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Adult hemodialysis patients, "paricalcitol" prescription, is there any difference between the corrected Ca and normal Ca?

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ABSTRACT

End-stage renal disease (ESRD) and renal-replacement therapy in our country as it is all over the world in the most preferred with form bicarbonate hemodialysis. The 19-nor1 itamini analog of D v 0.25-dihyroxyvitamin D2 (paricalcitol) in the use of hemodialysis as we have encountered an increasing preparate. This prescription drug is likely to bring additional costs by reason, is limited to reimbursement by insurance companies. In this study, serum Ca values, instead of using the value of serum correcrtedCa paricalcitol and this situation will be reviewed possible changes, see if it will be statistically significant. K / DOQI guide based on the study, 19-nor1 dihyroxyvitamin 0.25-D2 (paricalcitol) in prescription, correctedCa revealing whether the use is necessary. Hemodialysis centers and eight months in a special configuration, this study inclusion criteria was carried out with the participation of a total of 35 adult patients. In the blood serum of patients, albumin, iPTH, Ca and P 'is a look at "paricalcitol" treatment can be started, and this situation can not be taken into account when correctedCa fact if the differences of views can occur. Levels of serum Ca 9.2 mg / dl values in the prescription, 10.2 mg / dL, treatment was considered as the cut-off threshold (Turkey, institution of insurance reimbursement-2008). Patients were evaluated in four main groups, statistical studies were done. The groups this study; group A: the most in December 2008 on vitamin D treated 23 patients, 30% and least in June 2009 in 27 patients, 20%, paricalcitol prescription in writing correctedCa is running varied. Group B: total number of patients in this group of eight months were identified as 5. Group C: serum Ca value taken into account when paricalcitol prescribing criteria that match all on a monthly basis the total number of patients, and February, 28 patients and through most of June the 20 patients, at least as have been identified. Group D: serum albuminin'e correctedCa value calculated by taking into account patients' prescriptions to be written, consists of monthly total. Minimum number of patients in this group was 16 December 08'de most patients were found to be 25 in February 09'da. In Group C and Group D, the statistical study, p <0.05 as statistically significant results were found. During eight months in adult

hemodialysis patients this study shows that the serum Ca value of paricalcitol instead of always writing a prescription, the serum should be used for correctedCa. Perhaps the most important data to confirm these results, no doubt the magnitude of the difference between group C and group D was statistically significant and it is formed (p <0.05).

Key words: hemodialysis, paricalcitol, correctedCa, prescription.

İNTRODUCTİON

Stage V-called end-stage renal disease (ESRD), renal replacement therapies in our country is undoubtedly the most preferred all over the world, as in hemodialysis. Bicarbonate hemodialysis treatments in recent years in practice, stands out more. Many countries have now abolished the use of acetate dialysis solution (11,12,15). Studies have pre-hemodialysis plasma bicarbonate concentration of 20-23 mEq / L should be shown (15). Giving oral sodium bicarbonate to raise the level of pre-bicarbonate hemodialysis or dialysis bicarbonate solution to increase the level of applications, which still continues to date. Due to the risk of metabolic alkalosis after hemodialysis, the level of 20-23 on the removal of bicarbonate is not recommended. Studies in patients with exits on this level, as a result of hyperventilation and showed that the increase in arrhythmias (12.15). Hemodialysis solution Ca levels, typically 2.5 to 3.5 mEq / L is recommended. However, this level of calcium containing phosphate binder in patients using 2.5 mEq / L, Ca-free phosphate binder in patients using 3.5 mEq / L is recommended. In these levels, the clinical responses of patients and must be reorganized if necessary, to the values of iPTH (15). As we have seen both bicarbonate, and calcium levels appears to be the parameters for each patient that requires a special setting. Acute regulation of prescribed time, the hemodialysis solution is also important for the Ca^{2+} level 'is. Van der Sande and et al, did a study, the level of calcium in hemodialysis solution as 3.0 mEq / L lower than if, are at increased risk for hypotension (12). Hypotension is the most frequently encountered complications of hemodialysis is vascular access (AV fistula, etc.) to prevent entry by the effect, directly affecting the treatment of a serious condition. In fact, in recent years, the long-term hemodialysis patients with hypotension, renal transplantsyon priority on the agenda is the recognition. According to the studies of serum calcium level is low, in addition to hypotension in patients, increases the incidence of tetany and convulsion (15). This situation carries risks, most importantly, the patients not completing the four-hour hemodialysis force it. More research on the value of serum calcium in hemodialysis patients, serum calcium - is the relationship between mortality, predialysis serum calcium value of 9-12 mg / dL is recommended. 12mg/dL the level of risk is defined as the figures above and below the level of 7mg/dL (15). Hemodialysis patients with acute and chronic recipe is so important Ca^{2+}, an essential element of the important functions. Transported as protein-bound Ca^{2+} of 80% albumin and moved. End-stage renal disease (ESRD), hemodialysis patients with stage 5, the albumin 'is connected to the existing serious problems, it significantly affects the levels of total calcium (4). Adult hemodialysis patients with a normal albumin concentration of the target 4g/dl is accepted, albumin at 1g/dL change that, the concentration of calcium 0.8 mg / dl change. Book of the corrected amount of calcium as an information, correctedCa^{2+} = measured total Ca^{2+} + 0.8 x (4 – albumin level), calculated with the formula (11). In routine practice, however, a special calculation sheets are available and when the information is entered (albumin, Ca, P, iPTH), the computer automatically adjusted the amount of corrected calcium, and even calculates the amount of the correctedCa x P. Automatic calculation of this and similar statements, insurance reimbursement is updated according to the criteria prescribed clinicians manuscripts shows great ease. We make our aim in this study, serum calcium values, instead of using the values of serum correctedCa, paricalcitol prove the

