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QUALITY OF CLINICAL INDICATORS STANDARDS IN HEMODIALYSIS PADRÕES DE INDICADORES CLÍNICOS DE QUALIDADE EM HEMODIÁLISE ESTÁNDARES DE INDICADORES CLÍNICOS DE CALIDAD EN HEMODIÁLISIS

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ABSTRACT

Objective: to assess quality indicators in hemodialysis in a public hospital in northeastern Brazil. Method: a retrospective documentary study of a quantitative approach with 49 patients diagnosed with Terminal Chronic Kidney Disease on Hemodialysis program for more than three months. The data was collected with a form, and they were analyzed by statistical analysis, with absolute and relative numbers, and presented in two tables and a figure and analyzed based on the literature. Results: it was found that the sample had phosphorus and hemoglobin levels in non-compliance with recommended. There was a divergence in levels of albumin, hemoglobin and phosphorus to confront the national data, while in an international study, there was disagreement on ethnic variables and albumin levels. Conclusion: to know the indicators that did not meet the quality guidelines is the first step to preventing interventions and control complications. *Descriptors*: Renal Insufficiency; Chronic; Renal Dialysis; Quality of Health Care.

Objetivo: avaliar indicadores de qualidade em hemodiálise de um hospital público do Nordeste do Brasil. Método: estudo documental retrospectivo, de abordagem quantitativa, com 49 pacientes com diagnóstico de Doença Renal Crônica Terminal em programa de hemodiálise há mais de três meses. A coleta de dados ocorreu com o auxílio de um formulário e foram analisados por meio de tratamento estatístico, com números relativos e absolutos, apresentados em duas tabelas e uma figura e analisados à luz da literatura. Resultados: verificou-se que a amostra apresentava níveis de fósforo e hemoglobina em não conformidade com o recomendado. Observou-se divergência nos níveis de albumina, hemoglobina e fósforo ao confrontar os dados nacionais, enquanto que com estudo internacional houve discordância nas variáveis etnia e níveis de albumina. Conclusão: conhecer os indicadores que não atingiram as orientações de qualidade é o primeiro passo para intervenções de prevenção e controle de complicações. Descritores: Insuficiência Renal Crônica; Diálise Renal; Qualidade da Assistência à Saúde.

Objetivo: evaluar indicadores de calidad en hemodiálisis de un hospital público del Nordeste de Brasil. Método: estudio documental retrospectivo, de enfoque cuantitativo, con 49 pacientes con diagnóstico de Enfermedad Renal Crónica Terminal en programa de hemodiálisis con más de 3 meses. La recolección de datos fue con un formulario y fueron analizados por medio de tratamiento estadístico, con números relativos y absolutos, y presentados en dos cuadros y una figura y analizados basados en la literatura. Resultados: se verificó que la muestra presentaba niveles de fósforo y hemoglobina no en conformidad con lo recomendado. Se observó divergencia en los niveles de albumina, hemoglobina y fósforo al confrontar los datos nacionales, mientras que con un estudio internacional hubo discordancia en las variables etnia y niveles de albumina. Conclusión: conocer los indicadores que no afectaron las orientaciones de calidad es el primer paso para intervenciones de prevención y control de complicaciones. Descriptores: Insuficiencia Renal Crónica; Diálisis Renal; Calidad de la Atención de Salud.

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INTRODUCTION

In Brazil, most patients with Chronic Failure (CKF) performs hemodialysis treatment. According to the census of the Brazilian Society Nephrology (SBN) in 2013, 90.8% of patients on chronic dialysis were being treated by hemodialysis and 9.2% by peritoneal dialysis.1

Several guidelines have been suggested to assess the overall care received by patients on hemodialysis. These guidelines come with the growing and constant interest of improved management models that result in the provision of services with quality, low error rate, and lower costs. Some clinical indicators may be selected to assess the quality of treatment offered, with the selection of these indicators meeting the needs of each institution.

