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*Original Article*

# Assessment of management and treatment responses in haemodialysis patients from Tehran province, Iran

Mitra Mahdavi-Mazdeh[1,2], Mahnaz Zamyadi[3] and Mohsen Nafar[4]

[1]Department of Nephrology, Medical Sciences, Tehran University, [2]Director of Management Center of Transplantation and Special Diseases-MOH, Tehran, [3]Transplantation and Special Diseases Center (MOH) and [4]Department of Nephrology –Shahid Beheshti University of Medical Sciences, Iran

## Abstract

**Background.** Chronic kidney disease (CKD) and end-stage renal disease (ESRD) are emerging as globally important public health problems, and will necessitate improvements in health-care policy. ESRD incidence/prevalence data are not available from large parts of the developing world. The main objective of this study is to describe and assess the current clinical practices for patients on maintenance haemodialysis (HD) living in the province of Tehran.

**Methods.** In December 2005, an observational study was performed with 2630 patients (1505 males and 1125 females) from 56 different centres in the province of Tehran (the entire HD population), which has a population of 13.5 million inhabitants.

**Results.** The prevalence/incidence of HD was 194.8/77.3 p.m.p. The leading causes of ESRD were diabetes and hypertension. Population of 90.3 and 9% received three and two sessions per week, respectively, with a $KT/V$ mean value of $0.97 \pm 0.25$. All centres used synthetic membranes, and 68% of the sessions were performed using bicarbonate as a buffer. The type of vascular access was autogenous arteriovenous fistula in 91% of patients.

Our findings indicated that compliance with the K/DOQI recommendations for calcium–phosphorus management is difficult to achieve. Only 1.8% of patients achieved all four target laboratory tests.

For the management of anaemia, ferritin was the most commonly performed measure of iron status (76.7%). Iron deficiency was seen in <20% of patients (ferritin $\leq$200) and the mean value of haemoglobin (Hb) was $10.14 \pm 2.00$ g/dl.

**Conclusion.** The achieved standard of renal replacement therapy (RRT) in Tehran province, Iran is acceptable and in some aspects is comparable with European countries, but the number of ESRD patients is increasing in Tehran and worldwide. Increases in the number of HD centres, machines, shifts and kidney transplantations are taking place but cannot keep pace with the increasing number of patients. It is highly recommended that we try to increase peritoneal dialysis (PD) coverage and cadaveric transplantation, while keeping in mind that the prevalent population of individuals with CKD is estimated to be at least 20 times the number with ESRD.

It is not too ambitious to consider CKD prevention, and we should place initial focus on strategies and treatments that slow disease progression, in order to postpone RRT.

## Introduction

Over 1.5 million people worldwide are kept alive through haemodialysis (HD), peritoneal dialysis or transplantation. The number of those affected is forecast to double within the next decade. Chronic kidney disease (CKD) and end-stage renal disease (ESRD) are emerging public health problems that will require changes in health-care policies [1,2]. Because of funding restrictions, accessibility to dialysis and its quality and availability of donors in different countries, a gross diversity can be seen in the priority of offering preferred treatment modalities [3].

In order to facilitate effective future planning by healthcare authorities, reliable and up-to-date information on ESRD patient numbers, development trends, treatment modalities and outcomes is indispensable. Many national and international renal registries (the USRDS in USA, the Japanese Renal Registry and the ERA/EDTA renal registry in Europe) provide demographic and epidemiologic information on renal patients. Such reports provide a valuable base for comparisons between specified patient populations, and aid in the understanding of treatment practices and policies. However, similar information regarding ESRD incidence and different treatment modalities

*Correspondence to*: Mitra Mahdavi-mazdeh, Associate professor of Nephrology, Medical Sciences, Tehran University, Tehran, Iran.
Email: mmahdavi@tums.ac.ir

is not available from large parts of the developing world [2,4].

The prevalence/incidence of ESRD has been increasing in Iran from 238/49.9 p.m.p. in 2000 to 357/63.8 p.m.p. in 2006. The increase in the number of patients given renal replacement therapy (RRT) has been mirrored by an increase in the number of dialysis centres (227 in 2000 to 305 in 2006), machines, transplantation centres and even pre-emptive transplantations. The mean age of dialysis patients is 54.5 years (which contrasts with the mean transplantation age of 38 years) and the male to female ratio is 1.33. There has been no significant change in this ratio during this period. The advocated policy for younger patients in this country is transplantation [5,6].

Currently, 50% of ESRD patients in Iran are on HD, 47.5% are transplanted and 2.5% are on peritoneal dialysis. The Ministry of Health (MOH) is the main sponsor of the ESRD management program and acts through the Management Center for Transplantation and Special Diseases (MCTSD) [6].

