, between the first quarter (Q1) 2002 and the fourth quarter (Q4) 2005.

During Q1 2002 and during Q4 2005, 7,067 and 9,232 HD patients were treated in the selected countries, respectively. The mean age of the dialysis population in Q1 2002 ranged from 61 years in GB and

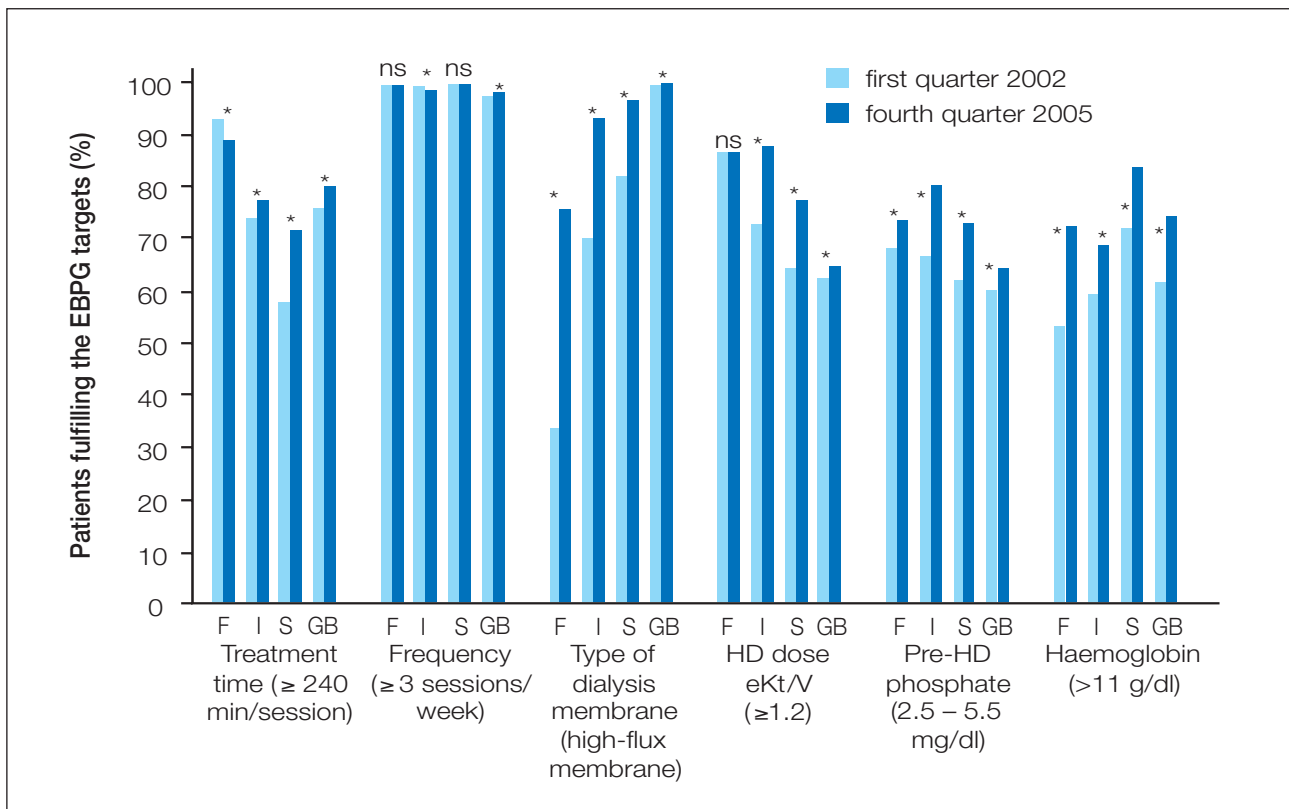


Fig. 1: Patients fulfilling the EBPG targets; F = France; I = Italy; S = Spain; GB = Great Britain; * $p < 0.05$ between time periods

France to 64 years in Spain. After four years of observation there was a trend for increasing age in all countries except France. In Q1 2002 the proportion of diabetics ranged from 14% to 20%. The only country where a trend towards a higher proportion of diabetics could be observed was France.

