

Research Article

Outcome of Chronic Hemodialysis Prescription in El-Minia University

El Minshawy O., Sharawy M., Kamal A, Fathy B. and Ragab M.

Department of Internal Medicine, El-Minia Faculty of Medicine

Abstract

Aim: Little is known about the effect of haemodialysis (HD) setting on outcomes of patients with end stage renal disease (ESRD). The study aimed at improving clinical outcomes of patients on haemodialysis in Minia unit. **Methods:** A prospective cohort of ESRD patients receiving HD (n=136) in Minia university unit were followed up for 12 months. **Subjects:** were assessed on clinical outcomes of dialysis adequacy (Kt/V) and blood hemoglobin, Uf%, pre dialysis SBP, catheter used, albumin level, bone minerals, hospitalization rate and mortality. Differences in these parameters between start & end of the study were analyzed by paired sample t-test. Tests were used to analyze the also difference in proportion of patients reaching the targets of previous parameters. **Results:** The mean pre dialysis systolic blood pressure, KT/V, URR, s. Ca, s. phos, s. albumin levels and hospitalization rate of HD patients at 12months were significantly higher than those levels at start of study. Mortality rate was 24(17.6%) which was decreased in this year comparing by it in 2007 as it was 18.2%. **Conclusion:** we could partially improve the clinical outcome in our hemodialysis unit. Hemodialysis was one of the most common procedures performed in U.S. hospitals in 2011, **Key Words:** haemodialysis, Prescription, blood hemoglobin

Introduction

In Egypt the prevalence of dialysis patients is presumed to be increasing⁽¹⁾. Hemodialysis (HD) still represents the main mode for renal replacement therapy (RRT) for end stage renal disease (ESRD) in Minia Governorate⁽²⁾. As renal replacement therapy becomes more widespread and more affordable, the measurement of patient outcomes and comparison with national and international benchmarks will be a valuable tool in planning health services and demonstrating effective use of resources⁽³⁾. Measuring quality has become a central theme in United States health care. Clinical practice guidelines (CPGs), other basis of best published clinical evidence and expert opinion, and clinical performance measures (CPMs) on the basis of those guidelines, are used as yardsticks to measure quality of care⁽⁴⁾. The current set of kidney disease CPMs that aggregate patient data include outcome measures (mortality, hospital readmission, and patient experience of care), intermediate outcome measures (dialysis adequacy and vascular access), process measure (blood trans-

fusion), and safety measure (blood stream infections and hypercalcemia) Holloway and Quill discuss mortality as a measure of quality and the implications for palliative and end-of-life care.

They conclude that mortality is a good quality measure for individuals with acute illness who are not supposed to die, but a poor quality measure for most patients who suffer multiple chronic diseases and are near the end of their life⁽⁵⁾. Another Performance measurements are embodied through setting up targets of several key performance indicators (KPIs) in every perspective, which allow easy monitoring and evaluation be done and proper responses be prompted to reach the targets in a more efficient way. In the most important patient perspective, 10 clinical KPIs are defined. These indicators involve the most important objectives in dialysis field. Physicians have a very important role in the operation of this performance management system. Physicians are responsible for setting the KPI targets, which are determined mainly according to the most recent scientific guidelines or publications,

such as K/DOQI with some modifications based on local situation after a thorough panel discussion. These targets will be modified periodically if new global consensus was created or difficult clinical situations were encountered⁽⁶⁾.

In Hong Kong, Clinical outcome measures were adopted two criteria used as part of the evaluation of quality of care for the HD-PPP program haemodialysis public-private partnership program (HD-PPP), as the clinical outcome measures for study. The target standard for dialysis adequacy measured by equilibrated, single pool or on-line Kt/V was ≥ 1.2 if patients were receiving three HD sessions per week, ≥ 1.8 if receiving twice weekly HD or a total weekly Kt/V ≥ 3.6 (including dialysis and residual renal function). The target standard for blood hemoglobin was set as ≥ 9 g/dL.

