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Quality of Care Assessment and Adherence to the International Guidelines Considering Dialysis, Water Treatment and Protection Against Transmission of Infections in University Hospital Based Dialysis Unit in Cairo, Egypt

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Abstract

Background: End stage Renal Disease (ESRD) has emerged as a major public health problem around the world. In recent decades, several important advances have been made in the therapy of hemodialysis (HD) with introduction of international guidelines to ensure the delivery of optimum care to HD patients. Increased mortality risk in HD patients unable to meet six targets in different areas of HD practice has been reported by the DOPPS investigators.

Aim and Methods: In this retrospective study, we assessed the current practice patterns of care for HD patients in the Kaser El-Aini Nephrology and Dialysis Center in comparison with Dialysis Outcomes Quality Initiative (DOQI) Guidelines, European Best Practice Guidelines (EBPG), CDC guidelines for prevention of transmission of infections among HD patients, and American Association for Medical Instrumentation (AAMI) standards for dialysis water quality.

Results: Mean URR% was 63±8.8% in prevalent HD patients. A-V Fistula was the vascular access in 91% of prevalent HD patients, whereas temporary catheter was used in 9% of cases mostly as a bridge till A-V fistula creation/ maturation. Bicarbonate was the base used in 80% of cases. 97% patients had thrice weekly sessions and 3% had twice dialysis sessions/week. Mean serum albumin was 4.19 ± 0.39g/dl, 66.66% of prevalent patients had serum albumin level >4g/dl. Mean serum calcium was 8.66 ± 1.4mg/dl, phosphorus was 6.26±2.54mg/dl with approximately 60% of patients had serum phosphorus level >5.5mg/dl. CaxPi product was higher than 55 in around 40% of cases and PTH level was in the range of 150-300pg/ml in around 10% of prevalent patients. Mean hemoglobin (HB) was 10.03 ±4.18g/dl in prevalent cases; however, around 70% of cases had hemoglobin level less than 11g/dl. Iron deficiency was prevalent as 18% of patients had serum ferritin <200ng/l and 34% had TST <20%. 70% of patients were HCV positive and 4% were HBsAg positive and all were negative for HIV serological test. Dialysis water was monitored regularly for chemical and bacterial contamination as recommended by the AAMI, but endotoxin assay is currently not included in the monitoring checklist. Annual mortality rate was 8% in 2007.

Conclusions: The current Audit revealed a reasonable quality of care for HD patients in the fields of vascular access care, dialysis adequacy and nutrition areas. It also reveals the need for improving anemia management and control of hyperphosphatemia with dietary counseling and more frequent dialysis. To fully meet guidelines targets, each patient should be treated in an individualized way with more counseling, nutritional education and individualized dialysis prescription. Besides, the unit needs to adopt primary and secondary intervention strategies to prevent and promptly correct any deviation from desired targets.

Key Words: *Quality dialysis – Water treatment – Infection control.*

Introduction

CHRONIC kidney disease (CKD) and end stage renal disease (ESRD) are emerging health problems that need long term often costly care **[1]**. While renal replacement therapy has improved many patients care, questions remain regarding the quality of care provided to patients by dialysis facilities. In a report issued by the United States General Accounting office, 16% of dialysis patients didn't have an adequate amount of toxins removed from their blood, 24% had anemia that was not brought under control and 19% of patients were dialyzing for extended periods using catheters **[2]**.

Clinical practice guidelines were established to provide recommended ranges for parameters associated with management of ESRD patients **[3-6]**. These guidelines addressed quality of care of ESRD with regard to the vascular access, anemia management, bone metabolism and nutritional assessments. Besides, quality of dialysis water has received special attention recently due to the large volumes of water each dialysis patient is exposed to during treatment **[7]**. The American Association

of Medical Instrumentations (AAMI) had issued guidelines of dialysis water treatment and quality of product water to ensure patients' safety [7]. To prevent transmission of infections in dialysis units, Centers for Disease Control and Prevention (CDC) set out guidelines to protect against spread of infections especially hepatitis B and C [8].

Infrequent, poorly targeted and inadequate inspections by survey agencies allow facilities quality of care problems to go undetected or remain uncorrected. Even when deficiencies are identified and facilities take corrective actions, little incentive exists for these facilities to remain in compliance. This problem is often seen in the developing counties' dialysis units where financial restrictions lie behind inability of dialysis units to reach proposed targets.