possible changes in prescription is exactly at this point is important. That is, if you study using correcedCa^{2+} prescribing, serum Ca^{2+} level statistically significantly different according to the writing of a prescription if, at that time as a result of laboratory analysis will be on the agenda by giving corretedCa^{2+} values. This situation constitutes the direction of the original study and the presentation of a new information service, conducts clinicians. The study will result in our opinion, the K / DOQI guidelines on the basis of eligibility criteria to ensure a uniform and two types of prescribing practice will last.

EXPERİMENTAL SECTİON

Methods

Each session, three sessions per week and at least four hours of follow-up of treated adult hemodialysis patients in this study, including in December 2008, June 2009, including the eight-month time span contains. In this study, carried out in a hemodialysis unit of a private, meet admission criteria (table1) and permits information from the special forms of 35 patients have been archived. Evaluation phase of the study, general surgeon (hiperparatroidi assessment), and anesthesiologist (convulsions assessment) and assessment of HBS-HCV-positive patient in the infectious diseases specialist, took active part. Owing to the importance of the blood samples were taken in predialysis patients. The samples, after the clinical coagulation process - the process of centrifugal device and subjected to electro- mag m 4812 and sera separated. Sent to the relevant laboratory in accordance with the cold chain. In the laboratory, with the VITROS 5.1 VITROS FS Architect 2000 SR 950 devices and Abott and Beckman Coulter Access 2 devices were used. Correct the tests are likely to be re-tried a second laboratory and the results are correct forms of data records has been done particular attention. The study prepared special forms in person by the physician, patients' Ca, CaxP and correctedCa, correctedCaxP values is obtained by registration. Adjusted Ca and correctedCaxP calculation technique has been preferred as the automated computer programs.

In our unit, "paricalcitol" as criteria for prescribing, Turkey, institution of insurance reimbursement-2008 with the foresight of the two restriction rule has been respected, the first of which, "dialysate calcium 1.25 mmol / L despite the use of albumin-corrected serum calcium 9.2 mg / dL and serum phosphorus below the 5 mg / dL, and under parathyroid hormone (iPTH) level 300 pg / mL in patients under hemodialysis treatment begins with " rule. Secondly, the "corrected serum calcium levels in the same patient group, 10.2 mg / dL or serum phosphorus levels of 6 mg / dl cut cases, exceed" has been the rule. The study followed six chapters grouped groupings. Group A, the Ca value of 9.2 mg / dL, while below, correctedCa value of 9.2 mg / dL on the determination of the patients on a monthly basis. Group B, the Ca value of 10.2 mg / dL, while below, correctedCa value of 10.2 mg / dL on the outgoing, ie, treatment failure patients on a monthly basis to include the numerical determination. Group C on a monthly basis all of our patients, iPTH, albumin, Ca, P, CaxP, with detection levels of vitamin D analogue (paricalcitol) required patients to use, includes monthly numerical findings. Group D, iPTH, albumin, and correctedCaxP correctedCa values, paricalcitol patients required the use of numerical findings on a monthly basis, Group E, the percentage of patients with slices of the evaluation group by months. Group F, the total includes the numerical evaluation of patients on a monthly basis. In our study, all of these stages, the data, the level of significance was analyzed by SPSS 17 statistical package program. Comparison of the corrected values in the normal and non-parametric tests for statistical analysis, Mann-Whitney U test was used. All patients who participated in the study have been subjected to special education by a dietitian, foods likely to affect blood biyokimyalarını excited about and follow up on this issue was a private patient, because studies of serum albumin, is affected by dietary phosphorus and calcium levels(8).

