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## The Implementation of Clinical Practice Guidelines (DOQI): Reality or Wish?

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### Introduction

Dialysis modalities provide life-saving therapy for thousands of individuals worldwide. It is clear nowadays that the mortality of dialysis patients is much higher than that of the general population. Evidence-based medicine is a clinical discipline that has emerged in the 1990's. It is a discipline that formalizes the long-practised principle of basing clinical practice on scientific evidence. Clinical practice guidelines have emerged as a useful tool in the hands of experienced nephrologists and their main purpose is to improve outcomes. Over the last years several organizations took an interest and have released guidelines on several topics.

The National Kidney Foundation (NFK) has established detailed guidelines for the treatment of dialysis patients. In 1997 NFK published the Dialysis Outcome Quality Initiative (DOQI) clinical practice guidelines (CPG) for anemia, which were updated in 2000. In 2003 new K/DOQI guidelines were released, which were referred to bone metabolism and dyslipidemia in dialysis patients. Improvement of anemia has resulted in decreased morbidity and mortality in dialysis patients. Disturbances in mineral and bone metabolism may result in bone disease, soft tissue and vascular calcifications and subsequently in atherosclerosis and cardiovascular disease, the leading cause of death in dialysis patients. Similarly the traditional risk factor of dyslipidemia should be aggressively treated in these patients.

The goal of these CPG is to improve outcomes and health status of patients with chronic kidney disease. However, the implementation of these guidelines is difficult to be achieved despite the efforts of healthcare providers. This was recently shown in the treatment of renal anemia in both the DOPPS and the ESAM studies, and in the treatment of bone mineral metabolism in the DOPPS study, where therapeutic targets were difficult to be achieved and control of these conditions was very poor.

Therefore, it seems reasonable every dialysis unit to assess its effort to achieve the guidelines targets and to repeat this procedure from time to time so that everyone can learn the difficulties which arise towards the implementation of these targets. In addition, this practice could provide useful feedback to task forces and expert committees to understand the limitations of healthcare providers and the reasons of poor implementation of the guidelines.

The **aim** of our study was the implementation and the achievement of therapeutic targets of K/DOQI CPG in our dialysis unit.

### Patients and Methods

Our study involved 104 dialysis patients (61 males and 43 females). Their mean age was  $65.8 \pm 12.7$  years. Seventy-two patients were on regular hemodialysis (HD) and 32 in peritoneal dialysis (PD). Their mean duration on dialysis was  $65.1 \pm 58.4$  months and 39 of them were diabetics. We assessed the implementation of clinical practice guidelines for anemia, dyslipidemia, hypertension and bone and mineral metabolism. The assessment was based on haematology and biochemistry screening on two consecutive months in HD patients and two consecutive visits in PD patients. The parameters evaluated were: Hb, calcium (Ca), phosphorus (P), CaXP product, parathyroid hormone (PTH), total cholesterol, triglycerides, HDL and LDL. The mean values were taken into account. Arterial blood pressure was measured before HD in sitting position after 15 minutes of resting and the mean value of the last two of three serial measurements, which were recorded at least 3 minutes apart from each other, was evaluated.

*DOQI clinical practice guidelines:* The recommended target for Hb in dialysis patients is 11g/dl. The targets for lipid control are  $LDL < 100$  mg/dl. If LDL is  $< 100$  mg/dl and fasting triglycerides  $> 200$  mg/dl, and non-HDL cholesterol (total cholesterol minus HDL)  $> 130$  mg/dl, treatment should be considered to reduce non-HDL cholesterol to  $< 130$  mg/dl. As it concerns the bone and mineral metabolism, the serum levels of phosphorus should be maintained between 3.5 to 5.5 mg/dl, the serum levels of total calcium should be maintained within 8.4 to 9.5 mg/dl. The serum calcium-phosphorus product should be maintained at  $< 55$   $\text{mg}^2/\text{dl}^2$  and the serum levels of PTH to a target range of 150 to 300 pg/ml. The target for control of hypertension is  $< 130/80$  mmHg.

