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Preliminary results of the Spanish Society of Nephrology multicenter study of quality performance measures: hemodialysis outcomes can be improved

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SUMMARY

Introduction: *The Spanish Society of Nephrology «Quality in Nephrology Working Group» (QNWG) was created in 2002. The aims of this group are the identification, diffusion, implementation and consolidation of a systematic, objective and comprehensive set of quality performance measures (QPMs) to help along the improvement of patient care and outcomes on hemodialysis, by means of strategies of feedback and benchmarking, and the design of quality improvement projects. The objective of this study is to present the preliminary results of a set of quality performance measures obtained in a group of Spanish hemodialysis centers, as well as to evaluate the repercussion of the application of the aforementioned thecniques on the observed results.*
Methods: *During 2007 a total of 28 hemodialysis units participated in the study; 2,516 patients were evaluated. A specific software was designed and used to facilitate the calculation of CPMs in each unit. The clinical indicators used refered to dialysis adequacy; anemia; mineral metabolisme; nutrition; viral infections; vascular access; mortality, morbidity (number and days of hospital admissions); and renal transplant. Every three months each center received its own data and its comparison with the rest of the group. Results: Except for hemoglobin levels we observed a global improvement. The percentage of centers reaching the stablished standards defined by the QNWG passed from 65% to 90.9% for Kt/V Daugirdas II (> 1.3 in > that 80%*

of the patients); from 71.4% to 77.2% for PTH (> 30% of patients with serum PTH between 150 and 300 pg/ml); and from 42.8% to 63.5% for phosphate (> 75% of patients with a serum phsphate < 5.5 mg/dl). More than 50% of centers showed an improvement in their final results as compared with their own initial results in all analyzed CPMs. Those centers that did not obtained an improvement in their results started the study with better percentages of acomplishment than those that showed a significant improvement in QPMs. (80.6 ± 15.4 versus 71.8 ± 16.6 respectively; p < 0.001).
Conclusions: *We are starting to make progresses in our knowledge of clinical results in our hemodialysis units, although there is still a long way to go over. To monitor and share CPMs results within hemodialysis centers might help to improve their results as well as to reduce intecenters variability.*

Key words: *Quality. Hemodialysis. Clinical performance measures. Health quality management system.*

RESUMEN

Introducción: **En el año 2002 se creó el grupo de trabajo sobre Calidad en Nefrología de la SEN (CNSEN). Los objetivos de este grupo han sido la identificación, difusión, implantación y consolidación de una herramienta de Gestión de la Calidad en Hemodiálisis, sistemática, objetiva y global, basada en la recopilación de Indicadores de Calidad, las estrategias de retroalimentación (Feedback) y Benchmarking, y el diseño de Planes de Mejora y Evaluación Global. El objetivo de este estudio es presentar los primeros resultados de los indicadores de calidad obtenidos en un grupo de centros españoles, así como evaluar la repercu-**

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sión de la aplicación de las mencionadas técnicas en los resultados obtenidos.

Métodos: Durante 2007 se ha ido incorporando al estudio un total de 28 unidades de hemodiálisis de todo el ámbito nacional. El número total de pacientes evaluados a lo largo del estudio ha sido 2516. Los indicadores han sido recogidos mediante un software informático específico de calidad, que permite calcularlos con facilidad. Los indicadores de cumplimiento se refieren a las siguientes áreas: adecuación de diálisis, anemia, metabolismo mineral y óseo, nutrición, enfermedades víricas, accesos vasculares, mortalidad, morbilidad (ingresos hospitalarios) y trasplante. Cada tres meses los centros reciben sus datos comparados con los del resto del grupo.

Resultados: Se detectó una mejora de los resultados a nivel global, excepto en los niveles de hemoglobina. El porcentaje de centros que alcanzaron los estándares definidos por el CNSEN pasó del 65% al 90,9% en el caso del estándar de Kt/V Daugirdas II (> 1,3 en > del 80% de sus pacientes); del 71,4 % al 77,2 % en el caso del estándar de PTH (> 30% de sus pacientes con PTH entre 150 y 300 pg/ml); y del 42,8% al 63,5% en el caso del estándar de fósforo (> 75% de sus pacientes con fósforo < 5,5 mg/dl). Más del 50% de los centros mejoraron sus resultados con respecto al inicio del estudio en todas las áreas analizadas. Los centros que no obtuvieron una mejora en sus resultados partían de porcentajes de cumplimiento de los indicadores significativamente más altos que aquellos que si lograron mejorarlos (80,6 ± 15,4 *versus* 71,8 ± 16,6 respectivamente; p < 0,001).

Conclusiones: Estamos avanzando en lo referente al conocimiento de los resultados de la hemodiálisis, aunque el trabajo pendiente todavía es extenso. La monitorización de indicadores de calidad respecto a un estándar, y su puesta en común con otros centros puede contribuir a la mejora de resultados y a la disminución en la variabilidad entre centros.

Palabras clave: Calidad. Hemodiálisis. Indicadores de calidad. Sistema de gestión de calidad.

INTRODUCTION

According to the 2005 registry report of the Spanish Society of Nephrology (SEN),[1] there were 27,765 patients receiving renal replacement therapy in Spain, of which 50% were on hemodialysis. Despite its unquestionable social and economic impact,[2] we still do not know essential aspects of renal replacement therapy, such as adequate standards, risk-adjusted mortality or costs.