Different modalities of RRT are provided at no charge and are accessible to all. A fixed reimbursement rate is paid for dialysis in both public and private hospitals. The average cost of provision for each dialysis treatment without the human resource cost and maintenance drugs is $43.20. All patients with ESRD including renal transplant recipients belong to a group of patients called 'Patients with Special Diseases' and are eligible for government-provided medical insurance [6]. In 1975, a treatment program for ESRD was introduced and the Dialysis Management Center in the Ministry of Health was established. The number of covered patients in Tehran has gradually increased from 587 (106.7 p.m.p.) in 1991 to 2630 (195 p.m.p.) in 2005 [7].

The main objective of this study is to describe and assess the current HD management system for dialysis patients living in the province of Tehran. The gold standards for comparison were the targets recommended in the National Kidney Foundation Dialysis Outcomes Quality Initiative (K/DOQI) guidelines.

## Subjects and methods

Monthly blood samples were routinely taken from all HD patients for assessment of serum levels of calcium, phosphorus, haemoglobin (Hb) and other parameters. In December 2005, an observational study was performed that included the entire HD population (2630 patients; 1505 males and 1125 females) from 56 different units in the province of Tehran, an area encompassing 13.5 million inhabitants. The study variables included demographic data (sex, age, cause of ESRD and occupation), concomitant diseases, anaemia and calcium-phosphate managements. The mean of each laboratory variable from the past 2 months was collected on a form specifically designed for the study. Data were excluded when two consecutive measurements of that item were not available. This explanation has been described in the 'number of patients' column in Table 3.

### *Statistical analysis*

Statistics were mainly descriptive and were according to the study objectives. Results are expressed as arithmetic means ± SD.

## Results

The mean age of patients in this study was 53.4 ± 17.1 years. Twenty-eight percent were illiterate. Diabetic nephropathy and hypertension were the leading causes of ESRD (59.6%), whereas other causes were chronic glomerulopathies (8.5%), adult renal polycystic kidney disease and urologic diseases (each 4.3%) and diseases of unknown aetiology (17%). About 4% of maintenance dialysis patients in Tehran were non-Irianian (mainly from Afghanistan).

Patients were on maintenance HD for 49.0 ± 17.9 months. 2376 patients (90.3%) received three dialysis sessions per week and 236 (9%) received two sessions per week. The duration of each dialysis treatment was 234 ± 17.4 min. The mean $KT/V$, as a measure of adequacy of dialysis, was 0.97 ± 0.25. Demographic data are reported in Table 1 and are stratified by age groups. Also important was the dialysis solution buffer, which was bicarbonate in 34.9% of patients at the time of the study and this, increased to 68% in Tehran by end of 2006. Other epidemiological data, comparing Tehran to Iran as a whole, are shown in Table 2.

Because of varying quality of the water source, water for the dialysate was ultimately purified by water treatment systems in all centres. Although two types of biocompatible dialysers (Haemophan and polysulfone) were in use in 2005, only polysulfone was used by the end of 2006. Reprocessing of haemodialysers for reuse is not practiced in this country.

Types of dialysis access were autogenous arteriovenous fistula (AVF) in 91%, polytetrafluoroethylene (PTFE) grafts in 3%, permanent catheter in 4% and transitory catheter in the remaining 2% of patients. The incidence of AVF use and temporary catheter use at the start of chronic HD was 35.7 and 56.3%, respectively.

The mean values for calcium, phosphorus, intact PTH (iPTH) as well as Hb, and ferritin, all in comparison with K/DOQI guidelines are presented in Table 3. Dialysate calcium concentration was 2.5 mEq/l.

Based on national guidelines, all patients have access to calcium carbonate as the phosphate binder and calcitriol as active Vitamin D. Other drugs for calcium and phosphorus management are not covered by insurance because of budget limitations.

Based on the data in Table 3, only 1.8% of the patients achieved four of the target laboratory tests. As defined by K/DOQI, 34.2 and 75% of patients achieved three and two targets, respectively.

