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Some profiles of diabetic CKD patients with AVF on haemodialysis

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Abstract

Background: Diabetes mellitus is one of the major chronic non communicable diseases that affect millions globally. Diabetic nephropathy is a serious complication of diabetes mellitus, often leading to end stage kidney disease (CKD). **Objectives:** The aim of this study was to assess some profiles of diabetic end stage kidney disease patients with AVF on haemodialysis at baseline and adequacy of treatment after three months follow up regarding different clinical and laboratory parameters.

Methodology: The current prospective study was carried out in the haemodialysis unit in AL-Hussein Teaching Hospital (Iraq / Thi-Qar) from April to July 2016. The number of patients included in the study was (24) patients.

Results: The majority of patients were not educated and 50 % of them were smokers. The adherence rate of the patients with haemodialysis schedule was 50%. The prevalence of HCV infection was significantly higher among adherent than non-adherent patients.

Conclusion: The management of diabetic end stage kidney disease patients with AVF on maintenance haemodialysis is considered inadequate and there was a high rate of acquiring viral hepatitis C infection after beginning sessions of hemodialysis.

Key words : AVF, CKD, hemodialysis, diabetic nephropathy, Iraq.

الخلاصة:

ا**لخلفية** : يعتبر مرض السكر من الامراض المهمة و غير المعدية و يصيب الملايين في انحاء العالم. عجز الكلية المزمن الناتج عن مرض السكر من المضاعفات التي تنتج عن هذا المرض المزمن.

ا**هداف الدراسة**: ان الهدف من هذه الدراسة هو التقييم لبعض ملامح العجز الكلوي الناتج عن مرض السكر المزمن بعد اجراء عملية الربط الدائمي لهم و اجراء الغسل الدموي لهم في البداية و بعد المتابعة لهم لمدة ثلاثة اشهر لتحديد مدى كفاية الغسل الدموي.

الطريقة: هذه الدراسية الاستباقية الحالية انجزت في وحدة الكلية الصناعية في مستشفى الحسين التعليمي في الناصرية (العراق) من شهر نيسان الى شهر حزيران لسنة 2016. لقد كان عدد المرضى هو 24 مريض.

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النتائج: اغلب المرضى غير متعلمين و نصف عدد المرضى مدخنين. التزام المرضى بالغسل الدموي كان بنسبة (50%). عدد المرضى المصابين بالتهاب الكبد الفايروسي (سي) كان اعلى لدى الملتزمين بالغسل الدموي بالمقارنة مع المرضى غير الملتزمين بالغسل الدموي.

الاستنتاج: علاج المرضى المصابين بمرض العجز الكلوي المزمن الناتج عن مرض السكر المزمن و لديهم ربط مزمن في المرفق يعتبر غير كافي بالنسبة للغسل الدموي و هناك عدد كبير من المرضى الذين اصيبوا بالتهاب الكبد الفايروسي (س) بعد البدء بعملية الغسل الدموي.

Introduction

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.

Diabetes mellitus is one of the major chronic non communicable diseases that affect millions globally (Aastha, *et. al*, 2016). The global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014 (Mathew *et. al*, 2016).

Clinical presentation

Polydipsia (excessive thirst), polyphagia (excessive hunger), and polyuria (excessive production of urine) are the classic triad of symptoms associated with type 1 diabetes (Teresa, 2016). Individuals are often thin and are prone to develop diabetic ketoacidosis if insulin is withheld or under conditions of severe stress. Type 2 diabetic patients are often asymptomatic and may be diagnosed secondary to unrelated blood testing. Lethargy, polyuria, nocturia, and polydipsia can be present. Significant weight loss is less common; more often, patients are overweight or obese (Curtis, et. al, 2014).

Diagnosis

Diabetes mellitus can be diagnosed depending on Glycosylated haemoglobin (HbA1c) level or plasma glucose level, including two hour plasma level of glucose (2-h PG) value after 75g oral glucose tolerance test (OGTT) as well as the fasting plasma glucose (FPG) (Table 1-1).