Numerous studies have shown that attainment of some intermediate results, such as those referring to anemia, dialysis dose, calcium-phosphorus metabolism, albumin levels or type of vascular access, was strongly associated with morbidity and mortality in hemodialysis patients.[3,4] On the other hand, there is a center effect (variability in the results attributable to the quality of the care provided) which can be diminished with certain interventions.[5]

The Spanish Society of Nephrology «Quality in Nephrology Working Group» (QNWG, www.senefro.org) was crea-

ted in 2002. The aims of this group included the identification, diffusion, implementation and consolidation of a systematic, objective and comprehensive set of quality performance measures (QPMs) to aid in the improvement of patient care and outcomes on hemodialysis through feedback and benchmarking strategies and the design of quality improvement projects. At present, more than seventy professionals from various disciplines (nephrologists, statisticians, computer specialists and epidemiologists) belong to this group.

After the design and diffusion of a battery of quality performance measures for hemodialysis,[6] the working group developed a computer software to facilitate their calculation, whose implementation in the different centers was started in October 2006. These quality performance measures were collected on a three-monthly basis during 2007. It was not known whether the standards and objectives defined a priori in the QNWG's initial proposal for quality indicators[6] and in the different guidelines[7-9] will be appropriate for our population and to what extent they are being complied with. On the other hand, other studies have shown that monitoring of quality indicators[10] and sharing the results with other centers[11] helps to improve the results obtained. This multicenter study was designed with the aim of answering these questions and determining the most relevant areas of improvement in the hemodialysis process.

The objective of this study was to present the preliminary results of a set of quality performance measures obtained in a group of Spanish hemodialysis centers, and to evaluate the impact of application of these techniques on the results observed.

MATERIALS AND METHODS

Study design

A descriptive population study of the results of quality performance measures obtained in the participating centers.

A comparative before-after study after combining the pooled values of the indicators from all centers.

Patients

During 2007, a total of 28 hemodialysis units participated in the study. Eleven were hospital and thirteen nonhospital units, both public and private, from all areas of Spain. The study was started with 24 dialysis units and 738 patients (January 2007), increasing to 28 units and 1318 patients by the end of the year (December 2007). The total number of patients studied at the different study times and hence the number used in calculation of the different indicators analyzed varied depending on the inclusion of new patients or withdrawal of existing patients in each unit, as well as the different frequency of laboratory tests for some indicators in the centers. A total of 2,516 patients were evaluated over the study.

No exclusion criteria were applied: all patients in each unit at the time of the laboratory test whose data were in the computer program were included in the analysis of indicators.

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Indicators analyzed

The indicators collected (informative and clinical) were distributed by areas covering the different aspects of hemodialysis. The informative indicators included data on demographic characteristics, comorbidity, dialysis technique (duration, frequency, membrane types, blood flow) and treatments received for anemia and bone and mineral metabolism. The clinical indicators used referred to the following areas: dialysis adequacy, anemia, bone and mineral metabolism, nutrition, viral infections, vascular access, mortality, morbidity (number and days of hospital admissions), and renal transplant.

Methodology

Most of the participating units use the Nefrosoft® 3.0 (Visual-limes) (26 units) or Renasoft® (Baxter) (2 units) database, where the whole patient medical history is recorded in an electronic format. A specific software was designed for this study, which works coupled to this database, to facilitate calculation of the indicators.

After receiving the indicators obtained in each center, the individual results are pooled to obtain joint results providing a populational perspective, expressed as the mean, standard deviation and 75th percentile of the sample studied. Both individual and overall results are systematically and regularly reported to the staff in charge of care.

The method of working was to use the indicator modules to calculate the following indicator profiles: monthly profile (dialysis adequacy, hemoglobin, calcium, phosphorus, erythropoietin stimulating agent dose, different treatments), two-monthly profile (ferritin, PTH, albumin), and annual profile (vascular access, mortality, comorbidity, transplant). Each unit was allowed to calculate the indicators according to the frequency of the laboratory tests in that center. For example, 45% of centers measured dialysis adequacy every three or more months. A file is generated automatically every three months for each module (monthly, bimonthly or yearly), which is sent to an Internet address linked to the program for statistical analysis. All units provide all the data collected up to moment of sending. After processing the data, a report is prepared with the results of each center and sent to the relevant investigator, together with an overall report of the pooled results of all the centers. The results of each center are sent in the form of tables showing for each indicator of compliance the number of centers for which data are available, the result of each center, the mean and standard deviation of all centers, and the 75th percentile of the sample. The results are also shown for each group of indicators by a radar chart or spider-web chart in which the center can see its position relative to the mean of all centers and relative to the group of centers situated in the 75th percentile (current optimal value), which would be those who have obtained the best results for that indicator. Trend charts showing the change in the results of the center over the period studied for each indicator are also provided.

All the results expressed in this study refer to the values obtained in each center. They are expressed as the mean ± SD of the means of the centers and the percentages of compliance of the centers, not over the total patients studied.

Comparison between initial and 1-year results

The results obtained in the first quarter of the study, when the centers did not know their first results or the results of the other centers, were compared with the results obtained in the last quarter of the study. A total of 24 centers the participated in the study from the start were included in this analysis. The percentage of compliance was compared in the following areas: anemia, iron metabolism, dialysis adequacy, and bone and mineral metabolism, with at total of 15 indicators. The mean percentages of compliance of the indicators at the start of the study were compared between centers that improved or worsened their results.