Studies showed clearly that compliance with guidelines results in better outcome [9,10]. Port et al. [9] confirmed that dialysis dose levels below the Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines are associated with higher mortality risks. Studies of compliance with K/DOQI guidelines of anemia management showed that higher hemoglobin concentrations were associated with decreased relative risk for mortality and hospitalization [10]. A trend to increased hemoglobin concentrations was observed following publication of the European Best Practice Guidelines (EBPG) on anemia management for CKD patients [10].

Research for discovery of new investigations or new modalities of treatment is a noble mission for humanity. At least hundreds of millions of pounds have been spent on this type of research during the past decades with not as big an impact on the quality of the country's medical service. At the same time, the more pressing problem for Egypt and most of the third world countries, that affects national morbidity and mortality is left unsolved. Dialysis units in Egypt often lack standardized protocols that apply the most recent evidence based medical knowledge.

We plan to accurately assess the current compliance status of the Dialysis Unit at the Kasr El-Aini Nephrology and Dialysis Centre, Cairo University Hospital with the K/DOQI guidelines, CDC Guidelines and AMMI standards and measure the major patient outcomes. By doing this we can explore the potentials for improvement in the current practice. Areas of weakness can be highlighted for the scientific design of programs to improve the practice in the dialysis units within the University Hospitals. Findings from international studies support that claim. All the countries involved in the Dialysis Outcomes and Practice Patterns Study (DOPPS) showed better compliance with guidelines and better patient outcomes after publishing, compared to findings before the publication of the DOPPS [9].

Patients and Methods

The study revised clinical and laboratory data of 100 chronic hemodialysis patients attending the dialysis units at the Kasr El-Aini Nephrology and Dialysis Centre and King Fahd Unit from January 2007 to December 2007. The study looked at the extent of adherence to the K/DOQI, CDC and AAMI standards [3-8] including:

- The dialysis dose delivered to the patients and the frequency and method of measurement.
- The vascular access used to be assessed cross-sectionally to detect percentage of patients with arteriovenous fistulae (AVF) and the percentage of patients with temporary/permanent catheters.
- Hemoglobin and serum iron studies and the rate of prescription of intravenous iron and erythropoietin therapy. This includes the frequency of measurement of the above mentioned tests and targets achieved.
- Serum calcium, phosphorus and parathyroid hormone levels including frequency of measurements and targets achieved.
- Compliance to infection control guidelines and prevalence of hepatitis B and C infection among patients. The study will also assess the adherence to the CDC recommendations regarding hepatitis B vaccination of dialysis patients.
- Compliance to the AAMI standards for quality of dialysis water used.

Patients' outcomes will be measured by:

- Assessment of nutritional status using subjective global assessment scale (SGA) [11].
- Quality of life questionnaire (SF 36) [12].
- Assessment of the need for hospitalization using hospital records.
- Patient survival rate for the study period using hospital records.

Statistical analysis:

Data are shown as mean ± SD. Ranges and frequencies of different laboratory parameters are also given. In addition, we examined correlation between quality of life (QoL) and SGA scores on

the one hand and the targets achieved in anemia control, serum albumin, calcium, phosphorous and parathyroid hormone levels using Spearman correlation test. Statistical analysis was conducted using MedCal software version 9.3.9.0 (Broekstraat, Mariakerke, Belgium).

Results

Demographic data:

The study included 100 chronic hemodialysis patients. They were 48 females and 52 males. Mean age was 42.67+±12.56 years (range 17-71 years). They received 2-3 weekly hemodialysis sessions at the Kasr El-Aini Nephrology and Dialysis Center and King Fahd Dialysis units. The mean duration of hemodialysis therapy was 6.4±3.2 (range 1-17 years). Table (1) showed the main demographic and biochemical data of the study group.

Table (1): The clinical and biochemical data of the study group.