These criteria and standards were determined based on international best practice and expert opinion.⁽⁷⁾ Also, there were Two large observational studies in prevalent and incident patients have shown that the increasing number of unfulfilled therapeutic targets was associated with higher mortality and hospitalization rates. The main quality-of-care indicators are well defined. Numerous studies have documented that an increased risk for death and hospitalization was associated with lower levels of dialysis adequacy, increased anemia, lower serum albumin values, and the use of a vascular access other than an arteriovenous fistula (AVF) for hemo-dialysis. Consequently, clinical practice guidelines such as the Kidney Disease Outcomes Quality Initiative (KDOQI) or the European Best Practice Guidelines (EBPG) were developed in order to improve the quality of care and outcomes of hemodialysis patients⁽⁸⁾. But Rocco et al., considered The clinical performance measure targets were hemoglobin value of 11 g/dL (110g/L) or greater; serum albumin value of 4 g/dL (40g/L) or greater or 3.7 g/dL (37g/L) or greater, use of a fistula for vascular access; and measured single-pool Kt/V urea value of 1.2 or greater.⁽⁹⁾ The challenge is resources are limited: if dialysis facilities and physicians spend time and money

assuring dialysis adequacy, increasing AV fistulas, minimizing catheters, and reducing readmissions and blood transfusions to obtain their best five-star rating on Dialysis Facility Compare, little or no resources will be available for patient-centered measures.⁽¹⁰⁾

Methods

This prospective study was carried out on all chronic regular HD patients of Minia University HD unit in the period between February 2015 and February 2016 which included 136 chronic HD patients. All Patients on HD > 3 months in Minia University HD unit were included. Patients of acute kidney injury (AKI) or AKI on top of chronic renal failure were excluded. - paired sample t-test, for quantitative data to test significance of differences between the mean values of the study variables for comparison of the data after one year to the same group. The result were collected, presented and analyzed by using the 0.05 significance level and the 0.01 high significance level, P value of <0.05 was considered significant. All HD Patients were offered to participate in the study; standardized questionnaire was completed including demographics, family history, risk factors and possible etiology of ESRD. Blood Urea, Serum Creatinine, Iron, Ferritin, Albumin, Calcium, Phosphorus, Parathormone hormone which were calculated twice and Hemoglobin level which was calculated every 3 months. URR & Kt/v were calculated every 6 months.

Clinical outcome measures

We thought that measures of outcome of HD in Taiwan at year 2012 were most likely of other country measures to be applied in Minia unit, so we applied these measures in our research. Items of clinical key performance indicator (cKPI) as outcome of HD are 10 measures which are Volume control, pre dialysis systolic blood pressure, dialysis adequacy ,nutritional state, bone minerals, anemia, annual hospitalization rate and annual Hospital stay-day rate adding to these items the mortality rate as it can't be ignored when assessing the outcome.

Results

The socio-demographic and clinical characteristics of HD patients at baselin are displayed in Table 1.

Sex Male Female	72(53%) 64(47%)	BMI (Mean ± SD)	21.8±4.4
Age (Mean ± SD)	48.3±15.4	Occupation Unemployed employed	111(81.6%) 25(18.4%)
Dry weight (Mean ± SD)	65.5±15.4	1st vascular access Catheter Fistula A-V graft	127(93%) 8(6.3%) 1(0.7%)
Marital status Single Married Widow Divorced	22(16%) 92(68%) 16(12%) 6(4%)	2nd vascular access Fistula A-V graft Catheter	133(97.1%) 1(0.7%) 3 (2.2%)
Residence Rural Urban	78(57%) 58(43%)	Blood transfusion	93(68.4%)
UOP	68(50%)	Malignancy	2(1.5%)
HTN	72(53%)	DM	26(19%)
Start of HD (years) Mean ± SD	5.5±4.5	Respiratory disease	9(6.6%)
Duration of session (hours) Mean ± SD	4±0.3	Chronic liver disease	6(4.4%)
No. of fistula(Mean ± SD)	1.4±0.8	Echocardiography IHD Pulmonary HTN LVH	18(13.2%) 5(3.7%) 13(9.6%)

	At start	After 6 months	After 12 months	P value	
				1 vs 2	1 vs 3
KT/V(N=1.2) Mean ± SD	0.6±0.1	0.7±0.1	0.8±0.1	<0.001*	<0.001*
URR (N=65%) Mean ± SD	18.6±19.7	15.6±20.6	44.87±14.2	<0.003*	< 0.001*

URR was 18.6 (±19.7) at the start of research and 15.6 (±20.6) after 6 month of follow up with significant difference (p value < 0.003) and 44.9 (±14.2) after one year of the research with significant difference (p value < 0.001), **KT/V** was 0.6 (±0.1) at the start of research and of after 6 month 0.7 (±0.1) with significant difference (p value < 0.001) and 0.8(±0.1) after one year of the research with significant difference (p value < 0.001)

The mean hemoglobin value increased at different intervals, however the scale of the changes was small which probably resulted in the non-significant p value as the mean Hb level of the patients was 10.3 (±2.2) at the start of the study, become 10.4 (±2) after 3 month of the study and 10.8 (±2) after 6 month of the study, then become 10.3 (±1.6) at the end of the study with no significant difference (p value 0.55, 0.6, 0.1 and 0.4 respectively).