Statistical analysis

All data were analyzed using the SPSS 12.1 statistical package. Normality of the sample distribution was determined using the Kolmogorov-Smirnov test. Comparison of the means of compliance of the indicators between the first and last quarters of the study was performed using Student's t-test for paired data. The NcNemar test was used to compare the mean percentages of compliance of the indicators at the start of the study between centers that improved or worsened their results. The statistical significance level used was $p < 0.05$.

RESULTS

Description of indicators

The *demographic characteristics* of the centers participating in the study are shown in table I.

Table I. Demographic characteristics and comorbidity of the population in the different centers

Demographic data	Mean ± SD 2007
Mean number of new patients in the units (2007)	25.1 ± 19.1
Mean numbers of patients dialyzed in the units (2007)	94.1 ± 60.4
Mean age of incident population (years)	61.5 ± 7.5
Mean age of prevalent population (years)	66.1 ± 3.1
Mean time on hemodialysis of prevalent population (months)	59.4 ± 17.2
% prevalent patients with diabetic nephropathy	26.1%
% male	61.9%
Median Charlson's comorbidity index of incident population	7.4 ± 1.1
Median Charlson's comorbidity index of prevalent population	7.3 ± 0.9
Crude mortality rate	10.5 ± 5.6
Number of admissions per patient-year at risk	0.8 ± 0.4
Days of admission per patient-year at risk	7.4 ± 1.1
% of patients on waiting list for kidney transplant	21%
% of patients on waiting list who were transplanted	31%
HCV prevalence	13.8 ± 10.7
HBV prevalence	5.5 ± 6.1

The results expressed in the table are the means of the values obtained in each center, not of the overall population.

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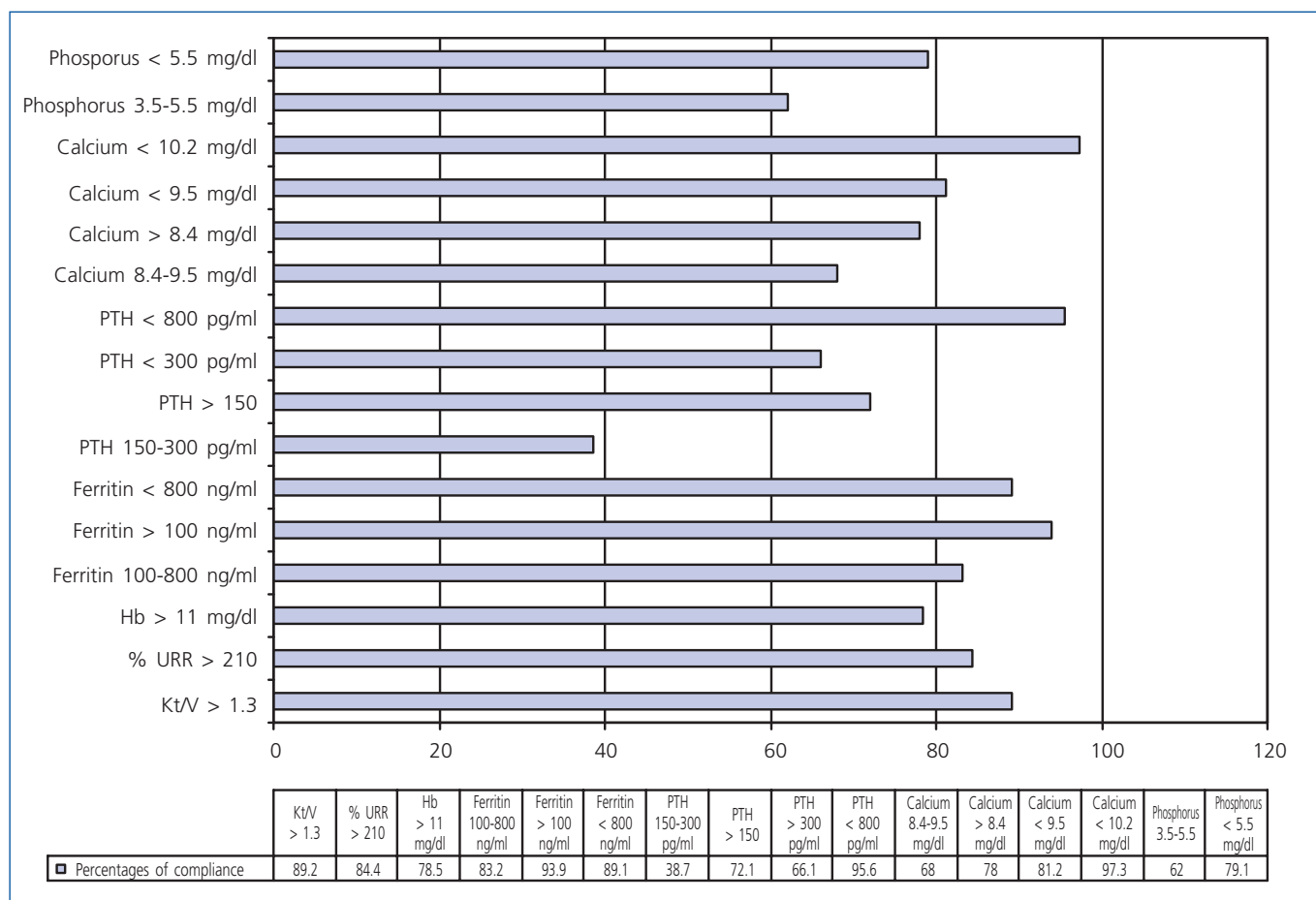|	Kt/V > 1.3	% URR > 210	Hb > 11 mg/dl	Ferritin 100-800 ng/ml	Ferritin > 100 ng/ml	Ferritin < 800 ng/ml	PTH 150-300 pg/ml	PTH > 150	PTH > 300 pg/ml	PTH < 800 pg/ml	Calcium 8.4-9.5 mg/dl	Calcium > 8.4 mg/dl	Calcium < 9.5 mg/dl	Calcium < 10.2 mg/dl	Phosphorus 3.5-5.5	Phosphorus < 5.5 mg/ml
Percentages of compliance	89.2	84.4	78.5	83.2	93.9	89.1	38.7	72.1	66.1	95.6	68	78	81.2	97.3	62	79.1

