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Multicenter prospective study on hemodialysis quality

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SUMMARY

In medicine a considerable amount of resources are used in research, but very little attention is paid to ensuring that the findings of research are implemented in routine clinical practice. This prospective study has the aim to evaluate the efficiency of some clinical management strategies (feedback, benchmarking *and improving plans) on haemodialysis treatment results in 4 different dialysis centres.*

We collected consensus data related to haemodialysis results every 6-8 months and informed each centre about its own results (feedback) *and how these related to the others* (benchmarking). *We designed improving plans for any bad result detected.*

By the end of two years of follow up, 294 patients had been included in the study. The results obtained at the end of the study had improved in comparison with those obtained at the beginning (statistically significant) for the following indicators: % of patients with Hb < 11 g/dl, % patients with Kt/v < 1.2, mean Kt/v, mean albumin, % patients with albumin < 3.5 g/dl y % patients with C reactive protein (CRP) > 5 mg/dl. No statistical changes were found in: mean erythropoietin (EPO) doses, blood pressure (BP), phosphorus plasmatic, calcium-phosphorus product, parathormone (PTHi) and vascular access distribution. We explained the absence of any improvement because of adequate start indicators in some areas (BP and vascular access), therapy with limited efficiency (calcitriol, calcium carbonate and others), lack of support resources (dietetic unit) or inadequate design/implementation of improving plans.

In conclusion, our intervention illustrates that combined clinical management strategies (feedback, benchmarking *and improving plans) are efficiency in improving some areas of haemodialysis treatment (anaemia, dialysis dose, nutrition and inflammation), although it does not improve calcium phosphate metabolism related indicators.*

Key words: ***Clinical management*. Feedback. Benchmarking. *Quality of care. Haemodialysis.***

ESTUDIO PROSPECTIVO MULTICÉNTRICO DE CALIDAD EN HEMODIÁLISIS

RESUMEN

En el ámbito médico se destinan muchos recursos a la investigación. Sin embargo, los esfuerzos encaminados a evaluar la eficacia de estrategias útiles para trasladar la evidencia científica disponible a la práctica clínica son relativamente escasos. El presente trabajo pretende estudiar la eficacia de ciertas medidas de gestión clínica (feedback, benchmarking *y Planes de Mejora) en el resultado del tratamiento con hemodiálisis mediante un estudio prospectivo realizado en 4 centros de diálisis.*

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Se procedió a la monitorización periódica (cada 6-8 meses) de indicadores de hemodiálisis previamente consensuados, informando de los resultados propios de cada centro (feedback) *y de éstos en relación al resto* (benchmarking). *Se elaboraron Planes de Mejora específicos en función de los resultados.*

Tras dos años de seguimiento el número total de pacientes incluidos ha sido de 294. Se ha obtenido una mejora estadísticamente significativa de los indicadores: % de pacientes con Hb < 11 g/dl, % pacientes con Kt/v < 1,2, media de Kt/v, albúmina media, % de pacientes con albúmina < 3,5 g/dl y % de pacientes con proteína C reactiva (PCR) > 5 mg/dl. No ha habido cambios estadísticamente significativos en los indicadores: dosis media de eritropoyetina (EPO), tensión arterial (TA), fósforo plasmático (P), Ca x P, parathormona (PTHi) y distribución de accesos vasculares. Las causas que explican la ausencia de modificación de éstos últimos son diversas: situación de partida adecuada de algunos indicadores (TA y accesos), recursos terapéuticos de limitada eficacia (vitamina D, quelantes y otros), recursos de apoyo insuficientes (unidades de dietética), o la elaboración/implantación incorrecta de Planes de Mejora.

En conclusión, los instrumentos de gestión clínica implantados, son eficaces para la mejora de los resultados asistenciales de ciertos aspectos de la hemodiálisis (anemia, dosis de diálisis, nutrición e inflamación), aunque han resultado de nula eficacia para mejorar los resultados del metabolismo calcio-fósforo.