Parameter	Mean ± SD (range)
Age (years)	42.67±12.56 (17-71)
Gender (M/F)	52/48
Vascular access (AVF/CVC)	91 /9
Hemoglobin (g/dl)	9.23±7.18 (5.4 -16.4)
Serum albumin (g/l)	4.19±0.39g/l (3.3-5.1)
Serum calcium (mg/dl)	8.66±1.47 (5-12)
Serum phosphorus (mg/dl)	6.26±2.54 (2.20-14)
PTH (pg/ml)	689.93±754.56 (6.9-3976)
Calcium x phosphorus product	55.00±15.16 (13-126.10)
URR%	63.5±8.7 (52-80)
SGA scores	6.13±0.32 (2-7)
QoL scores	66.25±11.90 (48-90)

Vascular access:

A-V fistulae were the vascular access in 91% of prevalent hemodialysis. Temporary or permanent central venous catheters (CVC) were used in 9% of prevalent hemodialysis cases mostly as a bridge till A-V fistula creation/maturation.

Anemia management:

Mean hemoglobin level was 9.23 ±7.18g/dl in prevalent cases (range 5.4-16.4g/dl). 73% of cases had hemoglobin level less than 1 1g/dl over the last 12 months. 9% of cases had a mean hemoglobin level > 12g/dl over the study period. 18% of patients achieved the target hemoglobin of 11-12g/dl during the study period. Mean serum ferritin was 640.34± 323.45ng/dl (range was 7.30-2000ng/dl). Iron deficiency was prevalent as 26% of patients had serum ferritin <100ng/dl and 44% had total iron binding capacity (TST) less than 20%. Serum ferritin was >800ng/dl in 31% of prevalent cases. 43% of dialysis patients had serum ferritin between 100-800ng/dl during the study period. Hemoglobin level was measured every two months and iron study was conducted every 3-6 months.

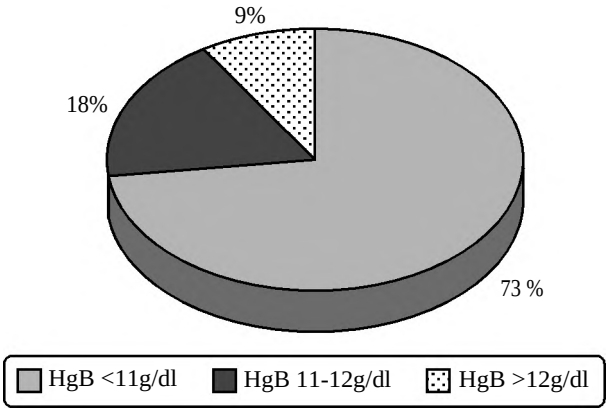

Fig. (1): Hemoglobin levels among prevalent hemodialysis patients.

Compliance to the CDC guidelines for infection control in hemodialysis unit:

Adherence to infection control guidelines are partially met on daily practice. Wearing gloves and hand washing are among practices that are not well adhered to by all nurses in all occasions. The practice of hand washing before and after patient contact remained low especially in busy shifts and reduced patient-nurse ratio. Nurses do sometimes care for patients and touch patients' equipment at the dialysis station without gloves. Otherwise, multiple dose medication vials are prohibited as well as common medication carts. Dialysis stations (chairs, beds, tables, machines) are disinfected and cleaned between patients.

All new cases are tested for hepatitis B, C infection using HBsAg test and anti HCV antibodies. Follow-up testing is performed every 6 months for anti-HCV antibodies and HBsAg status. Hepatitis B vaccination is not yet a routine practice for either dialysis patients or the healthcare personnel. 75% of prevalent dialysis patients are anti-HCV positive and 4% are HBsAg positive. HBsAg positive patients are dialyzed on separate machines in isolation room and have dedicated nurses. We do not isolate HCV infected patients from HCV negative patients. We do not dedicate separate machines or nurses to HCV infected patients.

Adequacy of hemodialysis and frequency of monitoring:

The delivered dose of hemodialysis was measured by the percent of urea reduction (URR) that was assessed every 1-2 months during the study duration. Mean URR% was 63.5 ±8.7% in prevalent

cases. 66% of patients had a mean URR% >65 over the study period. Bicarbonate dialysate was the base used in 80% of patients. 97% of patients had thrice weekly dialysis sessions and 3% had twice weekly dialysis sessions. Synthetic hemodialyzers were used for a single session; dialyzer reprocessing is not practiced in the unit.

Calcium, phosphorus and parathyroid hormone levels:

The mean serum calcium level was 8.66± 1.47mg/dl. 41% of dialysis patients had mean serum calcium level less than 8.4mg/dl. Serum calcium levels were between 8.4-9.5mg/dl in 30% of prevalent hemodialysis patients. 29% of dialysis patients had a mean serum calcium level more than 9.5mg/dl. Dialysate calcium concentration was 2.5mEq/l.