Figure 1. Mean percentages of compliance with quality indicators obtained in the different centers in 2007.

The results obtained for the quality indicators in the different areas analyzed: dialysis adequacy, anemia and iron metabolism, and bone and mineral metabolism, are expressed as percentages in figure 1 and as arithmetic means in table II.

The characteristics of dialysis and the data related to treatment of anemia, iron metabolism, and bone and mineral metabolism are shown in tables III and IV, respectively. The percentage of patients treated with lanthanum carbonate was not included as it is a recently marketed drug that will be included in future editions of the module of quality indicators. With regard to *nutrition,* the percentage of albumin determinations above 3.5 g/dl was 80%.

Table II. Arithmetic means of results of indicators

	Mean ± SD 2007
Arithmetic mean of 2nd generation Daugirdas Kt/V	1.6 ± 0.2
Arithmetic mean of hemoglobin levels (g/dl)	12.1 ± 0.4
Arithmetic mean of ferritin levels (ng/ml)	437.2 ± 100.5
Arithmetic mean of iPTH levels	287.7 ± 74.8
Arithmetic mean of serum calcium levels	8.9 ± 0.3
Arithmetic mean of serum phosphorus levels	4.6 ± 0.3

Table V shows the results obtained in the area of *vascular access,* expressed as the median and 25th-75th percentiles and as the percentage of centers complying with the quality objectives defined in the guidelines for vascular access.

Table VI shows the results obtained in the last quarter by the centers participating in the study compared with those published in the Annual Report ESRD Clinical Performance Measures Project (USA) corresponding to the last quarter of 2006.

Comparative before-after study

The percentage of centers that complied with the standards defined was greater at the end of the study than in the baseline assessment when centers still did not have the data from other units (table VII).

Except for hemoglobin levels, we observed an overall improvement, although this improvement was only statistically significant in the area of bone and mineral metabolism (calcium and phosphorous levels) (fig. 2). More than 50% of centers showed an improvement in their final results as compared with their own initial results in all areas (table VIII). The centers that did not obtain an improvement in their results started the study with better percentages of compliance of the indicators than those that showed a significant improvement in their percentages of compliance (80.6 ± 15.4 *versus* 71.8 ± 16.6, respectively; p < 0.001) (table VIII).

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Table III. Dialysis characteristics: duration, frequency, membrane type, technique and blood flow

	Mean ± SD 2007
Mean hours of dialysis per week	11.8 ± 0.8
Mean blood flow prescribed	348.4 ± 28.7
% patients with more than 4 hours per session	60 ± 18
% patients with 3 or less session per week	95 ± 5
% patients with synthetic membranes	90 ± 18.5
% patients with low-flux membranes	3.3 ± 10.6
% patients with medium-flux membranes	40.0 ± 27.6
% patients with high-flux membranes	56.7 ± 35.3
% patients with conventional HD	89 ± 17

The results expressed in the table are the means of the values obtained in each center, not of the overall population.

DISCUSSION

The preliminary results obtained in up to a total of 28 hemodialysis units that participated in the study over 2007 are presented. The analysis of these results allows us to detect future areas of improvement as well as the potential of this strategy of comparative evaluation of quality indicators.

The demographic characteristics of the centers reveal the variability existing between centers in terms of the unit size, number of new patients annually, age of the dialysis population or prevalence of viral infections, among others. This study did not analyze the possible influence of these characteristics or the impact of the different treatments and dialysis techniques used on the differences in the results obtained between units; these aspects will be addressed in depth in subsequent studies.