Palabras clave: ***Gestión clínica*. Feedback. Benchmarking. *Calidad asistencial. Hemodiálisis.***

INTRODUCTION

In many fields of Medicine, therapeutic outcomes obtained under «ideal» circumstances, i.e., in well-controlled prospective studies (efficacy), and those obtained under «real» conditions, i.e., observational studies (effectiveness) many times differ. The presence of this fact suggests that there is a significant range for health care improvement. In this sense, it is paramount to design strategies allowing reducing the distance between research and daily practice, and thus the outcomes variability since this may have an impact on reducing morbimortality and health care costs[1]. This difference between efficacy and effectiveness has also been detected within Nephrology and Hemodialysis, in Spain as well as in other countries[2-4]. For instance, the DOPPS study (an observational study), in Spain, revealed a prevalence of 36% of patients with a Kt/v < 1.2, whereas Arenas, in an interventional study, obtained a prevalence value of 11.6%[5,6]. The reasons explaining this fact are several and complex: organizational problems, limited resources, lack of quality management tools, misconception errors among professionals and others.

Several studies seem to show that the use of certain clinical management tools may be effective to achieve health care improvement and make efficacy and effectiveness come closer. Thus, most of them have shown to be effective tools for health care quality improvement: interactive educational meetings, feedback (giving and receiving information on results obtained), benchmarking (knowing the results of the center as compared with other centers), reception of messages alerting on deviation from established goals, correct identification, and the establishment of realistic areas for improvement and, especially, combined actions[1,2,7-12].

However, and spite of the great amount of financial resources focused on research, there are no multicenter studies done with a panel of indicators evaluating the efficacy of strategies useful for dialysis in order to translate available scientific evidence into the clinical practice. The aim of this work is to assess the efficacy of implementing several clinical management tools (feedback, benchmarking, improvement plans, and interactive education) on the outcome of the hemodialysis process by means of a multicenter study.

MATERIAL AND METHODS

The hypothesis set up is the following: «performance of the proceeding of renal function replacement therapy with hemodialysis by means of a working methodology based on clinical management tools (feedback, benchmarking, improvement plans, and education) may induce a significant improvement in health care outcome.»

A prospective study has been undertaken in four dialysis centers. Study subjects comprise all patients belonging to each one of the four hemodialysis units from February of 2003 and February of 2005.

All four centers have proceeded to the implementation of a set of clinical management tools, which are basically the following:

1. Consensus and assumption of relevant hemodialysis indicators. These indicators must meet the following criteria:
   a) correlation with hemodialysis-associated morbimortality.
   b) modifiable by effective therapeutic instruments.
   c) simple and automated, i.e., generated by all dialysis units without an additional technical or organizational effort[8,13].

Due to the number of patients and duration of follow-up, this work lacks sufficient statistical power to observe changes in morbidity and mortality indicators (such as cardio-

vascular events or others), thus the inclusion of such indicators has not been considered.

