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SEVENTEEN YEARS' EXPERIENCE OF PERITONEAL DIALYSIS IN IRAN: FIRST OFFICIAL REPORT OF THE IRANIAN PERITONEAL DIALYSIS REGISTRY

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♦ ***Background:*** **To facilitate planning, national renal registries provide reliable and up-to-date information on numbers of patients with end-stage renal disease (ESRD), developing trends, treatment modalities, and outcomes. To that end, the present publication represents the first official report from Iranian Peritoneal Dialysis Registry.**

♦ ***Methods:*** **The prevalence, demographics, and clinical characteristics of patients on peritoneal dialysis (PD) were collected from all PD centers throughout the country.**

♦ ***Results:*** **By the end of 2009, the prevalence of ESRD was 507 per million population in Iran. The most common renal replacement modality was hemodialysis (51.2%), followed by kidney transplantation (44.7%), and then PD (4.1%). The mean age of PD patients was 46 years, and the most common causes of ESRD were diabetes (33.5%), hypertension (24.4%), and glomerulonephritis (8.2%). Overall patient mortality was 25%, with cardiac events (46%), cerebral stroke (10%), and infection (8%) being the main causes of death. The 1-, 3-, and 5-year survivals were 89%, 64%, and 49% respectively. The most common cause of dropout was peritonitis (17.6%). *Staphylococcus* (coagulase-negative and *S. aureus*) was the most prevalent causative organism in peritonitis episodes; however, in more than 50% of episodes, a sterile culture was reported. Mean baseline serum hemoglobin and albumin were 10.7 g/dL and 3.6 g/dL respectively.**

♦ ***Conclusions:*** **Our registry results, representing the second largest report of PD in the Middle East, is almost comparable to available regional data. We hope that, in future, we can improve our shortcomings and lessen the gap with developed countries.**

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KEY WORDS: End-stage renal disease; renal replacement therapy; peritoneal dialysis registry.

Reliable and up-to-date information on the number of patients with end-stage renal disease (ESRD) and on developing trends, treatment modalities, and treatment outcomes are crucial to facilitate planning by health care authorities. In this regard, national and international renal registries provide valuable demographic and epidemiologic information about renal patients. Worldwide, the essential objective of registry systems is to improve the quality of patient management by establishing a comprehensive database that facilitates review of patient records from follow-up visits and better evaluation of the disease course, reminds medical staff about the timing of certain evaluations, facilitates referral of patients from one center to another (uniform records), and helps with

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planning to improve the quality of patient care (comprehensive database).

The first peritoneal dialysis (PD) registry in Middle East was introduced by Turkey (1). After Turkey, Iran is the second country in the region to have established a computerized PD data system. Using the Hakim software (Electronic Health Record: Pegahsoft, Tehran, Iran) the Iranian PD registry (IPDR) was set up in 2004. The registry collects data from all PD centers treating patients with kidney disease throughout the country. The registry report of 2006 was presented at Iran's International Congress of Nephrology, Kish Island, 2009 (unpublished data). In the present paper, we provide a detailed analysis of Iranian continuous ambulatory PD (CAPD) patients during the 15-year period from 1995 to 2010, and we try to place the findings in a global context. It is important to mention that, despite 17 years' experience, the PD prevalence in Iran unfortunately continues to be low, at 4.1%. The Iranian model for kidney transplantation (2) and the model of physician reimbursement are among the most important factors explaining this low PD utilization.

METHODS

To establish the IPDR, coordination between a number of organizations was necessary. As a consequence of several meetings between the Iran Society of Nephrology, the CAPD Club of Nephrologists, the research centers of Tehran University of Medical Sciences, various CAPD units, the Samen Pharmaceutical Company, the Kar-O-Andisheh Engineering Corporation (Baxter Healthcare's representative in Iran), and the Iranian National Kidney Foundation, the IPDR was established in 2004. Ten CAPD centers—Mashhad, Tehran, Isfahan, Tabrize, Euromia, Kerman, Shiraz, Zahedan, Yazd, and Kermanshah—initially participated in the registry. However, the rate of participation was gradually increased to 36 centers in 2010. The Shafa research center, which heads the IPDR, was involved in budget planning and obtaining data. The executive and operational tasks were acknowledged by the Department of Organ Transplantation and Special Diseases, Deputy of Medicare, Ministry of Health in Iran.