For most of the indicators there was an increase of the percentage of patients fulfilling the EBPG targets in all countries. A large proportion of patients in each country achieved the targets recommended by the EBPG in Q4 2005. Although the differences between the countries in reaching the targets were clearly larger in Q1 2002, in Q4 2005 differences still were present. All these findings are shown in **Figure 1**.

Similar results have already been reported by the Dialysis Outcomes and Practice Patterns Study (DOPPS), the largest international observational study of dialysis practice patterns.

France was the only country showing a significant decrease (-3.5 days/patient year, $p < 0.01$) in the hospitalization rate. Minor significant increases of hospitalization were detected in all the other countries. Mortality decreased in France (ns) and in GB (ns), and increased in Italy (ns) and Spain ($p < 0.01$). The authors ascribe the overall maintained stable outcome, despite increasing age and number of comorbidities in dialysis patients, to the improved evaluated quality of care indicators.

In conclusion, differences in care of HD patients between countries still exist. The FME CQI programme allows some of these differences to be overcome leading to an improvement in the quality of the treatment delivered. CL

Richards N, Ayala JA, Cesare S, Chazot C, di Benedetto A, Gassia JP, Merello JI, Rentero R, Scatizzi L, Marcelli D. Assessment of quality guidelines implementation using a continuous quality improvement programme; Blood Purif 25, 221-8, 2007

2. Implementation of a vascular access quality programme improves vascular access care

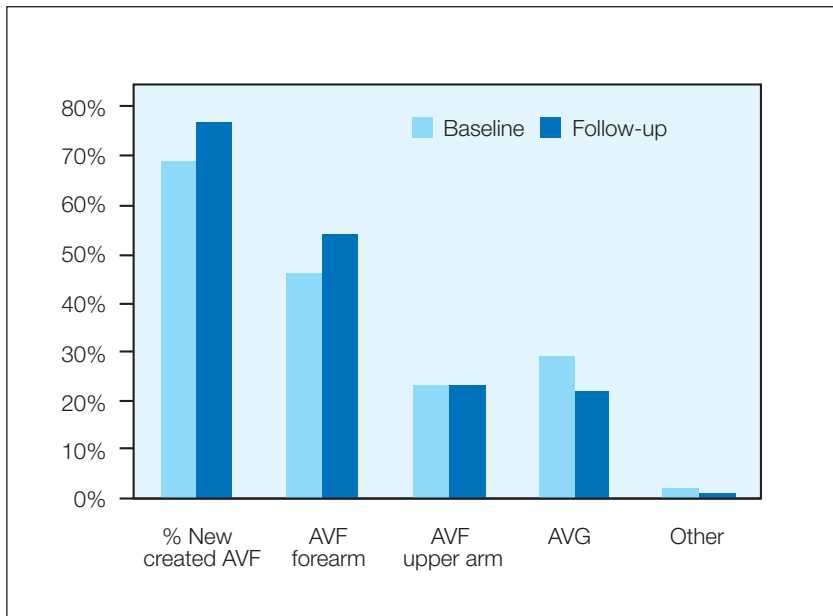
An adequate vascular access as well as its preservation is the precondition for a well-functioning haemodialysis (HD). Due to the increasing age and the rising comorbidity of HD patients it is becoming more and more difficult to create a well-fitting vascular access and to maintain its function. Vascular access complications are one of the leading causes for hospitalization and morbidity in patients with end-stage renal disease. Against this background, the National Kidney Foundation Disease Outcomes Quality Initiative (KDOQI) has published guidelines for vascular access, which were updated in 2006. The quality of adherence to these guidelines differs between facilities in the Netherlands. **Van Loon et al.** performed this study to improve the quality of vascular access care by implementing a quality improvement programme (QIP). By setting up this programme, they intended to increase awareness and commitment to vascular access, to monitor outcome parameters and to quantify the effectiveness of the initiative.

More than 50% of the dialysis facilities (27 centres) in the Netherlands were randomly selected and more than 2,300 patients during a three-year period were included. A task force group of nephrologists, radiologists, vascular surgeons and nurses was created to define standardized procedure protocols for the construction, maintenance and intervention of the vascular access. Within each centre a vascular access nurse was defined, who coordinated the tasks of the internal nephrologist, the surgeon and the radiologist to implement the QIP. At the end of the study, a comparison between the baseline data at study start and end of implementation of the QIP was performed.