2. Consensus on the establishment of realistic goals for each one of the indicators defined. These goals vary depending on baseline outcomes and their progression.
3. Indicators monitoring and referral to a Data Managing Center (DMC) with a established regularity (every 6-8 months). Indicators have been collected from all prevalent patients in the dialysis units for each one of the cut-offs done (independently of later being deceased or transplanted patients).
4. Reception of regular information on outcomes obtained by the center itself (feedback) and by other centers, so that each center may compare its outcomes with those from other centers (benchmarking).
5. Educational meetings including discussion of clinical guidelines, protocols, and particular cases, and elaboration of realistic Improvement Plans (every 6-8 months). Improvement Plans are done by each one of the participating centers when the target goal is not achieved for an indicator and only the center that has elaborated a Plan implements it. For instance, when the percentage of patients with a Kt/v < 1.2 within a center is significantly higher than that of the remaining centers, that center elaborates an *ad hoc* plan to improve the dialysis dose and implements it, but not the remaining centers. The plans were elaborated with a pragmatic criterion (summarily reflecting when and how to act and with what aim). The most significant Improvement Plans done throughout these two years have been:
   - Anemia Improvement Plan: implemented in two of the four centers, and basically aiming at studying (iron metabolism, inflammation, dialysis dose, vitamin deficiency, occult hemorrhages, and other less frequent causes) and treating anemia with iron, EPO, darbepoietin (in one center) and other less common therapies (vitamin supplements, etc.).
   - Dialysis Dose Improvement Plan: implemented in three centers, and basically including the modification of dialysis duration (three centers), blood and bath flows (three centers), access review (three centers), and use of higher permeability membranes (one center).
   - Ca-P Metabolism Improvement Plan: implemented in three centers; it has generally contemplated dietary changes, assessment of treatment adherence, review of calcium in the bath, prescription of chelating agents, vitamin D (oral or IV). During the study, paracalcitol or cinacalcet have not been used in none of the centers.
   - Nutrition Improvement Plan: implemented in one center; it summarily included the review of dialysis dose and hemoglobin, the exclusion of intercurrent diseases, and the administration of oral nutritional support (it did not contemplate prescription of intradialysis parenteral nutrition).

Demographical and associated morbidity data have been collected from each center. Included morbidity data have been: time on dialysis, late referral to the nephrology department, associated pathology, and etiology of renal failure.

The information is prospectively gathered by each center and entered into a database specifically designed. It is e-mail sent to the DMC for use. Each patient is entered in the database with a specific code so that confidentiality and protection of personal data are assured in agreement with current regulations. The data are processed by the DMC, which gives information back on each center outcomes and on the whole set of grouped data (feedback and benchmarking). This feedback information is also sent through the e-mail.

The different variables are coded and registered on an excel datasheet, performing an statistical analysis with the SPSS software for Windows (version 12.0). A descriptive analysis of the variables is done. Inferential statistical analysis is done with the indicators at the beginning of the study (baseline cut-off, before the intervention, on February of 2003) and at the end of the study (on February of 2005). The association between two quantitative variables is done by Pearson's or Spearman's correlation, depending on whether the variables are normally distributed or not. When two or more qualitative variables are compared, the Chi-square test is used. Differential analysis between groups is done by the Student's t test or Mann-Whitney U test (depending on whether the variables are normally distributed or not within the groups) and ANOVA or Kruskal-Wallis H, similarly depending on whether the variables are normally distributed or not within the groups. A statistical analysis for adjusting co-morbidities or other confounding factors has not been done.

RESULTS

Regular monitoring of previously indicators chosen by consensus between the four participating centers, described in Table I, was done. These indicators include anemia and cardiovascular disease, dialysis dose, calcium-phosphorus metabolism, nutrition and inflammation, and vascular accesses.

The total number of patients included into the study was 294 (table II). Other results on demographics and associated morbidities are shown in table II by centers.

Baseline and initial results corresponding to February of 2003 (before the intervention), and final results corresponding to February of 2005 (two years of intervention) are shown in table III.

The statistical study done reflects the presence of statistically significant differences ($p < 0.05$) between initial and final outcomes for the following indicators: % of patients with Hb < 11 g/dL (31.3 *vs* 22%), mean Kt/v (1.36 *vs* 1.44), % of patients with Kt/v < 1.2 (30% *vs* 15%), % of patients with albumin < 3.5 (32.6 *vs* 15.1), mean albumin in g/dL (3.7 *vs* 3.9), and % of patients with CRP > 5 mg/dL (7.4 *vs* 2.6).