Mean serum phosphorus was 6.26±2.54mg/dl in prevalent dialysis patients during the study period. 40% of dialysis patients had serum phosphorus level less than 5.5mg/dl. 60% of dialysis patients, on the other hand, had serum phosphorus more than 5.5mg/dl. 58% of patients had a mean calcium phosphorus product less than 55 and 42% had calcium phosphorus product more than 55. The mean serum parathyroid hormone level (PTH) was 689.93±754.56 (range 6.9-3976pg/ml). 39% of patients had serum PTH level <300pg/ml, 11 % had serum PTH between 300-600pg/ml, 20% had serum PTH between 600-1200pg/ml and 30% of patients had serum PTH level more than 1200pg/ml.

Adherence to quality of dialysis water standards (AAMI standards):

Product water chemical testing, both biochemical and bacteriologically, is compliant with AAMI guidelines that advise to perform annual biochemical analysis of product water and to do microbial cultures (aerobic and anaerobic) monthly. Corrective measures are routinely undertaken if colony count exceeds the allowable limit (50 CFU) **[7]**. Testing for endotoxin is not included yet in the monthly microbial testing.

Dialysis outcomes:

Survival:

Annual mortality rate in year 2007 was 8%. Causes of death included cardiovascular events (4 cases), sepsis and multiple organ failure (2 cases), and sudden death (2 cases). Expired ESRD patients were significantly older compared to surviving patients ($p<0.05$) and had previous history of cardiovascular disease. There were no significant differences in URR, vascular access, hemoglobin, calcium, phosphorus, PTH and albumin levels between expired and surviving patients.

Nutritional status:

Serum albumin mean level was 4.19±0.39g/l (range 3.3-5.1g/l); 67% of prevalent dialysis patients had serum albumin level >4g/l. Mean SGA score was 6.13±0.32 (range 2-7). 77% of patients had SGA scores in the range of 6-7 (mild malnutrition to well nourished). 19% had SGA scores in the 3-5 (mild to moderate malnourished). 4% were severe malnourished.

Quality of life:

Eleven patients had QoL scores <50, 13 patients had QoL scores ranged 50-60, 40 patients had QoL scores 60-70, 20 patients had QoL scores 70-80 and 16 patients had scores greater than 80. There were no signification correlations between age, gender, hemoglobin, URR, calcium, phosphorus, calcium, PTH and albumin levels on one hand and QoL scores on the other hand.

Discussion

The study revealed partial compliance to the K/DOQI guidelines in the study centre. Vascular access creation rate showed excellent adhesion to the K/DOQI guidelines in our unit. AVF was the predominant dialysis access used in prevalent dialysis patients, whereas CVC was used in 9% of prevalent cases. The lower prevalence rate of CVC among dialysis patients in the present study is attributed to two main reasons 1) high rate of AVF creation and 2) the relatively long duration of RRT among prevalent cases of the study unit. DOPPS has shown that dialysis facilities with higher catheter use display substantially higher risks of mortality and all cause hospitalization **[13]**. DOPPS analyses suggest that reducing catheter use could provide one of the largest possible gains in patient longevity in many participating countries **[14]**. Several studies have shown variable rates of AVF use in different countries **[15-17]**. AVF accounts for 80% of all vascular access in Spain, 53% of prevalent Canadian patients and 91% of prevalent dialysis patients in Tehran **[15-17]**.

Another area of excellent compliance to K/DOQI guidelines is nutrition. 67% of prevalent dialysis patients had serum albumin level >4g/l. 77% of patients had SGA scores in the range of 6-7 (mild malnutrition to well nourished). However, our unit lacks a dedicated dietician and we do not monitor regularly other nutritional indicators like energy and protein intake, muscle mass, serum bicarbonate and visceral protein pools as recommended by the K/DOQI **[18]**.

66% of patients had a mean URR% >65 over the study period. We have reported persistent adequate dialysis dose among dialysis patients in the Kasr El-Aini Dialysis units [19-22]. The main limitations behind the lack of achievement of URR >65 in the other patients are poor blood flow, fixed dialyzer size ($1.2m^2$) and difficulties in extending dialysis time beyond 4 hours because of high patients' turnover rate. United States Renal Data System (USRDS) report revealed that 56.7% of dialysis patients achieved spKt/V >1.2 [23].