Grup A: The value of serum Ca 9.2 mg / dL, while the value of serum correctedCa 9.2 mg / dL or higher number of patients with this condition and the distribution by months (Table 3). In other words, should not take prescription correctedCa value is taken into account, patients prescribed post. December: 6 patients, January: 5 patients, February: 0 patient, March: 4 patients, April: 3 patients, May: 3 patients, June: 3 patients, on July 3 as a patient, a total of 27 patients were identified.

Grup B: The value of serum Ca 10.2 mg / dL, while the value of correctedCa 10.2 mg / dL on the number of patients with, namely the serum of patients required discontinuation of therapy on a monthly basis according to the value correctedCa numerical distributions. In this group, the distribution by months, December: 1 patient, January: 1 patient, April 1 patient, May: 2 patients, 5 patients in total have been found to be, February, March, June, July and have been identified in patients.

Grup C: In total 35 patients who fit our criteria and were included in the study, the serum calcium value on a monthly basis according to the total number of patients in treatment. Distribution of patients by months; December: 23 patients, January: 28 patients, February: 25 patients, March: 25 patients, April: 25 patients, May: 25 patients, June: 27 patients, July: 20 patients, the prescription to be written The number of patients who qualify for the monthly average, 24.75, respectively.

Grup D: In total 35 patients who fit our criteria and were included in the study, the monthly number of patients treated according to the value of serum correctedCa. In other words, Group D = Group C-Group A + Group B (correctedCa value to be written according to the prescribed number of patients actually prescribed according to the value D = patients with serum Ca - + correctedCa correctedCa according to the value prescribed by the value of treatment needs to be cut will not take patients). Distributions of the patients, December: 16 patients, January: 22 patients, February: 25 patients, March: 21 patients, April: 21 patients, May: 20 patients, June: 24 patients, July: In 17 patients, who qualify for prescriptions to be written The number of patients per month on average is 20.75, respectively.

Grup E: patients should continue treatment according to the value of serum Ca, correctedCa value considering the number of patients should not receive a prescription medication needs to be cut and the number of patients% in rate. By months of the % of rates, December: 30%, January: 21%, February: 0%, March: 16%, April: 16%, May: 20%, June: 11%, July: 15% were identified as.

Grup F: Follow-up study that fits our criteria and assessment of the total number of patients on a monthly basis. All months, 35 patients were follow-up. One of the important findings from the groups identified in the study, the statistical study between Group C and Group D, $p < 0.05$ significant difference as has come out. However, the numerical values of the average between the two groups, Group C, patients with an average 24.75, 20.75 in Group D as a patient, ie 12% have been identified as a serious difference.

Tablo1. Inclusion and exclusion criteria for evaluation of patients

1.Adult hemodialysis patient and three sessions per week 4 of treatment, agrees to be bicarbonate not to see the treatment of peritoneal dialysis.
2.Restriction diet that rich foods, calcium and albumin-balanced diet balanced to accept the application.
3.Treatment drug start; “serum iPTH > 300 pq/mL, serum Ca < 9.2 mg/dL, serum P <5 mg/dL” accepted that rule.
4.Treatment cut of; “serum iPTH < 300 pq/ml, serum Ca > 10.2 mg/dL, serum P >6 mg/dL” accepted that rule.

Table2: "paricalcitol" usage policies (Turkey BUT 2008)

(1). Hemodiyalizat calcium 1.25 mmol / l despite the use of albumin-corrected serum calcium 9.2 mg / dl and serum phosphorus, 5 mg / dl, and parathyroid hormone (iPTH) levels> 300 pg / ml in patients at the start of the hemodialysis treatment.
(2). Corrected serum calcium levels in the same patient group, 10.2 mg / dL or serum phosphorus levels 6 mg / dl cut of if passed.
(3) Related conditions such as in patients under hemodialysis treatment or dialysis-certified in internal medicine nephrology / child health and diseases specialist physicians organized by one of the doctors or the medical report pursuant to 3 months of dialysis dose can be prescribed by physicians certified.
(4) Research results will be prescribed in the annex. Recipe repeat prescription should be attached to the results of new tests.