The proportion of patients with hemoglobin level ≥ 100 g/L was 52.2% which increased to 70% at the end of the study.

Table: Hb levels and corresponding p-values, mean and variance values

	At start	3 months	6 months	9 months	12 months
Hb(10-12mg/dl)					
Mean \pm SD	10.3 \pm 2.2	10.4 \pm 2	10.6 \pm 1.7	10.8 \pm 2	10.3 \pm 2
P value vs 1		0.55	0.6	0.1	0.4

The mean body weight change (predialysis weight – postdialysis weight), as a surrogate for interdialysis weight gain (IDWG), was 2.6 \pm 1.04 kg at the start of the study which become 2.08 \pm .6 by the end with significant decrease (P value: 0.001), (UF%) was 4.1 \pm 1.8% at the start of the study which become 3.3 \pm 1.3 by the end with significant decrease (P value: 0.001).

The pre dialysis systolic blood pressure was in arrange of 130.4 \pm 20.3 at the start of the study which was decreased to arrange of 120.9 \pm 21.2 at the end of the study with significant difference (p value <0.001). Further, the proportion of patients with pre dialysis systolic blood pressure (pre-SBP) \leq 150 mmHg) was 76.1%at the start of the study and this proportion become 91.1% at the end of the year.

Table: Showing the difference between IDWG, UF% and pre systolic B.P at start&at the end of the study

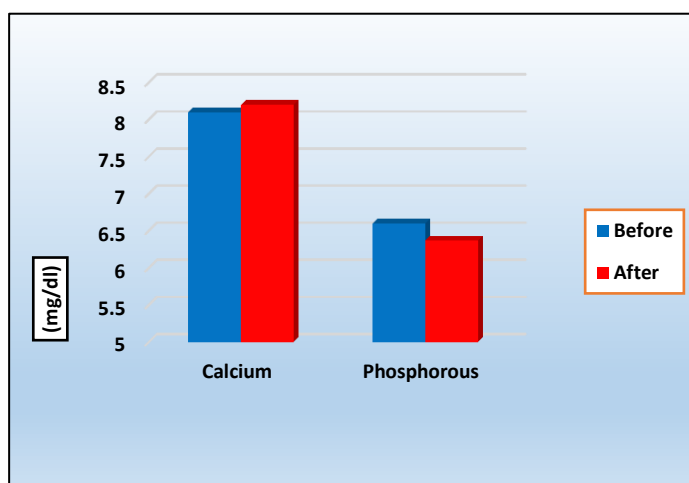
	At start	At end	P value
IDWG	2.6 \pm 1.04	2.08 \pm 0.6	< 0.001*
UF%	4.1 \pm 1.8	3.3 \pm 1.3	< 0.001*
Pre-SBP (Mean \pm SD)	130.4 \pm 20.3	120.9 \pm 21.2	< 0.001*

Calcium levels were tested for the entire sample size (n=136) at start& end of the research which clarify that the mean values of calcium (mg/dL) over time shows that between 0and 12 months, mean levels increased as the mean s. Ca level of the patients was 8.1(\pm 0.2) at the start of the study and become 8.2(\pm 0.3) at the end of the study by asignificant difference (p value<0.001), the mean values of phosphate decreased as the mean s.phos. Level of the patients was 6.6(\pm 0.6) at the start of the study and become 6.4 (\pm 0.6) at the end of the study by significant difference (p value<0.005). the proportion of patients

with phosphate level <5.5 mg/dL is up to 11.5% at the start of the study this percent increased to 31% at the end of the study. Parathyroid hormone levels were found to be unchanged at the end of the study as the mean PTH level of the patients was 660.9(\pm 501.8) at the start of the study and become 718.6(\pm 529.6) at the end of the study by insignificant difference (p value<0.12), Albumin Measurement The mean s. albumin level of the patients was 3.8(\pm 0.4) at the start of the study and become 4.1(\pm 0.3) at the end of the study by significant difference (p value<0.001).