### Results

The control of anemia was considered satisfactory in 77 patients (74%), in whom the target value of Hb was  $\geq 11.0$  gr/dl. In 60 patients serum LDL was within the defined therapeutic limits ( $LDL \leq 100$  mg/dl or non-HDL  $\leq 130$  mg/dl) (58%). Hypertensives ( $BP \geq 130/80$  mmHg and/or use of antihypertensive agents) were 75 out of 104 patients (72%). From the 72 HD patients, 54 (72%) were hypertensives and from the 32 PD patients the hypertensives were 21 (66%). From the subgroup of diabetics (n=39) hypertension was observed in 29 (74%), while in the non-diabetics (n=65) hypertension was found in 46 (70%). 68 of the 75 hypertensive patients were receiving antihypertensive agents. Control of hypertension was achieved in 17 of the 75 patients (23%) and all of them were non-diabetics.

The management of secondary hyperparathyroidism in clinical practice proved to be the most difficult. Serum calcium (Ca) was within the target limits ( $8,4\text{mg/dl} \leq \text{Ca} \leq 9,5\text{mg/dl}$ ) in 51 patients (49%), phosphate (P) ( $3,5\text{mg/dl} \leq \text{P} \leq 5,5\text{mg/dl}$ ) in 52 patients (50%) and the CaXP product was below  $55 \text{ mg}^2/\text{dl}^2$  in 76 patients (73%). Values of PTH between 150-300 pg/ml were found in 28 patients (27%). It is worth noticing that control of renal osteodystrophy, including all four parameters, as it is defined by the DOQI, was achieved only in 9 patients (9%). Moreover, only 3 of the 104 patients (3%) proved to have overall compliance and control for anemia, dyslipidemia, hypertension and secondary hyperparathyroidism.

### Discussion

Our study confirms the difficulty of DOQI guidelines to be achieved. In our study the control of anemia was quite satisfactory, since 3 out of four patients achieved the target given by DOQI. A significant proportion of our dialysis patients met the criteria for successful dyslipidemia treatment. In contrast, we were far away from the goals in treating bone and mineral metabolism. Finally, although the blood pressure control was poor, we were not surprised, because we knew that this goal is difficult to be reached in patients with kidney failure.

We wondered what was going wrong. Are we the only ones who cannot prescribe the optimal treatment in our patients? Comparing the results of our study to those of the two large-scale studies, DOPPS I and DOPPS II, regarding the management of mineral metabolism, we have slightly more patients within guidelines limits. In fact the proportion of patients fell within the guideline range for all 4 values was double in our study than those in DOPPS I and DOPPS II, but still was too low. Measuring anemia the proportion of patients with  $\text{Hb} > 11\text{g/dl}$  was higher in our study than many other European countries. Comparing our results to those of ESAM 2003 the management of anemia was slightly better in our study (74 versus 66%) and this was perhaps due to higher proportion of PD patients in our study.

Our results in meeting the targets in mineral metabolism are almost identical to those of Aly et al, who recorded 140 patients for 6 months and they found that the levels of serum calcium and serum phosphorus fell within the range recommended by the K/DOQI guidelines 49 and 36% of the time respectively. 57% of the calcium x phosphorus product measurements were  $< 55 \text{ mg}^2/\text{dl}^2$  and PTH levels were within the recommended values in 20% of the determinations. Only 7% of the determinations met all four criteria simultaneously.

To our great disappointment we recognized that less than 3% met the overall four DOQI guidelines we examined. This is the first report of combined DOQI guidelines evaluation in dialysis patients to our knowledge. It can be assumed that if we had added and other DOQI parameters such as, dialysis adequacy and nutrition parameters none of our patient had the optimal treatment.

We can hypothesize that the guidelines have set high standards for the management of complications of renal failure, goals very difficult to be achieved. We conclude that much more effort is needed from health care professionals to provide the best care to their dialysis patients, to improve the outcome.

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