Table3: 8-month time period, the patient distribution according to groups

	A	B	C	D	E	F
December. 08	6	1	23	16	%30	35
January.09	5	1	28	22	%21	35
Febbruary.09	0	0	25	25	%0	35
March. 09	4	0	25	21	%16	35
April. 09	3	1	25	21	%16	35
May. 09	3	2	25	20	%20	35
June. 09	3	0	27	24	%11	35
July. 09	3	0	20	17	%15	35

February 2009, except for all the months between the group C and group D has a statistically significant difference (P = 0.001 <0.05).

A: by months and serum Ca value of 9.2 mg / dL, while the value of serum correctedCa 9.2 mg / dL and above the number of patients (correctedCa value taken into account, should not take prescription, prescription patients post).**B:** by months and serum Ca value of 10.2 mg / dL, while the value of correctedCa 10.2 mg / dL is the number of patients (according to the value correctedCa patients required cut of therapy). **C:** by months and serum Ca value of the total number of patients who qualify according to the prescriptions to be written. **D:** according to months correctedCa value be able to prescription numeral total patients. **E:** by months, the on going treatment of patients according to the value of serum Ca, correctedCa value considering the number of patients should not receive a prescription medication needs to be cut and the number of patients % in rate. **F:** the total number of patients matched the inclusion criteria and follow-up.

Figure1: corrected Ca prescription should be written considering the assessment of % count on for months.

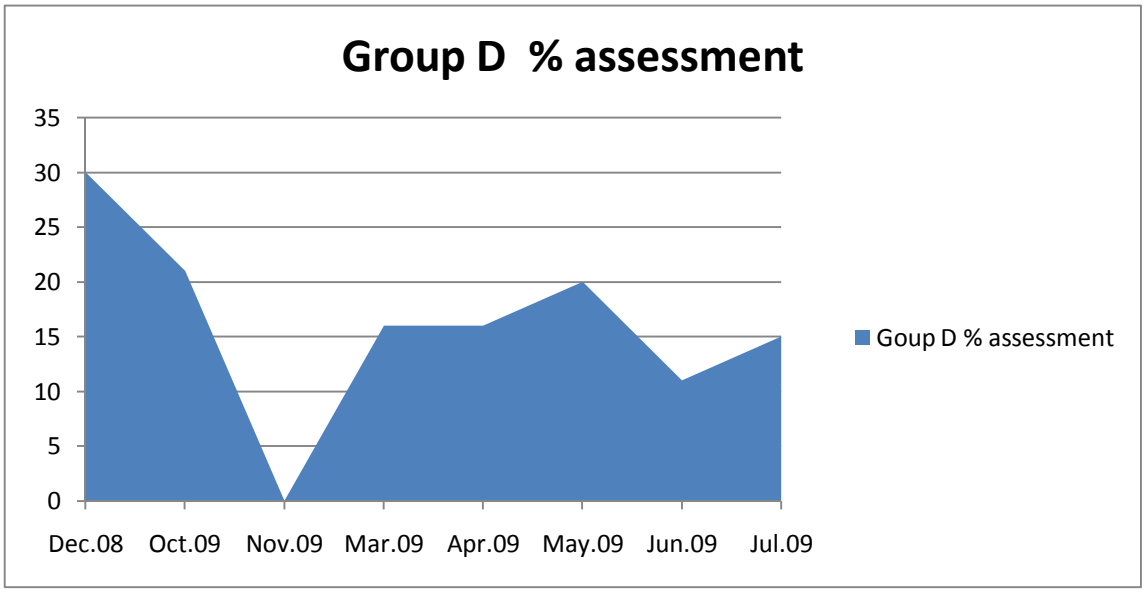
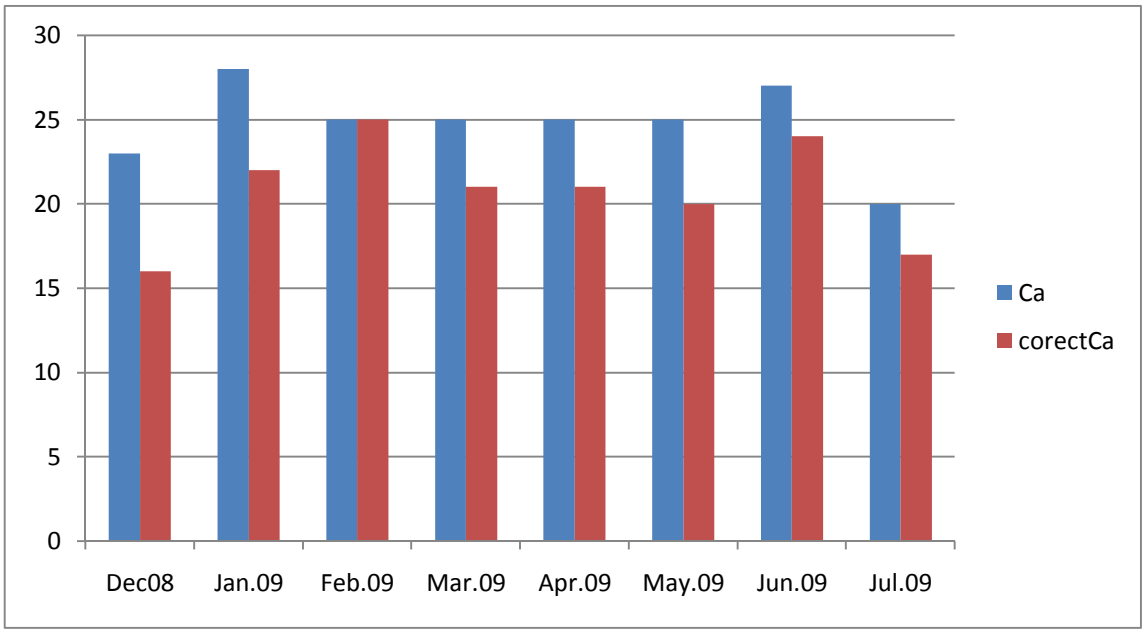