**Table 1.** Demographic data stratified by age groups

| Age | Prevalent patients (%) | Prevalence/incidence (p.m.p) | M/F ratio | Three sessions/week (%) | Mean dialysis time (h) | Prevalence of AVF (%) | Hb mean (g/dl) |
|---|---|---|---|---|---|---|---|
| 0–14 | 28 (1.1) | 2.1/0.89 | 16/12 (1.33) | 22 (76) | 3.84 ± 0.39 | 20/28 (71) | 8.79 ± 2.51 |
| 15–24 | 119 (4.5) | 8.8/4.4 | 71/48 (1.48) | 106 (89) | 3.87 ± 0.32 | 107/119 (90) | 9.59 ± 2.39 |
| 25–44 | 605 (23.0) | 44.8/13.85 | 367/238 (1.54) | 567 (94) | 3.89 ± 0.30 | 552/605 (91) | .92 ± 2.06 |
| 45–64 | 1088 (41.4) | 80.6/30.9 | 590/498 (1.18) | 995 (91) | 3.90 ± 0.29 | 985/1088 (91) | 10.18 ± 1.95 |
| 65–74 | 576 (21.9) | 42.7/25.4 | 327/249 (1.31) | 507 (88) | 3.89 ± 0.30 | 527/576 (91) | 10.42 ± 1.91 |
| >75 | 210 (8.0) | 15.5/1.19 | 132/78 (1.69) | 175 (83) | 3.91 ± 0.24 | 190/210 (90) | 10.48 ± 1.85 |
| Total | 2626 | 194.5/77.3[a] | 1503/1123 (1.34) | 2372 (90) | 3.90 ± 0.29 | 2381/2626 (91) | 10.15 ± 2.00 |

[a]The age of 0.67 p.m.p of incident patients was not in the records.

**Table 2.** HD in Tehran province compared with Iran

| | Tehran province | Iran[a] |
|---|---|---|
| Total population (million) | 13.5 | 70 |
| Transplantation incidence (pmp) | 33 | 26.5 |
| HD prevalence/incidence (pmp) | 194.8/77.3 | 200.2/63.8 |
| No. of HD units | 56 | 305 |
| Three sessions/week | 90 | 61 |
| M/F ratio | 1.34 | 1.32 |
| Bicarbonate buffer based | 68% | 63% |
| Patient/machine ratio | 5.1 | 5.1 |

[a]The data for Iran are from the national registry of MCTSD (MOH) [7].

The routine protocol for anaemia management in Iran includes recombinant α-erythropoietin and iron sucrose for intravascular iron.

Ferritin was the most commonly performed measure of iron status (76.7%) compared with serum iron and total iron binding capacity (TIBC). Iron deficiency was seen in <20% of patients (ferritin ≤200) and 48.2% had Hb level of <10 g/dl. Mean dose of Epo was 102.45 ± 29.10 IU/Kg/W (range: 44.79–428.58).

More than 50% of patients were unaware that PD was available as a modality for renal replacement therapy. The remaining patients, who were familiar with PD, were concerned about risk of infection (26.3%) and lack of equipment (38.4%).

Of the 36% of patients who were eligible for transplantation based on physician notes, only 7% registered for the transplantation waiting list from deceased donors. Sixty-nine percent of transplanted patients on HD in 2006 were from Tehran (626/909).

Fifty-five percent of patients were vaccinated for hepatitis B and 2.4, 8.4 and 0.1% were HBSAg, HCV Ab and HIV Ab positive, respectively. Population of 70.3% was HBSAb positive. All HBSAg positive patients were dialysed on separate machines.

In regards to prevalence of Hepatitis B and C, the rates of HCVAb positive patients in Tehran (8.4%) were higher than in the rest of the country (4.5%), whereas percentages of HBSAg positive patients were not significantly different. Although vaccination is free and accessible to all, 30% of patients refused this treatment.

## Discussion

This article provides an overview of HD patients for 2005 in Tehran. Although ESRD affects only 0.05–0.07% of the population, its treatment consumes a considerable portion of national health resources [3]. It is clear that life-saving dialysis produces enormous strain on the resources of all countries, especially those with emerging economies [8]. If we take into account our population characteristics as well as the increase in ESRD incidence, and consider the required budget for providing dialysis to foreign patients (4% of dialysis patients of the province), maintenance of the current supply systems for this treatment will be harder to achieve in the near future. Since the end of civil war in Afghanistan, both government authorities and UNHCR (United Nations High Commissioner for Refugees) have worked to facilitate the voluntary repatriation of all refugees to their home country. Because there are no HD facilities in Afghanistan, repatriation of those refugees on chronic HD in Iran would result in their death [9].

In the face of increasing numbers of ESRD patients in the coming years, it is important that, according to our study, >50% of HD patients were unaware of PD, a comparable and possibly cheaper modality of renal replacement therapy [10,11]. The proportion of ESRD patients treated by PD was <1% (2 p.m.p.) in 2000 and reached 2.5% in 2005 (9.7 p.m.p.) [5,6]. Because of the efficiency of PD treatment and satisfaction of patients receiving this modality, we believe that more patients should be fully acquainted with this treatment option, which may help to support the increasing numbers of ESRD patients [12].