In Brazil, most of the institutions adopt the guidelines of the quality committee of the National Kidney Foundation (NKF), responsible for preparing the updated guidelines titled Kidney Disease: Improving Global Outcomes (KDIGO), to guide the treatment provided in the renal function replacement. From these parameters, it is possible to check the results in patient care in Renal Replacement Therapy (RRT).^{2,3}

The main indicators presented by these guidelines are: adequacy of dialysis, by standard urea clearance (KT/V) above 1.2 and urea removal index (IRU) greater than 65%; the type of vascular access to perform the treatment, recommending the use of arteriovenous fistula (AVF) for more than 65% of patients; nutrition, keeping appropriate albumin rates exceeding 3.5g/dl; control of anemia with hemoglobin levels (Hb) greater than 11g/dl appropriate ferritin (greater than mg/ml); bone disease control, corrected by maintaining calcium levels (less 10,2mg/dl), phosphorus (less than 5.5 mg/dl) and parathyroid hormone (PTH), should be below; and quality of life.

The impact of dialysis quality control systems has been evaluated in observational studies, and its implementation allows interventions that improve the care indicators. There is also growing evidence that these indicators are correlated with morbidity and mortality in patients with chronic kidney disease.³

In the health area, quality services are also an increasing demand. The increasing incidence and prevalence of chronic kidney failure, in addition to the high costs of substitution treatment of renal function, has led health financing sources, both public and private, requiring maximum efficiency to ensure a better relationship between

The maintenance of these goals is not always easy. For this reason, the NKF - KDIGO develops protocols and establishes recommendations including better dialysis, management of anemia and approach to vascular access to improve survival of dialysis patients.²

resources used and the results obtained.

Made available annually by the Census of SBN and Dialysis Outcomes and Practice Patterns Study (DOPPS), data on the characteristics of patients on RRT allow to perform analysis of sociodemographic characteristics of patients on hemodialysis, as well as the analysis of outcome indicators and processes assistance. Thus, the RRT units now have comparative references in the care of the quality control offered to their patients.

This study aims to evaluate the laboratory indicators of quality of dialysis patients undergoing hemodialysis in a public hospital in northeastern Brazil.

METHOD

Documentary and retrospective study with a quantitative approach, performed in Barão de Lucena Hospital (HBL), located in Recife/PE. The study population consisted of patients registered in the hemodialysis program in HBL. The sample consisted of those who were being treated in January, February and March 2013. The study included individuals who were performing treatment assiduously, three times a week, diagnosed with Chronic Terminal Renal Disease, and were on hemodialysis for at least three months. Exclusion criteria were patients with registered records in service for less than three months or not filled. Data collection was performed only after approval by the Ethics Committee Research of the Agamenon Magalhães Hospital (CAE: 15231513.5.0000.5197). At all times, the resolution 466/12 of the National Health Council which provides for guidelines on research involving human beings in Brazil have been respected.

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Sociodemographic variables were analyzed (gender, age, ethnicity, monthly income, and education) and underlying disease to characterize the sample. In addition to being included data related to vascular access, standard urea clearance (KT/V); urea removal index (IRU); and hemoglobin (Hb), ferritin, albumin, calcium, phosphorus and parathyroid hormone (PTH). These were based on NKF goals - KDIGO.

Data collection was from January to March 2013 with the aid of a form; 67 patients underwent dialysis in HBL. However, only 45 met the pre-established criteria, as five were excluded because they are individuals with Acute Renal Failure, nine had started treatment less than three months ago, two were transferred to other services in the period related to the collection, three were treated dialysis in transit (came from other services for treatment for a short period), and three did not perform the treatment with assiduity. The data were analyzed using statistical analysis, with absolute and relative numbers, and presented in two tables and a figure and analyzed based on the literature.