Table: S.Ca, S. Phosphorus, PTH, & s. albumin levels and corresponding p-values, mean and variance values

	At start	After 12 months	P value
Calcium(mg/dL) Mean ± SD	8.1±0.3	8.2±0.2	< 0.001*
Phosphorous(mg/dL) Mean ± SD	6.6±0.6	6.37±0.6	<0.005*
PTH(pg/dl) Mean ± SD	660.9±501.8	718.6±529.6	<0.12
Serum albumin Mean ± SD	3.8±0.4	4.1±0.3	< 0.001*



A total of 136 of the patients 17.6% (24) died during the twelve month follow up period.

Hospitalization

The hospitalization rate was 1.6 ± 0.7 hospital events per patient year for the year 2014, it became 1.1 ± 0.3 with significant decrease (P value: 0.001). Further, 47.7% of patients underwent at least one admission

during the year 2014 whether it becomes 8.8% at the year of the study.

Hospital stay-day rate of at year of study was 0.9±0.2 whether Day rates for the year 2014 was 2.04± 2.9 with significant decrease (P value: 0.001)

Table 12: Hospitalization rate hospital stay days rate per year:

	Year before study Mean ± SD	Year of study Mean ± SD	P-value
Hospitalization per yaer	1.6 ± 0.7	1.08 ± 0.3	< 0.001*
hospital stay days per year	2.04± 2.9	0.9 ± 0.2	<0.001*

Discussion

Incidence of ESRD requiring renal replacement therapy is increasing steadily and places a tremendous burden on the healthcare budget even in developed countries⁽¹¹⁾HD still represents the main mode for renal RRT for ESRD in Minia

Governorate, 96.3% during the year 2002⁽²⁾ 97.2% during the year 2005⁽¹³⁾ and 97% during the year 2006.⁽¹²⁾ In the current study, the mean age of the patients was (48 ±15). In this study, 52.9% of the dialysis patients were men and 47.1% were women whereas, 65.7% of the dialysis patients

were men and 34.3% were women whereas in 2008, across Egypt, 55.2% of dialysis patients were men and 44.8% were women⁽¹⁾. In the current study, we found that only 6.3% of patients were prepared with a permanent vascular access when initiating dialysis which was 20% in a similar study in Assuit in 2014.⁽¹⁴⁾ thus reflecting the lack of awareness among treating physicians and primary healthcare physicians of the optimal time frame for referral to nephrologists; also, some nephrologists may be unaware of the optimal time frame for the preparation of a patient for renal replacement therapy.

The Death rate in our study was (17.6%) because of infection or cardiovascular complications while the death rate in study was (18.2%) in 2007, while it was (19%) in 2006.⁽¹²⁾ while in 2005 it was and (21%).⁽¹³⁾ The mortality rate considered one of the clinical outcome measures in some papers as the target was the percentage $\leq 18\%$ yearly which agree with our research.⁽¹⁵⁾ This decrease may reflect better care for patients with ESDR and more efficient dialysis.

Clinical outcome: We thought that measures of outcome of HD in Taiwan at year 2012 were most likely of other country measures to be applied in Minia unit, so we applied these measures in our research. Items of clinical key performance indicator (cKPI) as outcome of HD are:⁽⁷⁾

Volume control: IDWG, was 2.6 ± 1.04 kg at the start of the study which become 2.1 ± 0.6 by the end with significant decrease (P value:0.001). The relative IDWG, as represented by delivered ultrafiltration as percentage of postdialysis weight (UF%) was $4.1 \pm 1.8\%$ at the start of the study which become 3.3 ± 1.3 by the end with significant decrease (P value:0.001) which is less than the target of (cKPI) (the target was $\leq 5\%$) IDWG, was 2.28 ± 1.01 kg, (UF%) was $3.98 \pm 1.65\%$ in Taiwan; 2012.⁽⁷⁾

Hypertension: The mean pre dialysis systolic blood pressure was 130.4 ± 20.3 at the start of the study which was decreased to 120.9 ± 21.2 at the end of the study with significant difference (p value < 0.000). further, the proportion of patients with pre

dialysis SBP ≤ 150 mmHg) was 76.1% at the start of the study and this proportion become 91.1% at the end of the year which is equal to the target of (KPI) (the target was $\geq 80\%$ Of the patients had pre-SBP ≤ 150 mmHg)⁽⁷⁾