Kidney transplantation, which offers considerable lifetime savings and a drastic improvement in patient quality of life, is the most cost-effective treatment for ESRD [13]. It was therefore surprising that dialysis patients were unwilling to accept transplantations from deceased donors, which are provided totally free of charge. Only 7% of eligible patients registered for the transplantation waiting list from deceased donors. Most patients prefer to have kidneys from live donors. In Iran, the law allowing transplantations from deceased donors was recently passed in the year

**Table 3.** Mean values for calcium, phosphorus, intact PTH (iPTH), haemoglobin and ferritin compared with DOQI guidelines (shown in the Variable column)

| Variable | Number of patients | Mean value | Number (%) | | | |
|---|---|---|---|---|---|---|
| Phosphorus (mg/dl) | 2186 | 5.43 ± 1.51 | 3.5–5.5 (mg/dl) 1141(52.2) | >5.5 mg/dl 896(41) | | <3.5 mg/dl 149(6.8) |
| Calcium (>8.5) mg/dl | 2201 | 8.98 ± 1.23 | (<8.5) mg/dl 731 (33.2) | | | >10.2 300(13.6) |
| Ca×P ($mg^2/dl^2$) | 2148 | 48.70 ± 14.89 | <55 ($mg^2/dl^2$) 1548 (75.1) | | | >72 ($mg^2/dl^2$) 167 (7.8) |
| iPTH (150–300) pg/ml | 499 | 205.52 ± 190.21 | 150–300 pg/ml 138 (27.7) | >300 pg/ml 121 (24.2) | | <150 pg/ml 240 (48.1) |
| Haemoglobin (g/dl) | 1684 | 10.14 ± 2.00 | ≥11 (g/dl) 596 (35.4) | 8–11 (g/dl) 839 (49.8) | | <8 (g/dl) 249 (14.8) |
| Ferritin (ng/ml) | 1142 | 576.32 ± 486.77 | 101–499 467 (40.9) | 500–799 261 (22.9) | ≥800 298 (26.1) | ≤100 116 (10.2) |

2000, and this may partly explain the low transplantation rate from deceased donors. In addition, with this new system it competes with a well-established living-unrelated donor renal transplantation program, which has been government-funded and compensated since 1988 [13,14]. Also important is a shortage of deceased donors due to cultural complexities and other societal factors. A campaign directed at the general population and medical professionals may help to reverse this trend. A major attempt should also be made to coordinate activities in intensive care and transplantation units. This strategy would require a special effort to provide hospital personnel with managerial and communication skills to identify potential donors and to interact with grieving families. There is a high incidence of transplantation in Iran (26.5 p.m.p.) and a modestly short waiting list [13,14]. These conditions indicate that although the adequacy of dialysis is questionable, the ability to provide transplantation, especially for young patients, may prevent the long-term complications and harmful outcomes associated with inadequate dialysis.

Low $KT/V$ values were mainly due to low blood flow because of acetate buffer, non-compliance of patients and the limited number of machines in some centres.

Obtaining and maintaining adequate access to the circulation remains a major impediment to the long-term success of HD. In general, AV grafts provide a much less desirable access option than arteriovenous fistulas (AVF) because the initial placement of a catheter or graft, instead of the timely construction of an AVF, increases morbidity and mortality in chronic HD patients. Furthermore, a delay in providing an adequate AVF entails a significant increase in treatment-related costs. In Spain, AVFs account for 80% of all vascular access in prevalent patients. AVF use in Canadian prevalent (53%) and incident (26%) patients was lower than recommended by Canadian guidelines (60%), and lower than in Europe [prevalent (74%), incident (50%)] [15,16]. AVF is the advocated access route in Iran [prevalent (91%), incident (37.5%) in Tehran].

The strict maintenance of serum calcium and phosphorus levels within the range of K/DOQI guidelines was difficult of achieve for many reasons. The primary causes were the use of phosphate binders containing high calcium doses together with active vitamin D use and patient non-compliance. Previously published studies also mentioned this problem. The DOPPS study originating from seven countries showed that only 4.6 and 5.5% of patients in 2001 and 2004, respectively achieved all four targets [17]. Maduell *et al.* [18] and Yokoyama *et al.* [19] observed that only 9 and 7.3%, respectively achieved all four targets.