The battery of indicators collected in the study was in some aspects more extensive than the battery recommended in the recent QNWG publication. The software tool allowed easy evaluation of the different aspects of hemodialysis with a large number of indicators, providing us with a broader vision of the problem studied. Analysis of a problem considering only the percentage of patients complying with a certain range takes away information, often crucial, to know the reality we are assessing. It is therefore interesting to know not only the percentage of patients within the range, but also the percentage of patients who are above or below this range. Other aspects, such as measurement of blood pressure, although undoubtedly important, were not evaluated as this possibility of measurement was not available with the software tool. It is important that the time required for calculation of indicators measured does not outweigh the advantages of
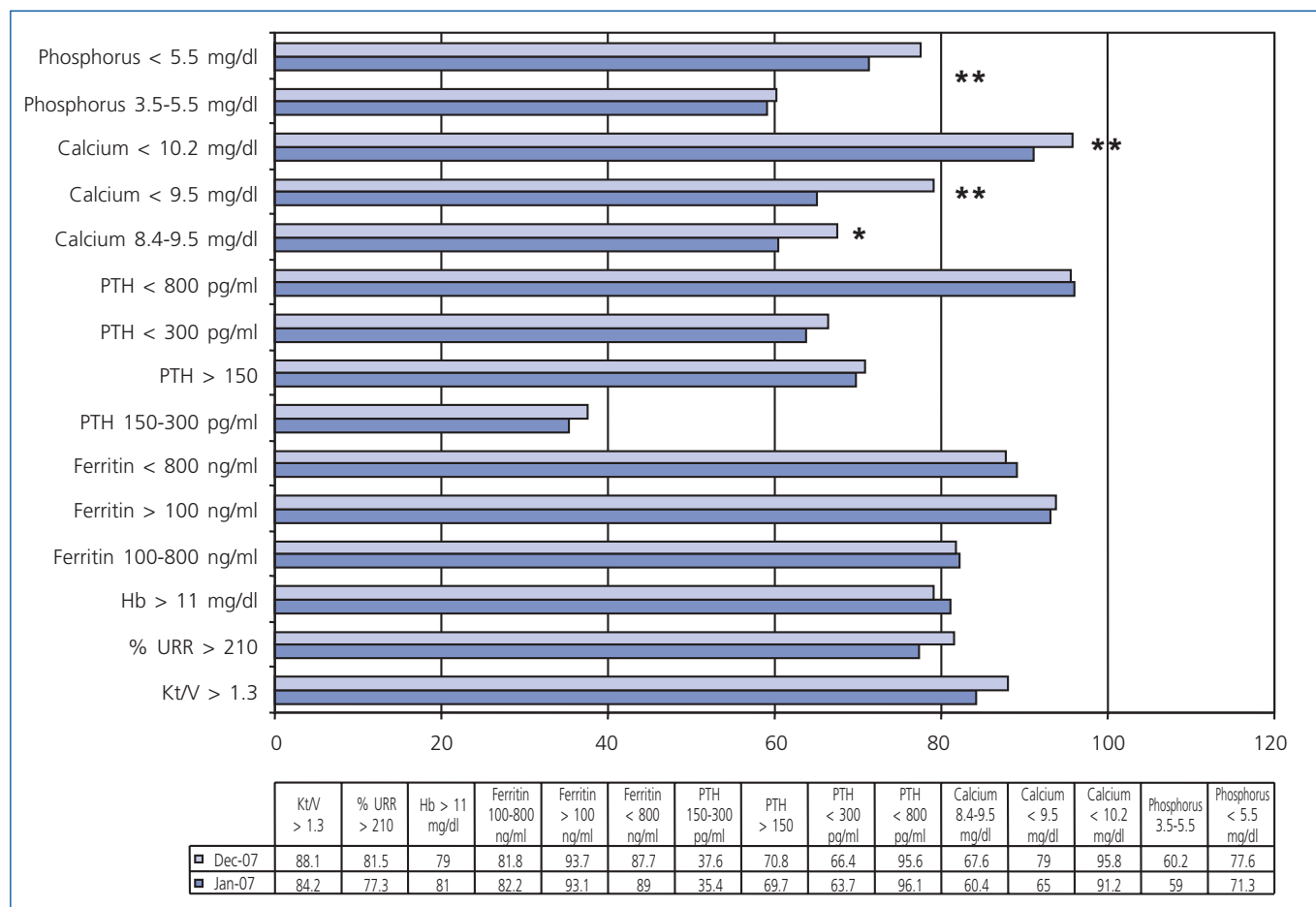

		Kt/V > 1.3	% URR > 210	Hb > 11 mg/dl	Ferritin 100-800 ng/ml	Ferritin > 100 ng/ml	Ferritin < 800 ng/ml	PTH 150-300 pg/ml	PTH > 150	PTH < 300 pg/ml	PTH < 800 pg/ml	Calcium 8.4-9.5 mg/dl	Calcium < 9.5 mg/dl	Calcium < 10.2 mg/dl	Phosphorus 3.5-5.5	Phosphorus < 5.5 mg/dl
⊡	Dec-07	88.1	81.5	79	81.8	93.7	87.7	37.6	70.8	66.4	95.6	67.6	79	95.8	60.2	77.6
■	Jan-07	84.2	77.3	81	82.2	93.1	89	35.4	69.7	63.7	96.1	60.4	65	91.2	59	71.3

Figure 2. Comparison between percentage of compliance in January 2007 and December 2007 (* p < 0.05; ** p < 0.01) 24 units with complete year of follow-up.

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Table IV. Treatment of anemia, iron metabolism and bone and mineral metabolism

	Mean ± SD 2007
Mean weekly EPO dose (U/kg/week)	150.0 ± 36.6
Mean weekly darbepoetin dose (U/kg/week)	0.8 ± 0.4
Mean EPO resistance index	12.9 ± 3.1
Mean darbepoetin resistance index	0.08 ± 0.04
% patients treated with erythropoietin	72 ± 17.3
% patients treated with darbepoetin	31.6 ± 7.2
% patients with dialysate calcium content of 2.5 mEq/l	32 ± 24
% patients with dialysate calcium content of 3 mEq/l	57.2 ± 22.5
% patients with dialysate calcium content of 3.5 mEq/l	24 ± 23.2
% patients treated with alphacalcidol	21.5 ± 17.3
% patients treated with paricalcitriol	24.6 ± 14.2
% patients treated with calcitriol	16.7 ± 14.6
% patients treated with calcimimetics	18.8 ± 6.8
% patients treated with phosphate binders (aluminium-containing)	15.2 ± 6.7
% patients treated with phosphate binders (calcium-containing)	44.6 ± 11.7
% patients treated with phosphate binders (sevelamer)	50 ± 18.4

The results expressed in the table are the means of the values obtained in each center, not of the overall population.

their measurement. It is for this reason that we basically adapted all the indicators that could be measured automatically with the previously described computer programs.