RESULTS

The distribution of the sample sociodemographic data (Table 1) shows that there was a slight predominance of males (58%). The prevalent age group was 50-59 years old (40%) and over 60 years old (36%). the **54**% Regarding race, declared themselves mulattos (56%), followed by black (24%), with the white race to a lesser extent (20%). The level of education was low since 33% were classified as functionally illiterate, 24% with 8 to 10 years of study and 20% with 4 to 7 years of study. The monthly income shows that 73% received 1 to 2 minimum wages followed by those who earned less than one minimum wage (22%).

Table 1. Absolute frequency and percentage distribution of chronic kidney failure of patients on hemodialysis of HBL in the first quarter of 2013 according to sociodemographic aspects.

- Variable	Category	n=49	%
Gender	Male	26	58
	Female	19	42
Age	≤ 29 years old	1	2
	30 - 39 years old	4	9
	40 - 49 years old	6	13
	50 - 59 years old	18	40
	≥ 60 years old	16	36
Race	White	9	20
	Black	11	24
	Mulatto	25	56
	Indigenous	0	0
Education	Functional illiteracy	15	33
	4 to 7 years of study	09	20
	8 to 10 years of study	11	24
	11 to 14 years of study	08	18
	≥ 15 years of study	02	5
Renda mensal	< 1 minimum wage	10	22
	1 - 2 minimum wages	33	73
	3 - 5 minimum wages	2	5
	> 5 minimum wages	0	0
Total		45	100

Regarding the age of the sample of HBL, the average was 55.54 years old, and there was a variation of 18-83 years old. According to Table 01, 76% of subjects were above 50 years old, and 40% aged 50-59 years old, considered an adult-aged sample.

Table 2. Sample distribution according to the disease based on CKF.

Based disease	n=49	%
Diabetes Mellitus	21	47
Hypertension	32	71
Glomerulopathies	5	11
Outros	4	9

It is observed in Table 02 that 71% had systemic hypertension, 47% had diabetes mellitus, being important to note that 38% (17 patients) showed an association between the two diseases.

Glomerulopathies were present in only five patients (11%) and other causes identified as pharmacological, and cysts accounted for only 9%.

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In the vascular access to perform HD, 78% had an arteriovenous fistula (AVF), 20% used dual lumen catheters with or without cuff and 2% used arteriovenous exert.

As for the results of laboratory tests (Figure 01), the variables were presented according to the frequency values outside the normal range for patients with CKF, that

is not by the recommendations of the NKF - KDIGO. The variables and results more frequently inadequate values were: hemoglobin (64%), phosphorus (49%) and PTH (38%). The other parameters showed a lower percentage of non-conformance: ferritin (20%), calcium (20%), albumin (7%), IRU (20%) and Ktv (16%).

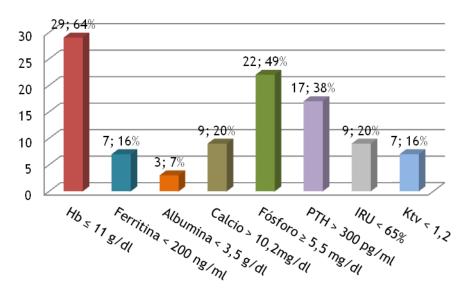


Figure 1. Percentage and absolute distribution of patients with tests in non-compliance with recommended rates by NKF-KDIGO. HBL, Recife (PE), in 2013.

Patients followed at HBL showed 64% of the sample with Hb levels below or equal to 11g/dl. Similarly, the phosphorus levels were increased ($\geq 5,5mg/dl$) in 49% of patients followed.

DISCUSSION

According to Table 01, 58% of the sample were males. These results were similar to the international study¹¹ and dialysis census of SBN¹ in which the first study 60% of patients were males and in the second study, there were 58%.

Gender differences in the progression of kidney disease may be related to hormonal and etiological aspects. The mechanisms responsible for these differences are potentially related to differences in the structure and glomerular hemodynamics, variations in production and local activity of cytokines and hormones, and direct effect of sex hormones on renal cells. The male becomes more susceptible to disease than women since men believe they are less vulnerable, and they seek fewer health services. This statement affects these individuals care less about their health, exposing themselves to more risk situations.