For the management of anemia, intravenous iron and erythropoietin therapy were provided by the administration in intermittent basis due to financial constraints. Correction of anemia to the K/DOQI target of 11-12g/dl was achievable in 18% of prevalent dialysis cases. The mean value of Hgb in our study (9.23 ±7.18g/dl) is lower than reported by the DOPPS study [24]. Mean Hgb levels were 12g/dL in Sweden; 11.6 to 11.7g/dL in the United States, Spain, Belgium and Canada; 11.1 to 11.5g/dL in Australia/New Zealand, Germany, Italy, the United Kingdom and France; and 10.1 g/dL in Japan [24]. Iron deficiency was prevalent as 26% of patients had serum ferritin <100ng/dl and 44% had total iron binding capacity (TST) less than 20%. Correction of anemia was associated with improved well being, quality of life, cardiac function and patient outcomes [25-26]. Achieving KDOQI target for anemia is challenging in any developing country because of the limited governmental budget and poor personal incomes.

Another area of weakness area is maintenance of calcium and phosphorus metabolism within KDOQI targets in our dialysis patients. Mean serum phosphorus was 6.26±2.54mg/dl in prevalent dialysis patients during the study period. 60% of dialysis patients, on the other hand, had serum phosphorus more than 5.5mg/dl. These data are comparable to the data reported by the DOPPS study [9]. The overall 7 countries serum phosphorus by guideline categories above >5.5mg/d was reported in 50.4% of patients (DOPPS I, 1999) and in 46.6% of patients (DOPPS II, 2002) [9]. The main reasons of poor phosphate control in our study group are dietary noncompliance, limited chances for getting frequent or daily dialysis, and unaffordable non calcium phosphate binders.

Our study show poor control of secondary hyperparathyroidism as PTH level was in the range of 150-300pg/ml in around 10% of prevalent patients. Around 50% of prevalent dialysis patients had PTH levels >600pg/ml. Achievement of PTH target within that recommended by the K/DOQI guidelines is the most difficult task for physicians due to difficulties in maintaining calcium and phosphorus levels within targets. The DOPPS study had reported an overall serum iPTH levels exceeding the K/DOQI target (i.e. >300pg/ml) in 28.6% of patients (DOPPS I, 1999) and in 26.1% of patients (DOPPS II, 2002) [9].

Infection control measures were considerably adhered to in the units especially in the care of hepatitis B patients. Wearing gloves and hand washing are two areas of weakness that need more training. Hepatitis C antibodies were positive in 75% of hemodialysis patients. Seroprevalence of HCV antibodies was reported to be high (49.1%) among ESRD patients in Egypt and was correlated significantly with blood transfusion [27]. Hepatitis B vaccination of the dialysis patients, nurses and staff is not carried out as a routine in the unit. The government pays around 18000 LE/year/patient to cover the combined cost of dialysis therapy, monthly investigations and treatment. This restricted fund makes universal vaccination difficult as it barely cover the cost of dialysis sessions and the necessary medications letting aside the costs of hepatitis B vaccination. The same applies for checking dialysis water for endotoxin as recommended by the AAMI [7].

The study showed impaired quality of life among prevalent dialysis patients. 40% of patients had SF36 scores in the range of 60-70. Poor quality of life had been reported in a previous cross sectional analysis of prevalent dialysis patients in our dialysis units [20-21]. Development of ESRD in the middle aged subject usually lead to disruption of patients' social and physical activities with subsequent psychological distress and poor quality of life [20-21]. The lack of association between laboratory parameters and QoL scores may suggest that socioeconomic factors, symptom burden and comorbidities are the main determinants of general health perception and physical and mental capabilities in this cohort of patients [20-21].

Annual mortality rate was as low as 8%. Old age, cardiovascular disease and sepsis were associated with mortality in the present audit. Cardiovascular disease, diabetes, and old age were associated with higher mortality rates in the DOPPS study [28]. The relatively low mortality rate in our dialysis population can be explained by their relatively young age, lower comorbidities rates, higher serum albumin achieved and low rate of use of central venous catheter.

To conclude, the study revealed a reasonable quality of care for HD patients in the fields of

vascular access care, dialysis adequacy and nutrition areas. It also reveals the need for improving anemia management and control of hyperphosphatemia with dietary counseling and more frequent dialysis.

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