Treatment

There are three major components to the treatment of diabetes: diet, drugs (insulin and antidiabetic agents), and exercise (Lisa & Craig, 2013). Appropriate treatment requires goal setting for glycemia, blood pressure, and lipid levels

(Curtis, *et. al*, 2014). The American Diabetes Association (ADA) metabolic goals for adults with diabetes mellitus are listed in Table 1-2. Treatment of T1DM requires providing exogenous insulin to replace the endogenous loss of insulin from the nonfunctional pancreas. Oral and injectable agents are available to treat patients with T2DM (Julie, *et. al*, 2013). Agents used for treatment of type 1 or type 2 diabetes are summarized in table 1-3 (Alvin, 2015)

Complications of diabetes mellitus

The complications of diabetes mellitus are progressive and almost resulting by chronic exposure to high blood levels of glucose (Nihat, *et. al*, 2015). Almost every organ in the human body is affected after prolonged hyperglycemia as listed in table 1-4 (Pranav, 2016). Prolonged hyperglycemia of diabetes gives rise to long-term complications that involve lesions of the small (microvascular) and large (macrovascular) blood vessels. Microvascular complications include retinopathy, nephropathy, and neuropathy (Veronica, 2013).

Definition of Diabetic nephropathy (DN)

Diabetic nephropathy refers to a characteristic set of structural and functional kidney abnormalities in patients with diabetes (Olugbenga, *et. al*, 2004).

Chronic kidney disease (CKD)

Definition

National Kidney Foundation (NKF) guidelines define CKD as glomerular filtration rate (GFR) less than 60 mL/min/1.73 m2 for three months or more or as kidney damage regardless of GFR (Levey, *et. al*, 2005).

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Aim of the study

The aim of this study was assess the some profiles of diabetic patients with chronic kidney disease on haemodialysis via AVF at baseline and adequacy of treatment after three months follow up period regarding different clinical and laboratory parameters.

Methodolgy

The current prospective study was curried in the haemodialysis unit in AL-Hussein Teaching Hospital (Iraq-Thi-qar Governorate-Nassiriyah city) during three months (from April to July 2016). The number of patients included in the study was (24) patients (16 males and 8 females), with age range of (24-78) years. Any diabetic patient with end stage chronic kidney disease requiring haemodialysis was included in the current study. According to these data the patients condition will be assessed regarding the achievement of target value for these parameters both at baseline and after three months follow up.

The data related to the study were collected using a data collection sheet designed for the purpose of the study. For each patient involved in the study the following informations were recorded:

1-Demographic characteristics of the diabetic patients on haemodialysis.

2-Disease characteristics of these patients (duration of haemodialysis, program of haemodialysis,.....)

3-Adherence to dialysis (The patient measures of nonadherence used in this study is skipping one or more dialysis sessions in 1month).

4-The following clinical and laboratory parameters were recorded at the beginning (baseline) of the study and after three months:

A-Glycosylated hemoglobin (HA1C %), blood pressure (BP), serum calcium, serum phosphorous, hemoglobin, serum albumin, and serum total cholesterol. **B**-Development of hepatitis B or C infections.

C-Clinical status of the patients [gastro - esophageal reflux disease (GERD) symptoms, bone pain, muscle cramps, and orthopnea].

Results

Table 1. Demographic characteristics of the patients

	Mean	SD	Range
Age	52.75	15.462	24-78
Number of children	5	3.290	0-11
Weight	65.76	10.406	48-92
BMI	25.28	4.833	18-39
		Number	Percent
Gender	male	16	66.67
	Female	8	33.33
Smoking	Smoker	12	50
	Nonsmoker	12	50
	Single	3	12.5
Marital state	Married	21	87.5
	Divorced and	0	0.0
	Widowed		
Level of education	Illiterate	11	45.83
	Primary	10	41.66
	education		
	Secondary	3	12.5
	education		
	Higher education	0	0.0

Table 2. Disease characteristics of the patients

	Mean	SD	Range
Duration of DM (Yrs)	13.63	5.65	4-25
Duration of HD (months)	7.58	8.304	3-41
		Number	%
Type of DM	T1DM	9	37.5
	T2DM	15	62.5
Program of HD	Once/wk	5	20.83
	Twice/wk	11	45.83
	Thrice/wk	8	33.33
Insulin therapy	Yes	21	87.5
	No	3	12.5
Co-existing disease(s)	HT	24	100
	IHD	8	33.33
	HF	3	12.5





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Table3.	Mean	values	of	BP	and	some	laboratory
parameters a	at baseli	ine (T1)	and	l afte	er thro	ee mon	ths (T2).