As for the age of hemodialysis patients, the studies highlighted the higher age groups. These findings can be attributed to the natural history of diseases such as diabetes mellitus and hypertension, leading to loss of kidney function over the years and it is also a result of poor eating habits and lack of physical activity throughout life, as well of genetics, stress and other determining factors.⁵

By analyzing the race of the individuals, it was realized that 56% were mixed race, and 24% were black. This data can be justified by the great miscegenation in the Northeast of Brazil, having increased incidence of brown. According to the Population Census conducted in 2010, 43.1% of Brazilians declared themselves mulatto while 7.6% were black.⁶

In an international study conducted in North America, Europe, and Asia, 61% of subjects were white, and 11% considered black. 11 This difference can be explained by the characteristics of the populations studied in DOPPS study, involving North-Americans, Europeans, and Japanese population.

Due to the high degree of miscegenation in Brazil, the evaluation of the influence of ethnic factors in kidney disease becomes difficult. Therefore, there is no conclusive evidence that African descent or other

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Brazilian ethnic minorities are particularly vulnerable to kidney disease.

According to data found, 33% of the sample was considered functionally illiterate, since they did not fit into four years of study. The education level directly influences the assimilation of the guidelines on the condition, so the lower the educational level, the more difficult it becomes to understand the diagnosis, the need to change habits and posology schemes.⁸

It is observed that 95% of individuals have an income less than two minimum wages, data similar to the survey conducted in the Northeast and South of Brazil. 9-8 The difficulty of access to health systems and inadequate control of diseases such as hypertension and diabetes may explain the association between low socioeconomic status and CKF. Also, the reduction in socioeconomic status negatively influences access to kidney transplantation and mortality in patients with CKF. 1

Low socioeconomic profile of hemodialysis patients is a causal factor and not a consequence of CKF.⁷ Thus, in individuals with lower income referral to a nephrologist is slow, contributing to a greater commitment of these patients starting renal replacement therapy.

Concerning the underlying disease, there was a prevalence of hypertension followed by DM as well as a high percentage of patients with two associated pathologies. In other studies, the results were similar, and the SAH and the DM responsible for changes of "target organ", as the kidneys. ^{7.9}

The DM and SAH patients may have several associated comorbidities that limit their survival and their quality of life before and during dialysis treatment. In their studies, Van and col¹⁰ say that survival at five years for diabetic hemodialysis is worse than in non-diabetics, 41.1% versus 62.7%, respectively.¹⁰

Regarding the type of vascular access used in patients treated at the HBL, it was found that 78% were using AVF, 20% of CDL (tunneled and non-tunneled) and only one patient with PTFE. In the DOPPS study, 66% were using AVF; 24% used CDL and 10% used PTFE.

According to SBN¹ census, 15.4% of patients were using CDL in Brazil. According to the recommendations of the NKF-KDIGO, the rate of patients with FAV should be

greater than 65% while the use of indwelling catheter should be less than 10% of patients.²

By analyzing the hemoglobin levels of patients, it is observed that 64% had levels below the recommended. This figure was higher than the SBN¹ census (33%) and DOPPS¹¹ study (38%), stating that these studies a smaller percentage of results were out of the recommendations in the NKF-KDIGO. In research conducted in the state of Maranhão, there were even greater rates of individuals (89%), suggesting a similar behavior among states in the Northeast.¹²

According to the NKF-KDIGO, anemia develops early during CKD, and it is almost universal in stage 5 of CKF. 13

The anemia in patients with CKF is a known risk factor for some adverse events including hospitalizations, cardiovascular disease, cognitive impairment, mortality. The major impact of anemia in this population is associated with decreased quality of life translated by decreased aerobic capacity, well-being, sexual function and cognitive function. Moreover, it can be associated with the occurrence of left ventricular hypertrophy and increased drop rate of glomerular filtration. 14