Figure2: when the number of prescriptions by months of Ca into account and consider correctedCa when the number of prescriptions (Group C and Group D).



Serum Ca and corrected serum Ca values with the exception of the months of February, there is statistically significant difference (P = 0.001 <0.05).

DISCUSSION

K / DOQI guidelines are being considered as the serum Ca value of serum correctedCa our country 'is also commonly used as treatment protocols. On the other hand, as a result of any laboratory correctedCa value of serum are not clinicians. This situation is brought difficulties, such as hemodialysis treatment protocol regulating the work of all physicians felt our team. The point we want to dwell on the debate, this difficulty in the regulation of the treatment protocol, but also stated that this situation will be a scientific basis. Explained the details of part of the

study findings, suggest precisely 'that, in February 2009, except for all the months between group C and group D has a statistically significant difference (P = 0.001 <0.05). If we open this finding a bit more, what it means to be summarized as follows; correctedCa value of serum treatment protocols must be taken into account, otherwise you may be prescribing errors. A similar study might be the subject of our study is lack of discussion about the subject and so far the only scientific study of the nature of transport, maybe 'cause we use such an expression may have been ambitious. However, according to our opinion, these evaluations, will offer new perspectives on the subject, the new trials will be conducive to the beginning and most of all, I will be the subject vehicle to carry scientific platforms. As shown in our study, statistically significant data are we talking about a scientific (Table 3, P <0.05). Here you opened the discussion about movement, working as a team, we want to deal with two suites of solutions. The first of these, brought samples to laboratories in all patients, serum albumin and serum calcium values are considered together. If the second suggestion, depending on levels of serum albumin (eg, serum albumin value 4g/dL and six) in serum of patients correctedCa value can be calculated. The first of these, bring an additional burden in terms of budgets, cost analysis If done appears to be a suggestion of possible criticism at, something to remember, and the value of serum albumin, serum correctedCa value as well as laboratory parameters of vital importance. Owen et al in 1993, Held et al 1994, 1996 and Churchill et al suggest that 'the serum albumin level 4.0g/dL' below thought, the risk of mortality in hemodialysis patients with end stage renal disease is increasing dramatically. However, in addition, the Yazar H et al 2009 and lasted 34 months, 70 adult hemodialysis patients with follow-up prospective study of mortality in similarly dramatic results were revealed (7). Modern medical science, "reduction of mortality," the basic objective when considering the fact that the proposal into the health of the scientific basis and the real direction of society is emerging more clearly. In our opinion, the second proposal, the selected patients and physicians in the service of patients presenting in the form of Ca correctedCa calculated values, ie, if given as a result of laboratory analysis, an approach that should be considered with the same perspective.

RESULTS

We know that results achieved in two main headings:
1. correctedCa value of serum and serum Ca value "paricalcitol" vary in terms of writing prescriptions, and this is valuable statistically (p <0.05).
2. patients whose serum albumin levels 4g/dL, treatment protocols, regulations and prescriptions, these values must be calculated taking into account the value of serum correctedCa be written.

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