	T1	T2	P-value
HB (Mean ±SD) g/dL	8.04±1.070	7.48±1.886	0.206
HbA1c % (Mean ±SD)	9.63±2.965	9.82±2.974	0.577
Serum calcium (Mean ±SD) mmol/L	2.38±0.450	2.20±0.240	0.077
Serum phosphorus (Mean ±SD) mg/dL	5.74±1.385	6.32 ± 1.199	0.113
Serum albumin (Mean ±SD) g/L	31.67±5.639	30.98±6.712	0.577
Serum total cholesterol (Mean ±SD) mg/dL	188.83±38.830	212.09±72.366	0.058
SBP (Mean ±SD) mmHg	147.08 ±16.83	166.71±18.80	0.0003
DBP (Mean ±SD) mmHg	78.58 ± 12.25	81.04 ±13.31	0.334



and after three months (T2).

Table 4.	Prevalence viral hepatitis (B or C) at baseline
	(T1) and after three months (T2).

	Number (%)		P value
	T1	T2	1
Hepatitis B infection	1 (4.16%)	2 (8.33%)	0.551
Hepatitis C infection	1 (4.16%)	5 (20.83 %)	0.080

Table 5. Adherence of the patients with the haemodialysis schedule

	Num	P value	
	T1	T2	
Hepatitis B infection	1 (4.16%)	2 (8.33%)	0.551
Hepatitis C infection	1 (4.16%)	5 (20.83 %)	0.080

Table 6. Prevalence of patients with normal or targetlevel after three months (T2) in adherent and non-
adherent patients.

	Normal or target level	Number of patients with Normal or target level		P value
		Adherent T2 (N=12)	Non-adherent T2 (N=12)	
HB	10-12 g/dL	1	0.0	0.307
Serum calcium	2.2–2.6 mmol/L	7	8	0.673
Serum phosphorus	2.5-4.3 mg/dL	0.0	2	0.139
HbA1c	<7%	3	2	0.615
Serum albumin	40–50 g/L	3	0.0	0.064
Serum total	<200 mg/dL	7	7	1
cholesterol				
BP	<140/90 mmHg	2	0.0	0.139

Table 7. Values of BP and some laboratory parameters after three months (T2) in adherent and non-adherent patients.

	Adherent T2 (N=12)	Non-adherent T2 (N=12)	P-value
HB (Mean ±SD) g/dL	8.29 ± 1.88	6.675 ±1.57	0.0757
HbA1c % (Mean ±SD)	9.04±3.02	10.59±2.83	0.178
Serum calcium (Mean ±SD) mmol/L	2.19±0.15	2.22±0.31	0.781
Serum phosphorous (Mean ±SD) mg/dL	6.63±1.16	6.01±1.20	0.090
Serum albumin (Mean ±SD) g/L	34.33±6.75	27.62±4.91	0.009
Serum total cholesterol (Mean ±SD) mg/dL	213.58±88.15	210.6±56.34	0.922
SBP (Mean ±SD) mmHg	160.92±21.15	172.5 ±14.8	0.212
DBP (Mean ±SD) mmHg	78.5±15.39	83.58 ± 10.93	0.424

Table 8. Prevalence of some symptoms in adherent patients compared to non-adherent patients after three months.

	Num	Number (%)		
	Adherent T2 (N=12)	Non-adherent T2 (N=12)		
GERD symptoms	6	3	0.205	
Colic	6	4	0.407	
Bone pain	10	10	1.000	
Orthopnea	6	4	0.407	
Muscle cramps	9	10	0.615	

Table 9. Prevalence of viral hepatitis (B or C) in adherent patients compared to non-adherent patients after three months.

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	Numbe	P value	
	Adherent Non-adherent T2		
	T2 (N=12)	(N=12)	
Hepatitis B infection	2	0.0	0.139
Hepatitis C infection	5	0.0	0.012

Discussion

End-stage kidney disease causes irreversible, severe kidney failure for which patients require treatment with dialysis or kidney transplantation to survive. Hemodialysis (HD) is one of the main modalities of renal replacement therapy.