Two indicators were used for assessment of the degree of *dialysis adequacy:* second generation Daugirdas Kt/V value and weekly URR, with the idea of covering patients not only with three but also with more dialysis sessions (these patients receive the dialysis dose by increasing the frequency of their sessions). The mean percentage of compliance of the centers was 89.2% for the Daugirdas Kt/V and 84.4% for the weekly URR, which reveals a high degree of compliance in the area

of dialysis adequacy. Some centers, whose patients maintained good residual renal function, did not achieve the objectives defined using the Daugirdas Kt/V, but did so with the total Kt/V, so it was considered necessary to include this indicator in the future to take into account those patients with residual diuresis (data not shown).

If we analyze the standards defined for the percentage of patients with Daugirdas Kt/V > 1.3, we can see that there are discrepancies between the guidelines for hemodialysis centers, more ambitious, which define a standard >88%, and the standard defined in the proposal for quality indicators of the SEN (> 80%). The degree of compliance after 1 year of study was 90% for the standard defined by the proposal of quality indicators of the SEN and 50% for the standard defined in the guidelines for hemodialysis centers, with more than half of centers showing an improvement in compliance since the start of the study. The DOPPS study revealed a 36% prevalence of patients with inadequate dialysis (Kt/V < 1.2) in Spain.[12] Both the guidelines for hemodialysis centers and the K-DOQI guidelines recommend performing this measurement monthly;[18,19] however, almost half of centers (45%) did so every three or more months. Both results allow us to detect opportunities for improvement. First, the dialysis dose needs to be increased in at least 20% of patients, and second, it would be recommendable to increase the frequency of its measurement in 45% of the centers participating in the study.

With regard to *anemia,* 19% of patients had a hemoglobin level < 11 g/dl at the start of the study. According to the standard established in the guidelines for hemodialysis centers, less than 15% should have a hemoglobin level below 11 g/dl, and so it seems that a certain proportion of patients could still benefit from more adequate treatment of anemia. Although more than half of centers improved their overall results in this area, the percentage of compliance decreased from the start to the end of the study, and this was the only indicator in which an improvement was not observed. It is possible that the controversy regarding the upper limit of hemoglobin target levels,[13] which should not exceed 13 g/dl,[14] may have influen-

Table V. Results of indicators for vascular access in the center studied

Indicator	Median (25th-75th percentiles)	% centers complying with objectives	Guideline objectives
% incident patients with mature VA	50 (34.5-61.2)	0%	> 80%* > 75%**
% incident patients with AVF	45.4 (31.5-55.2)	0%	> 80%*
% incident patients with graft	1.9 (0-6.7)	85.7%	< 10%*
% incident patients with temporary catheters	13.0 (5.4-39.2)	42.8%	< 10%*
% incident patients with permanent catheters	25 (8.2-34.5)	28.5%	< 10%*
% prevalent patients with AVF	67.2 (55.8-79.8)	19.0%	> 80%*
% prevalent patients with graft	4.7 (1.7-12.6)	71.4%	< 10%* < 12%**
% prevalent patients with temporary catheters	3.4 (0.5-6.3)	80.9%	< 10%*
% prevalent patients with permanent catheters	15.9 (12.9-19.7)	14.2%	< 10%*

Incident patients refers to patients who started hemodialysis during 2007. Prevalent patients refers to patients on hemodialysis as of December 31, 2007. The results are expressed as the median of the results of the indicator obtained in the different centers, and indicate that half o fthe centers had higher and half lower values than the value shown.
* Source: Proposal for quality indicators of the SEN, Guidelines for vascular access.
** Source: Guidelines for hemodialysis centers.

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Table VI. Results of the Spanish multicenter study in 2007 compared with the data published in the 2006 Annual Report ESRD Clinical Performance Measures Project (USA)

Indicator	2007 annual data from Spanish centers	2006 annual report USA
Dialysis adequacy		
% pts with Kt/V > 1.3 (2nd generation Daugirdas)	88.1%	94%
Arithmetic mean of Daugirdas Kt/V	1.6 ± 0.2	1.6 ± 0.3
Anemia		
% pts with HB > 11 g/dl	79%	84%
Mean of hemoglobin levels (g/dl)	12.1 ± 0.5	12.0 ± 1.2
% pts with ferritin > 100 ng/ml	93.7%	95%
% pts with ferritin > 800 ng/ml	12.3%	24%
Vascular access		
% incident patients with AVF	45.4%	54%
% prevalent patients with AVF	67.2%	44%
% prevalent patients with permanent catheters	15.9%	21%

The data expressed in this table refer to the last quarter of 2007 in Spain and the last quarter of 2006 in USA, except for the percentage of incident patients with VAF in Spain which refers to the whole year of 2007.

ced the results. It is thus considered necessary to include the percentage of patients with hemoglobin < 12 g/dl as an indicator in the future. This will probably contribute to an increased variability of this indicator, as has already been shown in the literature,[15] which will lead us to modify the standard to adapt it to the new reality.