Vascular access: The second vascular access used was AV fistula by 97.1%, so the central venous catheter used was 2.2% which is less than the target of (cKPI) in 2012 (the target was $\leq 8\%$). Whether up to 73.9% of patients still use native arteriovenous fistula as their vascular access and those with CVC composed only 5.8% of the total dialysis patients in 2012.⁽⁷⁾

Dialysis adequacy: URR was $18.6 (\pm 19.7)$ at the start of research and of range of $44.9 (\pm 14.2)$ after one year of the research with significant difference (p value < 0.001) ,There was a significant effect of treatment on Kt/V levels in this study as it was $0.6 (\pm 0.1)$ at the start of research and of arrange of $0.7 (\pm 0.1)$ after 6 month of follow up (p value < 0.001) and of arrange of $0.8 (\pm 0.1)$ after one year of the research (p value < 0.001) whether it still less than the target of (cKPI) (the target was ≥ 1.5)⁽⁷⁾

Nutrition: The mean s. albumin level of the patients was $3.8 (\pm 0.4)$ at the start of the study and become $4.1 (\pm 0.3)$ at the end of the study by significant increase (p value < 0.001) which is more than the target of (cKPI) (the target was ≥ 38 g/L)⁽⁷⁾, and above the target In another paper as it was ≥ 3.8 g/dl in 60% of the patients⁽¹⁵⁾

Bone minerals: The mean values of phosphate decreased as the mean s. phos. Level of the patients was $6.6 (\pm 0.6)$ at the start of the study and become $6.4 (\pm 0.6)$ at the end of the study by significant difference (p value < 0.005). It was in agreement with Significant decreases (P = 0.001) in mean phosphorus levels were seen in France, Germany, Spain, the United Kingdom, and the United States. But disagree with the statistically, but not clinically, significant decreases in mean calcium levels were observed in all countries except Germany, Spain, and Sweden in the same study⁽¹⁶⁾. But the proportion of patients with phosphate level

<5.5 mg/dL is up to 11.5% at the start of the study this percent increased to 31% at the end of the study which still less than the target of (cKPI) (Serum phosphate (P) \leq 5.5 mg/dL in \geq 60% of the patients)⁽⁷⁾. The mean s. Ca level of the patients was 8.1(\pm 0.2) at the start of the study and become 8.2(\pm 0.3) at the end of the study by significant increase (p value<0.001). The PTH level shown to be statistically insignificant change with p values (<0.12), which agree with the DOPPS study as there was No significant trend was seen in mean PTH levels in the overall DOPPS population (P=0.5), but in disagree with the results in the United States, there was a significant decrease of (P=0.008)⁽¹⁶⁾.

Anemia *The mean hemoglobin level was 10.3(\pm 2.2) at the start of the study, then become 10.3(\pm 2) at the end of the study with no significant difference. But the proportion of patients with hemoglobin level \geq 100 g/L was 52.2% which increased to 70% at the end of the study which equal to the threshold of (cKPI) (the threshold of hemoglobin level \geq 100 g/L in \geq 70% of the patients).⁽⁷⁾ *The mean transferrin saturation (TSAT) of all patients was 40.58 (\pm 27.19). 90% of the patients with TSAT \geq 20% at the end of the study which is more than the target of (cKPI). (The target: More than 80% of patients have adequate iron saturation status (TSAT \geq 20%).⁽⁷⁾

Hospitalization rate was 1.6 \pm 0.7 hospital events per patient year for the year 2014, it became 1.1 \pm 0.3 with significant decrease (P value: 0.001). But still less than hospitalization rate in Taiwan in 2011 & 2012 which were 0.611, and 0.581, respectively. among the causes of hospital admission were infection, vascular access complications, uncontrolled HTN or cardiovascular complications .Further, 47.7% of patients underwent at least one admission during the year 2014 whether it become 8.8% at the year of the study, whether, 44.4% of patients underwent at least one admission during the 2 years.⁽⁷⁾ The target in another papers was \leq 10 days/patient year⁽²⁰⁾. Hospital stay-day rate of at year of study was 0.9 \pm 0.2 whether hospital stay Day rate for the year 2014 was 2.04 \pm 2.9 with significant decrease (P value: 0.001)

which is less than the Day rates for the years 2011, and 2012 which were 3.49 and 2.12 respectively in Taiwan.⁽⁷⁾

Conclusions: According to the above described data of the cKPI criteria, we could improve partially the clinical outcome of our unit.

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