The QIP could be realized in 88% of the centres. The number of autogenous arterio-venous fistulas (AVFs)

increased significantly among new and prevalent patients from 69% to 77% ($p < 0.01$) s. **Fig. 2** and from 61% to 64% ($p < 0.01$), resp.

interventional treatment by PTAs and surgery in due time can prevent further complications and improve quality of life. KB



van Loon M, van der Mark W, Beukers N, de Bruin C, Blankestijn PJ, Huisman RM, Zijlstra JJ, van der Sande FM, Tordoir JH. Implementation of a vascular access quality programme improves vascular access care; *Nephrol Dial Transplant* 22, 1628 – 1632, 2007

Fig 2: Vascular access creation before starting the vascular access quality improvement programme and following implementation of the programme. AVF: arterio-venous fistula, AVG: arterio-venous graft

The use of temporary non-tunnelled subclavian vein catheters declined from 34% to 11 % ($p < 0.01$), whereas the use of non-tunnelled catheters in the jugular vein increased from 11% to 21% ($p < 0.01$). Interventional treatment of malfunctioning accesses by percutaneous transluminal angioplasty (PTA) increased from 0.39 to 0.50 interventions per patient/year ($p < 0.001$) and surgical interventions increased from 0.06 to 0.12 per patient/year ($p < 0.001$). The prevalence of arterio-venous graft thrombosis could be calculated by 0.41 per patient year, which is in line with former studies after implementation of a QIP.

To sum it up: after having implemented a vascular access quality improvement programme, the number of AVFs in new and prevalent haemodialysis patients was increased significantly. Moreover, an increase of

3. Which targets in clinical practice guidelines are associated with improved survival in a large dialysis organization?

In recent years several clinical practice guidelines have been developed to improve outcomes in patients with end-stage renal disease. The National Kidney Foundation Disease Outcomes Quality Initiative (KDOQI) has published several guidelines for patients with chronic kidney disease. For optimal treatment of these patients and to decrease mortality rates, many parameters should meet certain target ranges. But not all these recommendations are based on controlled, randomised and prospective studies. Some of them refer to observational studies or are even extrapolated from the general population like the recommendations on blood pressure (BP). The aim of the study of **Tentori et al.** was to investigate the relationship between satisfying the KDOQI guidelines on dialysis dosage (single-pool Kt/V), haematocrit, serum albumin, calcium, phosphorus, parathyroid hormone and mortality. In addition, the impact on mortality with regard to meeting the BP guidelines was investigated as well.

The authors analysed retrospectively the data of 13,792 incident haemodialysis (HD) patients. Patients were recruited from associated centres of US Dialysis Clinic Inc. from 1998 to 2004. The sample was representative for the United States Renal Data System. Follow-up began 120 days after start of HD, median follow-up was 569 days.

Over the time, the proportion of patients achieving the recommended targets of investigated guidelines increased significantly for four of the six parameters, however not for calcium and phosphorus. Referring to each individual parameter, achieving the target in 100% of all measurements for serum albumin (≥ 4.0 g/dl) led to the highest reduction in mortality of 73% (HR 0.27; CI 0.24 – 0.31). All in all, the more of the six

investigated parameters were fulfilled simultaneously, the lower the mortality rate. For satisfying the guidelines for all six investigated parameters a reduction in mortality of 89% could be observed (HR 0.11; CI 0.06 – 0.19, **Tab. 1**).

Tab.1: Hazard ratio and confidence interval (CI) for mortality associated with satisfying KDOQI guidelines for multiple parameters simultaneously (A parameter was defined to meet the KDOQI guidelines when at least 2/3 of the individual values during the 90-days period were within the recommended ranges.)