The registry data collection form includes 11 main questions providing information on the center; on the sociodemographic, clinical, and laboratory characteristics of the patients; and on patient treatment and follow-up. To keep the IPDR database up to date, the responsible PD nurses are required to report any change in the status of patients to the IPDR at 3-month intervals. Quality of the data collected is rechecked by a specially trained secretary supervised by a nephrologist. Whenever necessary, data are confirmed by a telephone call from the IPDR to the head of the specific center. Questionnaires are sent to the centers as printed material; completed forms are returned to the IPDR. The data are entered in the Hakim software, which was previously used by many Iranian medical research centers and also the Iranian national diabetes registry. In the software, the registry database has 11 headings, with a total of 430 questions related to consultation issues (92 questions), catheter insertion (38 questions), laboratory findings (40 questions), drugs (48 questions), complications (93 questions), and the natural history and termination of CAPD (24 questions).

Analysis of the registry data was performed using the Stata software application (StataCorp LP, College Station, TX, USA).The registry details are summarized as descriptive statistics (percentages, means, and medians). We examined patient survival (death being the outcome event) and death- and transplantation-censored technique survival [permanent transfer to hemodialysis (HD) being the outcome event]. Appropriateness for CAPD as a consequence of nonmedical characteristics such as personal hygiene, mood, learning ability, socio-economic class, occupation, home conditions, family support, visual ability, and manual dexterity were defined as nurse evaluation scores (NESs). Patients were categorized as positive selections if they were fully appropriate for PD based on medical and socio-economic status. Patients accepted for PD after they had been rejected for other modalities because of hemoaccess failure or multiple comorbidities were defined as negative selections.

RESULTS

PREVALENCE

In the present study, we analyzed the PD data for 1995 – 2010 (Figure 1). The mean follow-up period for our patients was 684.3 ± 533.9 days. The 38,060 adult patients receiving renal replacement therapy (RRT) in Iran yielded a prevalence of 507 per million population (pmp), which compares with 466 pmp in 2007 (3), representing a rise of 8.6% in RRT prevalence.

From 2001 to 2010, we observed an increase in the proportion of patients using the PD modality: PD constituted only 0.5% of RRT in 2001; by 2004, the percentage had reached 2.2%. In 2009 and 2010, the PD modality was respectively being used by 3.5% and 4.1% of all patients receiving RRT. In 2010, the most common RRT modality was HD (51.2%), followed by transplantation (44.7%), and finally PD (4.1%).

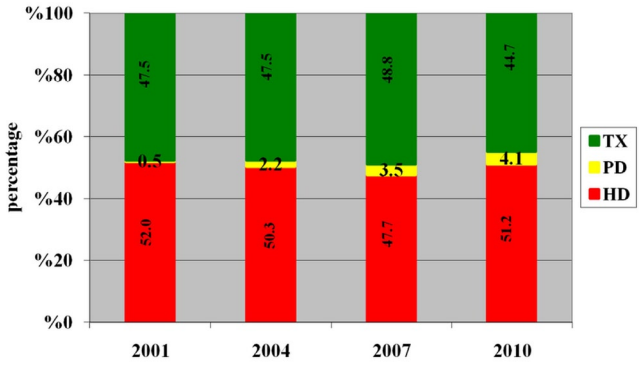

Figure 1 — End-stage renal disease requiring renal replacement therapy in Iran from 2001 to 2010. TX = transplantation; PD = peritoneal dialysis; HD = hemodialysis.

RESPONSE RATE

The average response rate to the various elements in the registry questionnaire varied. Personal and demographic questions such as age (97.7%), education (94.1%), marital status (87.9%), cause of ESRD (92.6%), and date of catheter insertion (98%) had the highest response rates. Laboratory characteristics such as 24-hour urine volume (57.3%), serum ferritin (39.9%), and serum parathyroid hormone (29.2%) were among the items least answered by the centers.

DEMOGRAPHICS

The mean age of the PD patients was 46.46 ± 20.38 years, with only 53 of them (2.4%) being more than 79 years of age. The group included 501 married and 1490 single individuals, and 1018 men and 1221 women. Systolic blood pressure was 100 mmHg or less in 6.7% of the patients (n = 123), and diastolic blood pressure was 65 mmHg or less in 10.8% (n = 195). The three most common kidney diseases leading to RRT in this group were diabetes mellitus, hypertension, and glomerulonephritis. Table 1 provides detailed information about baseline patient characteristics.