Opinion-based recommendations from K/DOQI guidelines indicate 2.5 mEq/l dialysate calcium concentration for routine use in dialysis units. This is the standard dialysis solution in Iran. Nevertheless, 3 mEq/l is most frequently given with the aim of obtaining an unchanged or slightly positive calcium balance. In the study by Aly *et al.* [20], in which all patients received 2.5 mEq/l dialysate calcium concentration, 72% had iPTH levels >300 pg/ml *vs* 24.2% in our study. This is in contrast with the concept that a dialysate calcium concentration of 2.5 mEq/l results in a negative calcium balance and stimulation of iPTH secretion [18]. In fact, a majority of our patients (48.1%) had low iPTH values. Achievement and maintenance of the iPTH target (27.7) is the most difficult task for physicians, and the present study emphasizes the difficulty in managing calcium–phosphorus metabolism [17–20].

For the management of anaemia, i.v. iron preparations differ substantially by country. For example, ferric hydroxide polymaltose serves as the only i.v. iron preparation in France, while ferric or ferrous gluconate comprises >80% of i.v. iron treatment in Germany, Italy and Spain. Iron sucrose accounts for >93% of i.v. iron use in the UK [17] and 100% in Iran. If less

expensive brands were substituted, resources could be reassigned to other priorities. We reported ferritin as the most common measure of iron status (76.7%), with this measure more prevalent in France, Italy, Spain and the UK (90%) and less in Germany (63%) [17].

Although iron therapy was acceptable, with 10% of patients having ferritin lower than 100 ng/ml, there is still room for improvement. The mean value of Hb in our study ($10.14 \pm 2.00$ g/dl) is lower than in the European countries of the DOPPS study [17]. Correction of anaemia was achieved in only 35% of patients, which may be due to low Epo doses and inadequate dialysis.

Finally, we examined the hepatitis B and C status of our patients. Although 30% of patients refused vaccination, hepatitis B virus (HBC) infection prevalence decreased from 4.3% in 2002 [21] to 2.8% at the time of the present study [7]. In order to reduce the risk of non-compliance and failure to respond to vaccination, we believe that vaccination should be mandatory in dialysis centres and should be encouraged in the pre-ESRD period.

Hepatitis C virus (HCV) infection is also common among patients with ESRD on dialysis. The prevalence of HCV infection among dialysis patients varies markedly from country to country [21–24]. For many years, blood transfusions were the main source of HCV infection in this patient population. The introduction of screening of blood products for anti-HCV has virtually eliminated transmission of HCV in blood transfusions [21,23]. Alavian *et al*. [21] in 2003 reported that 21% of HD patients in Tehran were HCV seropositive. By using the RIBA 2 complementary assay they confirmed that 13.2% [95% conflict of interest (CI): 11.3–15.1%] of patients were HCV positive [21]. It appears that the overall prevalence is decreasing largely due to improved blood screening. They also demonstrated that the duration of HD, irrespective of the number of blood transfusions and history of previous renal transplantations was an independent risk factor for the acquisition of HCV infection. This finding was also noted in other previous papers [22,23]. It appears that nosocomial transmission of HCV is related to the sharing of facilities in the HD environment for prolonged dialytic periods, repeated blood transfusions, surgical and dental procedures, multicenter visits for dialysis, application of infection-control policies and procedures, inadequate number and training of nursing staff and the isolation of infected patients and machines. It has been suggested that a strictly enforced isolation policy for HCV-positive patients may play a significant role in limiting HCV transmission in HD units. Such a policy drastically reduced HBV transmission in similar settings [25–27].

To reduce HCV infection, some have recommended shortening the duration of the HD period by early transplantation. However, the impact of renal transplantation on the course of HCV infection and the effect of pre-transplant HCV infection on survival among ESRD patients who have undergone renal transplantation are both controversial. Several investigators have reported a negative influence of HCV infection on patient survival, while others failed to show an effect on long-term patient or graft survival [21–24]. However, it seems that transplantation for suitable HCV positive patients not only offers better quality of life without serious adverse effects on patient or graft survival [22,27], but may also lead to a decrease in the burden of HCV, its complications and incidence rate in dialysis units [21,22].

## Conclusion

As a developing country, the achieved standard of RRT in Tehran province is acceptable and in some aspects is comparable to that of European countries. However, the number of ESRD patients is increasing, both in Tehran province and on a global scale [28,29]. Increases in the number of HD centres, machines, shifts and kidney transplantations are taking place, but cannot keep pace with the increasing number of patients. It is highly recommended that we try to increase PD coverage and cadaveric transplantation, while keeping in mind that the prevalent population of individuals with CKD is estimated to be at least 20 times the number with ESRD [29].

It is not too ambitious to consider CKD prevention, and we should place initial focus on strategies and treatments that slow disease progression [28,30], in order to postpone RRT.

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