The absolute or functional iron deficiency plays an important role in the pathogenesis of anemia in CKF. This occurs because the synthesis of hemoglobin depends on adequate supplies of iron. Hence, the need to restore or maintain adequate iron stores in patients with CKF.¹⁴

Ferritin has been a marker extensively used to evaluate the body iron stores, as well as to monitor the treatment of anemia in CKF. Changes in the level of iron in patients with CKF are subject to blood loss, sequestration by the reticuloendothelial system and decreased intestinal absorption.¹⁴

In the study population, 16% had ferritin levels less than 200 ng/ml, demonstrating that anemia in many patients is not linked to iron deficiency. In DOPPS study¹¹, 20% of subjects had lower ferritin to 200ng/ml.

Besides anemia, the nutritional status of patients on hemodialysis **CKF** must constantly monitored, since the be relationship between malnutrition and mortality in hemodialysis patients has been reported in numerous studies.^{3,16}

Changes in nutritional order in hemodialysis patients should be diagnosed

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early and corrected. When present, the protein-calorie malnutrition can worsen the clinical course, it favors the appearance of infections, increases the length of hospital stay and worsens the quality of life of these individuals. Nutritional changes contribute to abnormalities in bodily levels of amino acids, metabolic acidosis, endocrine disorders, heart failure, inflammation, infection, and anemia, among others. ¹⁷

As the CKF leads to a reduction in both the fat reserves as of lean body mass, looking for methods to quantify this depletion effectively is a constant. The dosage serum albumin is a widely used method because the purpose of the ease with which this protein can be measured, clinical nutritional marker frequently used in dialysis patients, the determinant of clinical events in this population. However, it is important to note that hypoalbuminemia indicates inflammation states, common among these patients.¹⁶

In a study by Silva et al., serum albumin levels below 2.5 g/dl were associated with risk of death 20 times higher when compared to reference values from 4.0 to $4.5 \, \text{g/dl.}^{18}$

In this study, it was found that only 7% serum albumin had less than desirable, that is, 93% of patients had albumin levels above 3.5 g/dl. The data of SBN¹ and DOPPS¹¹ study were higher, representing 15% and 23.7% with serum albumin below 3.5 g/dl.

The hyperphosphatemia is a very common condition among patients with chronic kidney disease, especially those undergoing hemodialysis therapy and it is associated with morbidity and mortality in these patients, especially related to cardiovascular events. The high calciumphosphorus product also brings harm, and it is considered secondary to the calcification of the coronary arteries, leading to ischemic heart disease, myocardial infarction, and cardiac arrest.³

In stage 5 of CKD, the risk of death increases when the serum phosphorus is above 5.0mg/dl. Thus, the maintenance of serum phosphorus levels within the normal range are associated with better outcomes.¹⁹

It is observed that 49% of patients had phosphorus levels above 5.5 mg/dl. Inadequate phosphorus levels were higher than SBN¹ census and DOPPS¹¹ study which

reached percentages of 36% and 34.3%, respectively. However, once again, it coincided with those obtained in research Maranhão, in which 44% of the patients had phosphorus levels above normal.¹²

The percentage of PTH patients with above 38% is suitable. This amount was in line with the DOPPS study data (40%).¹¹

Calcium levels were affected in 20% of the sample value similar to another study, in which 18% of patients were with hypercalcemia. 12

According to the NKF-KDIGO²⁰, a strong phosphorus control at levels below 6.5 mg/dl is of vital importance for patients on chronic dialysis, which should be achieved not only with the dialysis regime but primarily by manipulating the uptake of phosphorus in the gastrointestinal tract.

The results of a study in Europe²¹ showed that hyperphosphatemia patients in hemodialysis showed a good level of knowledge about the consequences and treatment of hyperphosphatemia, but a low adherence to recommendations regarding diet and use of phosphate binders.