In the other hand, we have not seen statistically significant differences for the following indicators: mean EPO dose in U/Kg/week (146.5 *vs* 136.78), % of patients with EPO dose > 300 U/Kg/week (8.6 *vs* 7.7), % of patients with SBP >140 mmHg (38.9 *vs* 36.6), % of patients with DBP >

Table I. Indicators assessed in the study

Scope and Parameter	Indicator
Anemia and cardiovascular disease	
Hemoglobin (g/dl)	Percentage of patients in the unit with Hb < 11 g/dl (% Hb < 11)
	Mean Hb
Erythropoietin (U/kg/wk)*	Mean dose in U/kg/week (mean EPO dose, U/kg/wk)
	Percentage of patients with EPO > 300 U/kg/wk (% EPO > 300 U/kg/wk)
Blood pressure (mmHg)**	Percentage of patients with mean SBP > 140 mmHg (% SBP > 140)
	Percentage of patients with mean DBP > 90 mmHg (% DBP > 90)
Dialysis dose	
Kt/v***	Percentage of patients with Kt/v < 1.2 (% kt/v < 1.2)
	Mean kt/v
Calcium/phosphorus metabolism	
Phosphorus (mg/dl)	Percentage of patients with phosphorus > 5.5 mg/dl (% P > 5.5)
Calcium x Phosphorus product	Percentage of patients with Ca x P > 55 (% Ca x P > 55)
PTH (pg/ml)	Percentage of patients with PTH 150-300 (% PTH 150-300)
	Percentage of patients with PTH > 800 (% PTH > 800)
Nutrition and inflammation	
Albumin (g/dl)	Percentage of patients with Albumin < 3.5 (% Albumin < 3.5)
	Mean albumin
C Reactive Protein (CRP, mg/dl)	Percentage of patients with CRP > 5 (% PCR > 5)
Ferritin (ng/ml)	Mean ferritin
	Percentage of patients with ferritin < 200 ng/ml
Vascular access	
Autologous AV fistulae	Percentage of autologous GAVFs (% autol. GAVF)
Synthetic graft	Percentage of patients with synthetic graft (% synthetic graft)
Permanent catheters	Percentage of permanent catheters (% Perm. cath.)
Temporary catheters	Percentage of temporary catheters (% Temp. cath.)

*Patients with darbepoietin (mcg/week) conversion multiplying by 200. **Pre-dialysis, one-month mean. ***Daugridas mono-compartmental, according to DOQI guidelines.

90 mmHg (6.4 *vs* 6.6), % of plasma P > 5.5 mg/dL (40.1 *vs* 41.4), % of patients with Ca × P > 55 (30.6 *vs* 34.9), percentage with PTH 150-300 pg/ml (27.9 *vs* 23.2), percentage of patients with PTH > 800 pg/ml (7.1 *vs* 3.4), mean plasma ferritin ng/mL (370 *vs* 424), and distribution of vascular accesses, or percentage of autologous GAVFs (79.9 *vs* 82.8).

We have studied the correlation between different variables and obtained for some of them very statistically significant results ($p < 0.01$). There is a positive correlation betwe-

Table II. Epidemiological data of patients included into the study shown by centers and data of associated morbidity (time on hemodialysis, late referral, and etiology of renal failure)

		Centers				
		1	**2**	**3**	**4**	**Total**
Number of patients		42	45	94	113	294
Age (mean ± SD)		72 ± 11,9	71 ± 12.8	68 ± 13.2	64 ± 14.6	67 ± 13.8
Gender	Male	57.1%	62.2%	57,4%	59.3%	59.5%
	Female	42.9%	37.8%	42.6%	40.7%	40.5%
Time on HD (months, mean ± SD)		24 ± 57.7	48 ± 62.9	46 ± 39	29.2 ± 39.8	36.3 ± 47.1
Late referral (Less than one month)		26,2%	27.3%	24.5%	6.2%	18.1%
Etiología of RF	Unknown renal disease	8 (19.0%)	17 (37.8%)	24 (25.5%)	25 (22.1%)	50 (25.0%)
	Glomerular renal disease	7 (16.7%)	3 (6.7%)	10 (10.6%)	14 (12.4%)	24 (12.0%)
	Interstitial renal disease	7 (16.7%)	6 (13.3%)	15 (15.9%)	18 (15.9%)	31 (15.5%)
	Adult polycystic renal disease	2 (4.8%)	1 (2.2%)	15 (15.9%)	6 (5.3%)	9 (4.5%)
	Vascular renal disease	8 (19.0%)	3 (6.7%)	13 (13.8%)	12 (10.6%)	23 (11.5%)
	Diabetes	5 (11.9%)	9 (20.0%)	15 (15.9%)	26 (23.0%)	40 (20.0%)