TABLE 1
Baseline Characteristics of Patients on Peritoneal Dialysis

Characteristic	Value (n)	Value (%)
Sex (men)	1081	45.47
Age		
<20 Years	244	11.2
20–29 Years	251	11.5
30–39 Years	245	11.2
40–49 Years	346	15.9
50–59 Years	430	19.7
>60 Years	666	30.5
BMI (kg/m^2)		
<19.9	359	20.7
20–24.9	847	49.0
25–29.9	418	24.2
>30	106	6.1
Education		
Illiterate	496	24.5
≥College	1286	63.4
University	246	12.1
Appetite		
Poor	166	9.9
Moderate	1233	73.6
Good	276	16.5
Comorbidities		
0	286	14.6
1	905	46.5
2	498	25.6
≥3	257	13.3
Cause of ESRD		
Diabetes	690	33.5
Hypertension	503	24.4
Glomerulonephritis	168	8.2
Collagen vascular disease	47	2.3
Polycystic kidney disease	87	4.2
Unknown	326	15.8
Others	239	11.6

BMI = body mass index; ESRD = end-stage renal disease.

OUTCOMES AMONG PD PATIENTS

Survival was calculated using the Kaplan–Meier technique. Patients were included if they had been on PD for at least for 90 days. Our overall patient mortality was 25%, with more than 93% of deaths not being directly related to PD complications such as peritonitis, sepsis, and so on. The main causes of death in our PD patients were cardiac events (46%), cerebral stroke (10%), and infection (8%). Mean patient survival at 1, 3, and 5 years was 89%, 64%, and 49% respectively (Figure 2). The patients remaining on PD at the end of years 1, 3, and 5 numbered 1544, 449, and 103 respectively. At the end of year 10, 7 patients were still on PD. Diabetic patients and those more than 40 years of age had a lower patient survival at all time points.

In univariate analysis, age, cause of ESRD, education, marital status, appetite, edema, type of selection (positive or negative), and NES were the factors that significantly affected patient survival. In multivariate analysis, diabetes mellitus [hazard ratio (HR): 1.88; p = 0.001], NES (HR: 1.26; p = 0.04), number of comorbidities

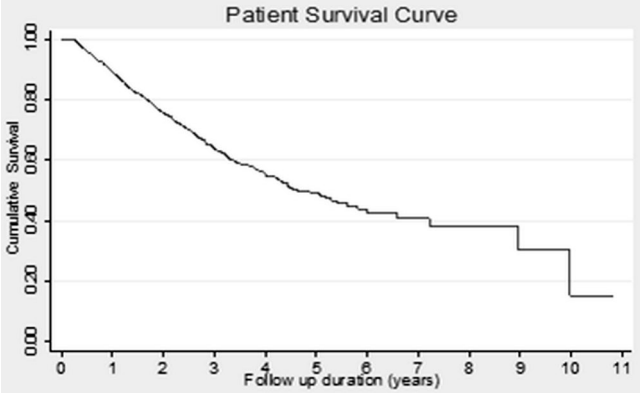

Figure 2 — Patient survival for peritoneal dialysis patients (Iranian Peritoneal Dialysis Registry, 2010).

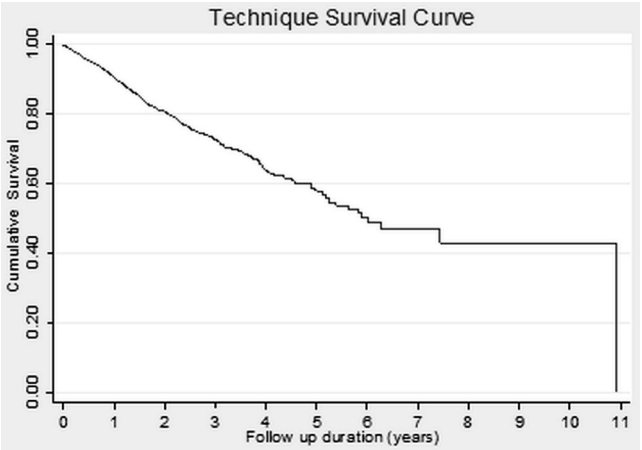

Figure 3 — Technique survival (death and transplant-censored) for peritoneal dialysis patients (Iranian Peritoneal Dialysis Registry, 2010).

(HR: 1.2; $p = 0.01$), high serum low-density lipoprotein cholesterol (HR: 1.003; $p = 0.03$), high serum albumin (HR: 0.42; $p = 0.0001$), positive selection (HR: 0.50; $p = 0.0001$), good appetite (HR: 0.6; $p = 0.0001$), and a low education level (HR: 0.84; $p = 0.04$) significantly affected patient survival.