No. of parameters satisfying KDOQI guidelines	Frequency (%)	HR (95% CI)
0	1.1	1.00
1	10.2	0.74 (0.59 – 0.93)
2	26.5	0.52 (0.42 – 0.65)
3	32.6	0.39 (0.31 – 0.49)
4	21.1	0.30 (0.24 – 0.37)
5	7.5	0.19 (0.15 – 0.25)
6	1.0	0.11 (0.06 – 0.19)

Of special interest is the fact that BP fitting the guideline for at least 75% of predialysis BP ($\leq 140/90$ mmHg) measurements was associated **with an increase of mortality of 90%** (HR 1.90; CI 1.73 – 2.10). Thus the authors emphasize the difficulty to extrapolate the recommended BP values from the general population to HD patients.

In conclusion, fulfilling simultaneously the recommended KDOQI guidelines on dialysis dosage (single-pool Kt/V), haematocrit, serum albumin, calcium, phosphorus, parathyroid hormone in HD patients led to a significant reduction in mortality. The best effect was seen for serum albumin. However, an achievement of the recommended BP values in HD patients led to an increase in mortality. KB

Tentori F, Hunt WC, Rohrscheib M, Zhu M, Stidley CA, Servilla K, Miskulin D, Meyer KB, Bedrick EJ, Johnson HK, Zager PG. Which targets in clinical practice guidelines are associated with improved survival in a large dialysis organization?; J Am Soc Nephrol 18, 2177 – 2384, 2007

4. Mineral metabolism parameters throughout chronic kidney disease stages 1 - 5 – achievement of K/DOQI target ranges

Numerous investigations have established a clear link between some of the comorbid conditions associated with chronic kidney disease (CKD) and mortality in haemodialysis (HD) patients, mostly in relation to cardiovascular events. Among these comorbid conditions, mineral metabolism disturbances have shown a strong association with the development of cardiovascular diseases. The aim of the present study by **Craver et al.** was to provide an in-depth description of the mineral metabolism situation of European CKD patients, and compare it with current recommended target ranges for stages 3 – 5 (K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease; Am J Kidney Dis 42: S1-S202, 2003 (suppl 3)).

This was a cross-sectional study performed in two Spanish nephrology out-patient clinics with similar treatment policies. 1,836 patients were included into the analysis and were classified in stages 1 – 5 according to K/DOQI guidelines. None of them had started HD. Most of the patients at stages 4 and 5 and some of those at stages 1 to 3 were advised to limit their intake of protein and phosphate by an experienced nephrologist and a nephrology nurse. Besides serum phosphate, calcium, Ca x P product and intact parathyroid hormone (iPTH), in a subgroup of patients additionally serum 25-hydroxyvitamin, D [25(OH)D₃], (n = 205), serum 1,25-dihydroxyvitamin, [1,25(OH)₂D₃], (n = 522), 24 h urine calcium (n = 319) and 24 h urine phosphate (n = 317) were collected. Treatment with calcium salts and/or calcitriol was also recorded.

Statistically significant differences among CKD stages were obtained in gender, age (CKD1, n=174, 49±15 y; CKD2, n=341, 60±14 y; CKD3, n=856, 72±12 y;