Table III. Pooled initial (February of 2003) and final (February of 2005) indicators

Indicator	Total	
	Initial	Final
Hb < 11 (%)	31.3	22*
Hb (Mean)	11.7	11.9
EPO (U/kg/wk) (Mean)	146.5	136.78
EPO > 300 U/kg/wk (%)	8.6	7.7
SBP > 140 (%)	38.9	36.6
DBP > 90 (%)	6.4	6
Kt/v < 1,2 (%)	30.0	15.0*
Kt/v (mean)	1,364	1,441*
P > 5,5 (%)	40.1	41.4
Ca x P > 55 (%)	30.6	34.9
PTH 150-300 (%)	27.9	23.2
PTH > 800 (%)	7.1	3.4
Albumin < 3,5 (%)	32.6	15.1*
Albumin (Mean)	3.7	3.9*
PCR > 5 (%)	7.4	2.6*
Ferritin (mean)	370 ± 285	424 ± 309
Autologous GAVF (%)	79.9	82.8
Perm. cath. (%)	9	7.3
Temp. cath. (%)	2.1	1.7

$p < 0.05$.

en Kt/v and Hb, Kt/v and albumin, albumin and Hb, albumin and time on dialysis, albumin and SBP, Ca and SBP, PTH and phosphorus, ferritin and Hb, and finally between ferritin and albumin. Thus, the greater the Kt/v, the greater the Hb and albumin and so on. On the other hand, there was a negative correlation ($p < 0.01$) between CRP and albumin, so that the greater the CRP levels, the lower the albumin.

DISCUSSION

In the present work we have obtained a significant improvement of some hemodialysis indicators, particularly those related to anemia, dialysis dose, nutrition and inflammation.

Regarding anemia, it is interesting to highlight that the decrease in the percentage of patients with low Hb (Hb < 11 g/dL) has occurred without an increase in EPO dose. We have analyzed the number of transfusions performed and although the information is not very accurate due to the retrospective nature, we observe that this value has not increased during the period 2003-2005. We believe that the reason explaining Hb improvement in those patients with the lowest values is multifactorial. The increase in dialysis dose has been a determining factor and the presence of a strong correlation between the Kt/v and plasma Hb supports its importance. Other issues that have had a considerable effect have been better anemia and nutritional status management and reducing inflammation. An increase in the percentage of patients using darbepoietin from 10% to 48% has been observed, although mainly focused in one center (varying from 0% to 92%) without Hb change in that center (mean Hb 12.2 *vs* 11.9, not significant, data not shown on the table), so that we believe that the greater darbepoietin use has not been relevant for reducing anemia. Plasma ferritin seems not to have played an important role either for improving anemia since ferritin measurement both at the beginning and at the end of the study has not changed, nor the percentage of patients with ferritin < 200 ng/mL (25 *vs* 28%, not significant, data not shown on the Table). The positive impact that the decrease of patients with low Hb has on myocardial disease, morbidity and mortality of dialysis patients[14-15] could be extrapolated to our population and represents an important objective outcomes improvement.

About the indicator of dialysis dose (Kt/v), it is known that it is the most important modifiable factor for survival of patients with end-stage chronic renal failure on hemodialysis[15-16], thus, we believe that the increase achieved is an important achievement that might translate into a decrease in morbimortality.