Diabetes mellitus is a growing epidemic and is the most common cause of CKD and kidney failure. Diabetic nephropathy affects approximately 20–40 % of individuals who have diabetes, making it one of the most common complications related to diabetes. Given the growing population in Iraq that is now affected by diabetes and thus, nephropathy, knowledge regarding treatment adequacy of diabetes and complications of CKD in those with nephropathy is of importance.

Concerning the age distribution of the patients, the current study showed that the age range of patients was 24-78 years with a mean value of 52.75±15.462 years. This mean age approximates that reported in Saudi Arabia (56.68 \pm 9.09 years) by (Rizwana, et. al.) of diabetic nephropathy patients on haemodialysis (Rizwana, et. al, 2014) and in agreement with global finding that the major part of diabetic people is between the age range of 40-59 years (Pranav, et. al, 2016). The number of male patients in this study was 16 patients (66.67%) while the number female patients was 8 patients (33.33%) (Male : Female ratio of 2 : 1). Diabetic women on HD in this study were less than men, which is similar to that reported by other studies. Men show faster progression of diabetic nephropathy and more often undergo dialysis therapy (De Hauteclocque, et. al, 2014). Previous studies indicated that it is sex steroids, rather than any other effects of sex, that determine the greater susceptibility of the male kidney to progressive renal disease. The generation and activation of transforming growth factor- β (TGF- β) is widely thought to mediate the adverse effects on the kidney of several metabolic pathways. Estrogens inhibit TGF-B production and its effects whereas androgens promote and accelerate TGF-β activity.

Regarding smoking habit, the result of the current study showed that (50 %) of the patients were smokers. Smoking, especially smoking after the diagnosis of

diabetes, was found to be associated with the presence of diabetic nephropathy (Hyungseon, et. al, 2016). Cigarette smoking has been associated with development of persistent microalbuminuria as well as overt nephropathy in diabetic patients. Among type 1 diabetics microvascular complications, with albuminuria and retinopathy were found to progress more in smokers and the former improved significantly when subjects ceased smoking. In a cross-sectional study of 1,203 type 2 diabetic patients, the prevalence smokers was higher in patients of with microalbuminuria (Esmatjes, et. al, 1996).

With respect to educational level, the majority of patients were illiterate (about 46%) or of primary education (about 42%). Previous study showed that literacy status is an independent risk factor for diabetic nephropathy where the risk for nephropathy increases as literacy decreases (Abdulhakeem, et. al, 2012). Studies have shown that the highest percentage of type 2 nephropathy was found in patients with no school education and the lowest percentage was found in patients who had university level education (Gohar, et. al, 2005). People with diabetes and low level of education have lower utilization rates of checks and services required for diabetes care; and therefore result in a worse outcome in terms of complications as reported by other studies. The mean duration of diabetes was $(13.63 \pm 5.65 \text{ years})$ which is comparable to that reported among Saudi diabetic patients with endstage kidney disease on dialysis which was (12.5 year). Duration of diabetes is a very important factor in the development of diabetic nephropathy as demonstrated in several studies. (Rudberg, et. al, 1997) found that the duration of disease was an important factor in the overall severity of glomerulopathy (Rudberg, et. al, 1997). Overt nephropathy caused by glomerulosclerosis first appears 10-15 years after the onset of type 1 diabetes and after 5 to 10 years in patients with type 2 diabetes. The current study showed that 37.5% of the total patients were type 1 DM while 62.5 % of them were type 2 DM. About 20- 30% of patients with type 1 or type 2 diabetes develop evidence of nephropathy, but in type 2 diabetes, a considerably smaller fraction of these progress to ESKD. However, because of the much greater prevalence of type 2 diabetes, such patients constitute over half of those diabetic patients on dialysis. With respect to the prevalence of co-existing diseases, all patients (100%) were hypertensive. Similar finding reported in Saudi Arabia. In addition, IHD was reported in one third of the patients. Hypertension, is an

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extremely common comorbid condition in diabetes and substantially increases the risk of both macrovascular and microvascular complications, including stroke, and coronary artery disease. In observational studies people with both D.M and hypertension have approximately twice the risk of cardiovascular disease compared with non-diabetic hypertensive people. Although cardiovascular disease is not specific to diabetes, it is more prevalent among patients with type 1 or type 2 diabetes than among those without diabetes. Type 1 diabetes is associated with at least a 10-fold increase in cardiovascular disease as compared with an agematched nondiabetic population. An association between hyperglycemia and cardiovascular disease has been suggested by some, but not all, studies of patients with type 1 diabetes. However, clinical trials of patients with type 1 or type 2 diabetes have not demonstrated a reduction in the occurrence of cardiovascular disease with long-term intensive diabetes therapy (Pisoni, et. al, 2004).