Secondary Hyperparathyroidism (HPS) of individuals was also evaluated, showing that 38% of the sample had intact PTH levels greater than 300 pg/ml. These values were similar to the DOPPS¹¹ study and higher than the Census of SBN.¹ The HPS is the main skeletal disorder - the fibrous osteitis - that occurs in the CKF. The elevation of PTH levels and the deficit of calcitriol are already detected in the incipient stages of CKD. During the CKF, metabolic disorders, such as hyperphosphatemia and hypocalcemia can be observed along those hormonal changes.¹⁹

The prevalence of HPS has increased due to improved quality of dialysis treatment consequently, increased survival. Thus, the patient developed the disease was slow and progressive evolution. Apparently subtle changes in the dialysis prescription as the calcium concentration in the dialysis solution or the kind of phosphate binder may influence the bone remodeling and PTH. The proper handling of these resources can be a very useful tool for maintaining appropriate levels of serum PTH and normalization of bone improvement. The most effective control of phosphorus helps to reduce the stimulation of parathyroid hyperplasia and PTH secretion. 19

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A study conducted in France reveals that only 33% of patients are with PTH in the normal range and also states that it is not easy to achieve good results with traditional therapeutic option.³

The success of treatment depends largely the understanding, motivation and determination of patients to changes and drug treatment. construction of educational approach should be highlighted as a strategy to stimulate the accession of these patients, reducing morbidity and mortality during treatment kidney disease.²¹

Several studies have shown that patients are receiving an inadequate dose of dialysis having higher mortality. The clinical signs and symptoms alone are not reliable indicators of dialysis adequacy, and this measurement performed at least once a month. The ratio of the IRU with mortality suggests that there is a progressive and significant reduction of this as the IRU is increased to above 60%. Comparison of patients with 65% to 69% with IRU patients with IRU below 60%, the authors observed that the latter had a higher risk of mortality. 15

Another widespread parameter is the Kt/V urea. The decrease of 0.1 unit on the Kt/V has been independently associated with increased number and days of hospitalization and increased costs. Therefore, the patients with low Kt/V urea had higher hospitalization and mortality rate than those with high Kt/V.³

Thus, the NKF-KDIGO recommendations involve prescribing an SPKT/V of 1.3, which corresponds to an average URR of 70%, so the patient receives an SPKT/V mininmum or 1.2 IRU average of 65%.³

In HBL sample, it was observed that 20% of patients had IRU less than 65% and a 16% Kt/V <1.2. The IRU has not been evaluated by the DOPPS (2013) and SBN, but they showed in their studies that we found a Kt/V below 1.2 in 19% and 20.9% of patients, respectively.

CONCLUSION

The systematic analysis of clinical indicators enables a real-time view of the quality of service and offers the opportunity to point and assertive interventions.

As for laboratory tests, it was found that a significant amount had phosphorus levels

and hemoglobin in non-compliance with recommended.

Confronting the study data with the Census of SBN¹, divergence was observed in the levels of albumin, hemoglobin, and phosphorus. In comparison with the DOPPS study, the variables with disagreement were ethnicity and albumin levels.

Knowledge of indicators that did not reach the NKF-KDIGO guidelines is important for the multidisciplinary team seeks effective interventions for prevention and control of such complications. This study identifies the need to promote educational activities for patients on hemodialysis, addressing the relevant aspects of the disease, treatment, prevention, control of intradialytic complications and medication adherence.

It is important to highlight that the identification of indicators that need intervention is the first step of the process involving the creation and an action plan in which the next step would be the record of corrective actions, responsible for the conduct and creating deadlines for reassessment.

In addition to the limitations of the retrospective study, such as memory and lack of data, the poor quality of notes represented a barrier present in several charts that were evaluated. To improve the quality of data, research the nursing report and record book CTDL implants were necessary, construct **AVF** in surgical, healing, thus the doubts arising dates, incorrect or missing data in medical records.

Another important aspect is that the institution does not have its mapped routines. Thus, it is questioned the tests collection technique with post-dialysis urea, which jeopardizes the reliability of the results of the IRU and Kt/v. Such enlightenment can only be done through an observational research.

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Quality of clinical indicators standards...

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