When evaluating the results of the indicators and the expectations for each one of them, especially those related to anemia or dialysis adequacy, it should be taken into account that no exclusion criterion was applied. The analysis of indicators included all patients, regardless of whether they had just entered the unit as incident cases, came from a hospital admission, or had an infectious complication from the vascular access or bleeding. The reason for this decision is that the evaluation of indicators must first serve to allow the center to determine its situation and to identify the patients with problems on whom action needs to be taken. It is likely that in some cases this may have influenced the results of a specific center versus the others, but the objective is not so much to obtain good results as to know and be able to take action on results that reflect the reality of our patients.

The standard establishing 80% as the percentage of patients with optimum ferritin levels (between 100 and 800 ng/ml) is considered adequate, since compliance was superior in 60% of centers, and increased from 47% at the start of the study. Bone and mineral metabolism was the area where the largest changes were produced in the study, and also where there is the largest gap for improvement and standardization of results. This may have been due to the fact that it is one of the aspects in which the largest conceptual changes have been introduced in recent years[16] and in which new therapeutic tools have emerged,[17] which have led to different treatment strategies.[18] This has no doubt had consequences that will need to analyzed at a later date. We do not know at this time which standards are most desirable, especially in a context of changing therapeutic resources, so we need to adjust the ob-

jectives to the best results obtained in clinical practice and analyze the factors that may have contributed to this improvement in results. Overall, mean attainment of the PTH target between 150-300 pg/ml by the centers was 37.6%. The standard defined, which was compliance in more than 30% of patients, was achieved by 77% of centers, whereas only 36% were able to achieve the objective of 40%. Therefore, it seem reasonable to maintain the defined objective of 30% for now. An in-depth analysis of the treatment data available in the study database would probably allow us to improve our knowledge of the best clinical practices as regards the use of calcium in dialysate, phosphate binders, calcimimetics or types of vitamin D.

The distribution of the patients not achieving the PTH target was 30% with suppressed PTH (< 150 pg/dl) and 33% with PTH levels above 300 pg/ml. More than half of centers complied with the objective of having less than 0.5% of patients with severe hyperparathyroidism, with calcimimetics having been introduced in 18.8% of patients. Calcium control was one of the aspects that varied the most during the study, with up to 67% of patients achieving calcium in the target range (between 8-9.5 mg/ml). Nearly 80% of patients had a serum calcium below 9.5 mg/dl and more than 95% below 10.2 mg/dl. There is no standard defined in this area on a population level, so these data may serve as a guide in the future.

On the other hand, phosphorus control is currently one of the most important problems in dialysis units. This indicator has been clearly associated with mortality and its compliance is associated with achievement of adequate adherence to treatment. Serum phosphate levels below 5.5 mg/dl were achieved by 77% of patients, and all centers exceeded the objective of 50% established in the guidelines for hemodialysis centers. It seems more reasonable to use the standard established in the proposal for quality indicators of the SEN (> 75%). Compliance with this standard went from 43% to 68.5% of centers

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Table VII. Percentage of compliance of the centers *versus* the standard defined by the Quality Management Group and the Guidelines for Hemodialysis Centers of the Sen

Indicator	Percentage of centers complying with the standards defined January 2007	Percentage of centers complying with the standards defined December 2007	Standards defined
% pts with Kt/V > 1.3	65	90.9	> 80% (*)
	45	50	> 88% (**)
% pts with Hb > 11	0	0	> 95% (*)
	47.2	21.7	> 85% (**)
% pts with ferritin between 100-800	47.6	60.8	> 80% (*)(**)
% pts with PTH between 150-300	71.4	77.2	> 30% (*)
	28.5	36.3	> 40%
% pts with PTH < 800	57.1	57.1	> 95,5% (*)
% pts with P < 5.5	42.8	69.5	> 75% (*)
	90.4	100	> 50% (**)

(*) Source: Proposal for quality indicators of the SEN. (**) Source: Guidelines for hemodialysis centers.

over 2007, and it is indicator whose plans and strategy for improvement depend largely on our efforts to increase patient adherence to treatment.[19]

Although measurement of albumin levels is a poor parameter to assess nutritional status, it is a known factor that is associated with mortality in hemodialysis. Twenty-two percent of patients in the study sample had albumin levels below the therapeutic range. When evaluating this indicator, it should be taken into account that there is significant variability in serum levels depending on the hydration state of the patient and the technique used for its measurement, in addition to the possible influence of the presence of an inflammatory state.

The guidelines for vascular access (VA) of the SEN establish as quality objectives that more than 80% of incident patients should have a mature VA at the start of hemodialysis. More than 80% of prevalent patients should have an arteriovenous fistula (AVF), less than 10% a graft, and less than 10% permanent catheters (PC). The annual rate of thrombosis should be less than 25% for AVF and less than 50% for grafts. Compliance with these currently defined quality objectives for vascular accesses in Spain is very low. Despite the differences in characteristics and location of the centers, the lack of compliance with some indicators is generalized and with very similar figures. It is striking that both the objectives and standards established for the same healthcare process are different in different countries; for instance, the guidelines for vascular access of the SEN recommend that an arteriovenous fistula should be placed in 80% of prevalent patients on hemodialysis,[20] while the objective established in the K/DOQI guidelines is ≥ 40%,[21] and the objective in Canada is > 60%.[22] This variability may be somewhat easier to understand between different countries. However, this study shows that variability exists even between centers from the same country. There is a need for better planning of vascular accesses in incident patients and for a change to objectives more in keeping with the current reality in Spanish, particularly in regard to permanent catheters and arteriovenous fistulas in prevalent patients.