Regarding adequacy of anemia treatment, only (4.16%) of the patients their Hb levels were within the target (10-12 gm/ dl) level at baseline and the same percentage (4.16%) reported after three months follow up. There was no significant difference in the mean Hb level between baseline and that reported after three months and the mean Hb level was higher in adherent than in non-adherent patients although not reach the level of significance. The mean Hb reported in the current study is lower than that reported in other countries (mean Hb levels were 12 g/dl in Sweden; 11.6-11.7 g/dl in the USA, Spain, Belgium, and Canada; and 11.1-11.5 g/dl in Australia, New Zealand, Germany, Italy, UK, and France)(Panagoutsos, et. al, 2002). The factors responsible for the low Hb levels in patients, compared with those of other countries may be related lack of consistent supplies of erythropoietin, non-adherence to dialysis and insufficient dialysis dose. There is good evidence that dialysis adequacy results in better control of anemia.

With respect to HbA1C level as a marker of glycemic control, only (20.83 %) of the patients had their HbA1C levels were within the target (<7%) level a baseline and the same prevalence reported after three months follow up. There was no significant difference in the mean HbA1C level between baseline and that reported after three months and the mean HbA1C level was lower in adherent than in non-adherent patients although not reach the level of significance. These data have revealed that diabetic patients undergoing dialysis

have very poor glycemic control. The percentage of patients achieved glycemic control in the current study is much lower than that reported by Brazilian study (59%) (Williams, *et. al*, 2006) and an American study (65%). In Iraq, this result is compatible with findings regarding the poor glycemic control among Iraqi diabetic patients in general. In a cross sectional study of 200 patients with type 2 diabetes in Al-Kadhimia Teaching Hospital / Baghdad city. The mean HbA1c was $9.4\pm2.6\%$ and the percentage of patients achieved glycemic control (HbA1c <7%) was only 27%.

Concerning serum calcium level, 50% of patients were had normal levels of serum calcium at baseline and increased to 62.5% after three months follow up with no significant difference between adherent and non-adherent patients in both mean levels as well as prevalence of patients with normal level in the second readings (after three months). The KDIGO (2009) guidelines suggested maintaining serum calcium levels in the reference range in patients with ESKD requiring hemodialysis. The prevalence of patients within the normal reference range reported in the current study for both readings (baseline and after three months) were higher than that reported by among 103 hemodialysis patients at Al-kindy teaching hospital in Iraq which was about 42%. With respect to serum level of phosphorous, only 12.5% of patients were had normal levels of serum phosphorous at baseline and decrease to 8.33% after three months follow up with no significant difference between adherent and non-adherent patients in both mean level as well as number of patients with normal level in the second readings (after three months). The KDIGO (2009) guidelines suggested maintaining serum phosphorous levels in the reference range in patients with ESKD requiring hemodialysis (Ali, et. al, 2016). The prevalence of patients within the normal reference range reported in the current study for both readings (baseline and after three months) were lower than that reported by other studies in Iraq (about 19%) (Djukanović, et. al, 2016) and Serbia (44.4%).

Regarding serum albumin level, only (12.5%) of the patients their albumin levels were within the reference range at baseline and the same percentage (12.5%) reported after three months follow up. The mean albumin level was significantly higher in adherent than in non-adherent patients. Albumin levels are lower in dialysis patients than among the general population and are a powerful predictor of mortality. Muhammad Anees *et al.*, found that 67% of hemodialysis patients were hypoalbuminemic and their mean albumin was

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32.4 g/L. Factors responsible for hypoalbuminemia may be unnecessary restriction in taking protein, metabolic acidosis, delayed gastric emptying, co-morbidities and underlying inflammation. Malnutrition in hemodialysis patients has been attributed to three main mechanisms: insufficient feeding, abnormal nutrient metabolism and nutrient losses due to dialysis procedures (Solati, *et. al*, 2008).