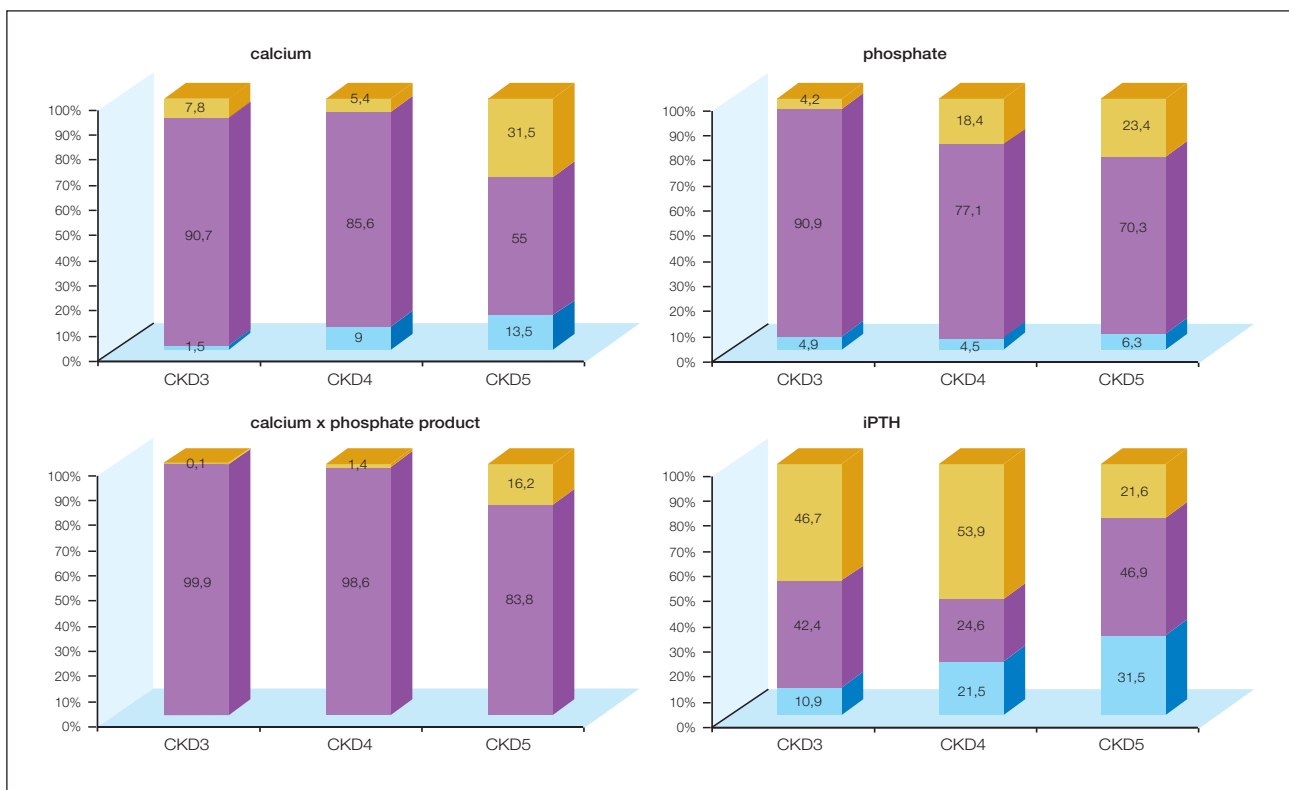


Fig. 3: Percentage of CKD stages 3–5 patients without dialysis reaching the ranges for serum calcium, phosphate, iPTH and Ca x P product within (middle part of the bars, in lavender), below (bottom part of the bars, in blue) and above (upper part of the bars, in orange) of K/DOQI target

CKD4, n=354, 75±12 y; CKD5, n=111, 74±15 y), serum creatinine, creatinine clearance, calcium and phosphate, Ca x P product, iPTH, treatment with calcium salts and/or calcitriol and 1,25(OH)₂D₃. No significant differences were found in CKD aetiology, diabetes and 25(OH)D₃ levels. **Figure 3** shows the percentage of CKD stage 3 to 5 patients without dialysis who accomplished the K/DOQI target ranges for the mineral metabolism parameters serum calcium, phosphate, iPTH and Ca x P product. The proportions of patients who achieved all mineral metabolism parameters recommendations were: 34.9, 18.4 and 21.6% for stages 3, 4 and 5, respectively.

Another finding was the early alteration of some mineral metabolism parameters. In particular, serum PTH and 1,25(OH)₂D₃, and urine calcium and phosphate levels already varied from stage 1 to 2 and did so progressively until stage 5. These early alterations are likely to be implicated in the origin of hyperparathyroidism and yet, according to the authors, in clinical practice, these parameters are seldom followed at these stages, and therefore no recommendations are given for management and prevention.

In conclusion, according to Craver et al., this was the first study to provide a complete description of the mineral metabolism parameters situation in a large CKD population before dialysis. It showed that the PTH recommended levels were difficult to obtain with current treatment options. CL

Craver L, Paz Marco M, Martínez I, Rue M, Borràs M, Martín ML, Sarró F, Valdivielso JM, Fernández E. Mineral metabolism parameters throughout chronic kidney disease stages 1 - 5 – achievement of K/DOQI target ranges; Nephrol Dial Transplant 22, 1171-6, 2007



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