Nutrition-related indicators have had a favorable progression. Serum albumin has been many times recognized as the laboratory parameter correlating the best with the risk for hospitalization and death among the dialysis population[17-18]. The inflammation indicator CPR has significantly improved, and it also presents a positive correlation with the risk for hospitalization[19]. Ferritin is another inflammation indicator that has not been changed, but it is also influenced by other aspects of inflammation. We believe that improvement in nutrition and inflammation is mainly related with the increase in dialysis dose and the decrease in anemia.

Regarding arterial hypertension, we have obtained significant differences between initial and final indicators. The lack of BP improvement may be explained by a low hypertension prevalence in our study as compared with other observational studies from our environment, such as the DOPPS study (45.3 *vs* 77.4%)[5].

About the results obtained for the calcium-phosphorus metabolism, they are discouraging. It is not easy to find observational studies to know and compare our situation. In the multicenter survey carried out by Díaz Corte[4] the Ca × P product was > 60 in 33% of the patients, and in our study this value was 22% and 28% before and after the intervention, respectively (22% *vs* 28%, N.S.). We believe that the reasons explaining the lack of improvement with these indicators are multifactorial: a starting point for our indicator somewhat better than that of the DOPPS study (Ca × P > 60 22% *vs* 33%, respectively); the presence of therapeutic resources only partially effective (the lack of use of paracalcitol and cinacalcet during the study should be taken into account and considered as a potential element for improvement); the existence of insufficient resources (nutrition units, difficulties for prescribing more dialysis

days, and others); lastly, the elaboration of inappropriate Improvement Plans or failing to implement them.

We have not obtained an improvement of indicators related with the vascular access. We believe that this is due to the fact that the indicator was already appropriated from the beginning (80% of autologous fistulae).

The limitations of this study are several. The first one is due to study duration; this report refers to the first two years of the study, and in order to observe a longer improvement a longer follow-up is required. Another important limitation emerging is determining whether the improvement of these indicators has been the result of the intervention or an improvement that might have been observed in other centers not carrying out any kind of intervention. To solve this limitation, it is necessary to retrospectively recruit control centers. This is a goal in which the authors are working now. Another limitation consists in that the number of patients and the follow-up time do not allow analyzing indicators related with morbidity and mortality. Finally, it is difficult to reproduce the implementation of Improvement Plans (since they reflect different aptitudes, attitudes, and resources of centers participating in the study), and this may explain the varying and little reproducible outcomes when only Improvement Plans are applied. In any case, the intervention should be regarded as a multiple approach (feedback, benchmarking, and education) and Improvement Plans are only a part of the whole.

Any effort for improving health care should necessarily be based on the design and implementation of indicators by which observing the changes occurred[7,8]. Nevertheless, its use in an isolate way is not sufficient to induce an improvement. Problems related with health care quality are extensive and complex, and thus their solutions should necessarily come from a combined approach. Grol[9] analyzes the effects of different strategies for health care improvement and he observes that they are generally limited (sending educational material, continuous medical education, Total Quality Management), or either they have a varying effect (use of opinion leaders, feedback) or are generally positive (sending deviation alert messages); but the most effective measure is the use of several strategies in a combined manner. A multiple approach (education, benchmarking and improvement plans when deviations from the objectives occur) was successfully used in a study for improving the dialysis dose[20] and similar others[11-12]. We have chosen a strategy with multiple intervention based on active participation of the center to reach a consensus on indicators and objectives, monitoring them, and providing regular outcomes information (feedback and benchmarking), as well as organizing educational meetings and the elaboration of Improvement Plans. According to our results, this strategy seems to be adequate to measure, induce, and objectify an improvement of health care provided.

Finally, we consider that creating a Voluntary Dialysis Quality Registry with few but relevant indicators would, with no doubt, contribute to knowing and diagnosing the current situation within our setting. This may constitute an appropriate starting point for establishing improvement goals, optimizing the available resources, reducing outcomes variability, and decreasing morbimortality rates of the dialysis population.

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