Concerning serum total cholesterol level, 62.5% of patients were had their levels within the target at baseline and decrease to 58.33% after three months follow up with no significant difference between adherent and non-adherent patients in both mean level as well as prevalence of patients with target level in the second readings (after three months). The mean level of serum total cholesterol level reported in the current study (in both readings) were higher than that reported by (Solati, et. al.) who found a mean level of (166±43) mg/dl) among 46 diabetic hemodialysis patients in Tehran (Iran) (Issam, 2009) and the percentage of patients with target levels (in both readings) were lower than reported among diabetic hemodialysis patients in Palestine (about 79%) (Mark, 2006). Cardiovascular disease (CVD) is the leading cause of death in patients with ESKD. When the ESKD population is divided into those with and without diabetes, the annual mortality rate is increased by approximately 40% in those with diabetes. Lipid abnormalities in diabetic patients on long-term hemodialysis therapy are more enhanced than those in nondiabetic uremic patients, suggesting that diabetic hemodialyzed patients are more prone to increase the individual risk for accelerated atherosclerosis to cause a higher incidence of cardiovascular diseases (Thamer Alsulaiman, 2015). The prevalence of patients achieving the target BP of (<140/90 mmHg) was only (33.33%) at baseline and significantly decrease after three months follow up (8.33%) indicating an inadequacy in achieving and maintaining the BP within the target level of diabetes (<140/90 mmHg) which is much lower than that reported in one Saudi study where 84.5% of diabetics patients had their BP below 140/90 (Wiam, 2012). Uncontrolled BP plays a major role in the development of macrovascular events as well as microvascular complications, including retinopathy and nephropathy, in patients with DM. In patients with a urine albumin excretion >30 mg/24 h or equivalent, the target blood pressure is $\leq 130/80$ mm Hg, however 24 urinary albumin excretion was not determined in the current study. The results of clinical findings (GERD, bone

pain, colic, orthopnea and muscle cramps) were in parallel to that of biochemical parameters with either no improvement (GERD, colic, orthopnea and muscle cramps) or even an increase in the prevalence (bone pain) indicating an inadequacy in symptomatic control also. Finally the prevalence of hepatitis B or C infection was (4.16%) for both types at baseline and increased after three months although not significantly. Three month prospective follow up of sero-negative hemodialysis patients revealed about (4.35%) and (17. 39%) rate of acquiring new infections with HBV and HCV respectively. These rates are much higher than that reported among Libyan hemodialysis patients during one year for both HBV (0.6%) and HCV (7.1%)reflecting poor standards of infection control practices in hemodialysis unit. Previous studies from the region show that with appropriate intervention, HCV infection rates in hemodialysis centers may be substantially improved. For example in Saudi Arabia, HCV prevalence reduced from 2.4% in 2001 to 0.2% in 2005 (Alavian, et. al, 2008) and in Iran from 14.4% in 1999 to 4.5% in 2006 2.4% in 2001 to 0.2% in 2005. The prevalence of HCV infection was significantly higher among adherent than non-adherent patients after three months. This may prove the role of HD machine in infection transmission. In Iran, the incidence of HCV in HD patients decreased by the use of dedicated HD machines for HCV infected patients. Additional studies may help to clarify the role of machine dedication in conjunction with application of universal precautions in reducing HCV transmission.

Conclusion

According to the results of the current study, we can conclude that the management of diabetic end stage kidney disease patients with AVF on maintenance haemodialysis [in the haemodialysis unit in AL-Hussein Teaching Hospital (Iraq / Thi-Qar Governorate / Nassiriyah city)] is considered inadequate as reflected by failing to achieve or maintaining the target values for most parameters and high rate of acquiring viral hepatitis B or C infections.

Recommendations

1.Better management is indicated for anemia, hyperphosphetemia, hypocalcemia and other disturbances of CKD patients.

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- 2. Education of importance of drug compliance for diabetic patients in both prevention and treatment of CKD.
- 3. Education of importance of drug compliance for treatment of hypertension, dyslipidemia and other risk factors in both prevention and treatment of CKD.
- 4. Good isolation of end stage kidney disease patients with hepatitis C and B from those with negative virology.
- 5. Prevention and early detection of hepatitis C and B in end stage kidney disease patients is mandatory.

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