One of the current challenges is to reduce the variability in the care provided,[23] which may be explained by multiple and complex reasons. Systematic, planned measurement of quality indicators and sharing with other centers can help to improve and standardize their results. With application of these improvement tools (feedback and benchmarking), an overall improvement was detected over the study period. More than half of centers improved their results in all indicators over the study, with calcium and phosphorus control being the area where the highest percentage of centers (around 80%) achieved the planned objectives. It is notable that the centers that improved their results over the study started from much lower levels of compliance than the centers that showed no change or worse results, whose percentages of compliance at the start of the study were already very high and hence difficult to improve on. Establishing the values that can be improved and those that are considered adequate or optimal will be one of the objectives of this group: the preliminary results of this study already point in this direction. Some centers were already using quality management systems and benchmarking and feedback technique prior to the study, which probably explains at least partially why no difference was noted in their results. The design of improvement plans to address the problems identified by the indicators will be one of strategies to implemented in the future by the Quality Management Group of the SEN.

An exhaustive analysis to define which quality indicators are worth measuring and which are the most appropriate standards remains to be done; here we have only discussed and compared the study results with the standards proposed by the SEN for some of the most relevant indicators. In view of the lack of overall data on hemodialysis in our country, these results may be useful as guide for the participating hemodialysis units. However, we should consider the limitation of the small number of participating centers compared to the total number of hemodialysis centers in Spain and the fact that these centers are especially involved and aware of quality improvement. Consequently, the results are biased and cannot be considered representative of the total popula-

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Table VIII. Percentage of centers complying with indicators at the start and end of the study in terms of the satandards stablished by the guidelines and percentage of centers improving their results after 1 year of follow-up (number of centers analyzed: 24)

Indicator	Percentage of centers improving results	Mean percentage of compliance of the indicator at the start of the study in centers improving results	Percentage of centers worsening results	Mean percentage of compliance of the indicator at the start of the study in centers worsening results	p (*)
Dialysis adequacy					
% pts with Kt/V > 1.3	60	80 ± 10.5	40	90.4 ± 7.6	0.02
% pts with URR > 210	65	76.6 ± 14.8	35	78.7 ± 15.8	0.7
Anemia					
% pts with Hb > 11	52.3	77.5 ± 8.2	47.6	84.1 ± 8.4	0.9
% pts with ferritin between 100-800	57.1	78.7 ± 11.5	42.8	86.8 ± 12.2	0.4
% pts with ferritin > 100	61.9	90.5 ± 9.8	38	97.2 ± 2.8	0.07
% pts with ferritin < 800	57.1	84.7 ± 10.4	42.8	92.3 ± 7.7	0.07
Vascular/osteodystrophy risk					
% pts with PTH between 150-300	61.9	33.2 ± 1.9	38	39.5 ± 11.1	0.1
% pts with PTH > 150	61.9	68.9 ± 10,0	38	68.9 ± 7.8	0.9
% pts with PTH < 300	66.6	61.7 ± 9.9	33.3	71.2 ± 14.2	0.08
% pts with PTH < 800	57.1	95.9 ± 5.1	42.8	96.2 ± 3.3	0.8
% pts with calcium between 8.4- 9.5	76.1	56.5 ± 10.2	23.8	73.4 ± 5.4	0.002
% pts with Ca < 9.5	85.7	61.7 ± 13.4	14.2	83.9 ± 7.2	0.01
% pts with Ca < 10.2	80.9	89.3 ± 6.8	19	99.5 ± 0.8	0.005
% pts with P between 3.5-5.5	57	53.2 ± 7.9	42.8	66.5 ± 6.2	0.001
% pts with P < 5.5	85.7	69.7 ± 11.6	14.2	81.4 ± 6.3	0.1

* The mean percentages of compliance of the indicator at the start of the study were compared between centers that improved or worsened their results (Student's t).

tion of patients on hemodialysis. It is hoped that a larger number of centers will join this project so that the data provided are truly representative of the Spanish hemodialysis population. A special effort was made to facilitate calculation of the indicators with a software designed specifically for this task, attached to the Nefrosoft® and Baxter® databases, which are the computer programs used as the electronic medical history by most dialysis centers. This allowed the quality indicators to be generated in all the dialysis units without an excessive effort. The Quality Management Group of the SEN is open to collaboration in the development of the modules of indicators specific to other databases; this would allow the incorporation of dialysis centers using other formats.

These preliminary results show the importance of defining standards that are adequately adjusted to the characteristics of the population we are treating and the new treatments available, and that they should be reviewed periodically and changed if necessary. It also allows us to compare our results with other countries, as shown in Table 6, where the results of the Spanish group are compared with the results of a large group of patients from the USA, a country with a long history of monitoring and dissemination of quality indicators.

We can conclude that we are making progress in our knowledge of clinical results in our hemodialysis units, although there is still a long way to go. To monitor and share CPM results with other hemodialysis centers might help to improve their results and also reduce intercenter variability.

FUNDING AND CONTRIBUTIONS

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