In 2010, death- and transplantation-censored technique survival at 1, 3, and 5 years was 90%, 73%, and 58% respectively (Figure 3). In univariate analysis, appetite and NES significantly affected technique survival. Multivariate analysis demonstrated that higher hemoglobin (HR: 0.91; $p = 0.01$) and NES (HR: 1.89; $p = 0.002$) remarkably affected technique survival.

In 808 patients, PD was discontinued because of transfer to HD ($n = 399$), renal function recovery ($n = 28$), or renal transplantation ($n = 381$). The causes of transfer to HD were peritonitis ($n = 214$, 53.6%), membrane failure ($n = 62$, 15.5%), mechanical obstruction ($n = 49$, 12.3%), catheter malfunction ($n = 31$, 7.8%), patient desire ($n = 12$, 3.0%), and other reasons ($n = 31$, 7.8%). The peritonitis rate was 1 episode in 25 patient–months. Table 2 lists the causative micro-organisms. It should be mentioned that none of our patients used automated PD or icodextrin.

TABLE 2
Causative Micro-organisms in Peritoneal Dialysis Peritonitis

Micro-organism	Value (n)	(%)
Gram-positive		
Staphylococcus aureus	125	11.1
S. epidermidis	175	15.6
Enterococcus	14	1.2
Streptococcus	27	2.4
Gram-negative		
Pseudomonas	38	3.4
Others	75	6.7
Fungus	45	4
Tuberculosis	5	0.4
Miscellaneous	7	0.6
Sterile	614	54.6
TOTAL	1125	100

PARACLINICAL CHARACTERISTICS OF PD PATIENTS

Baseline hemoglobin in the PD patients was 10.7 ± 1.7 g/dL and ranged between 5 g/dL and 19 g/dL in various centers. At baseline, the minimum and mean serum albumin concentrations were 1.3 d/dL and 3.6 ± 0.6 g/dL respectively. Table 3 details the paraclinical information for the PD patients. We observed that 1644 of 1930 patients had a serum hemoglobin reading lower than 12.5 g/dL, and 720 of 1801 had a serum albumin reading of less than 3.5 g/dL.

Data from the first and the most recent peritoneal equilibration test (PET) showed that most PD patients were high-average transporters (first PET: 44.3%; last PET: 42.3%), and as expected, the number of patients with high transport according to the PET increased over time (Figure 4).

DISCUSSION

A rise in the number of ESRD patients is a fact in all countries. The worldwide prevalence of ESRD in 2001 was 1479 pmp, a number that reached 1783 pmp in 2004 and increased again to 2310 pmp in 2008 (4). Similarly, we observed that the prevalence of ESRD patients in our

TABLE 3
Baseline Laboratory Characteristics of the Peritoneal Dialysis Patients

Characteristic	Value (*n*)	(%)
Hemoglobin (g/dL)		
<8	196	10.1
8–9.9	570	29.3
10–11.9	722	37.1
12–13.9	367	18.8
≥14	93	4.8
Albumin (g/dL)		
≤2.4	61	3.4
2.4–4.4	1574	87.1
≥4.5	172	9.5
Ferritin (ng/mL)		
≤199	550	41.2
200–799	617	46.2
≥800	168	12.6
Calcium (mg/dL)		
≤8.4	485	27
8.5–10.4	1199	66.6
≥10.5	115	6.4
Parathyroid hormone (pg/mL)		
≤199	821	73.1
200–500	211	18.8
≥500	91	8.1

country increased to 507 pmp in 2010 from 467 pmp in 2006.

According to available global data, the PD modality constitutes about 8.6% of all RRT, a figure that varies widely in different countries. In the Middle East, the penetration of PD relative to the ESRD population is 7.5% (5). In our registry, we observed a continuous increase in the PD modality from 2001 to 2010 (to 4.1% from 0.5%), which might be a reflection both of growth in the incidence rate and decline in the death rate. Still, we have to note that that our proportion of PD patients is lower than the global and regional proportion. The difference could partly be a result of the current Iranian model, in which most Iranian kidney transplant candidates have access to kidney transplantation and the government dedicates a large budgetary expenditure to support living unrelated donation and brain death donation programs (2), such that there has been no waiting list for transplantation since 1999 (6). In addition, a lack of any type of physician reimbursement and poor knowledge both in the general population and among health authorities about PD might contribute to the low rate of PD use in our country. Doctors in Iran provide PD free of charge. In public

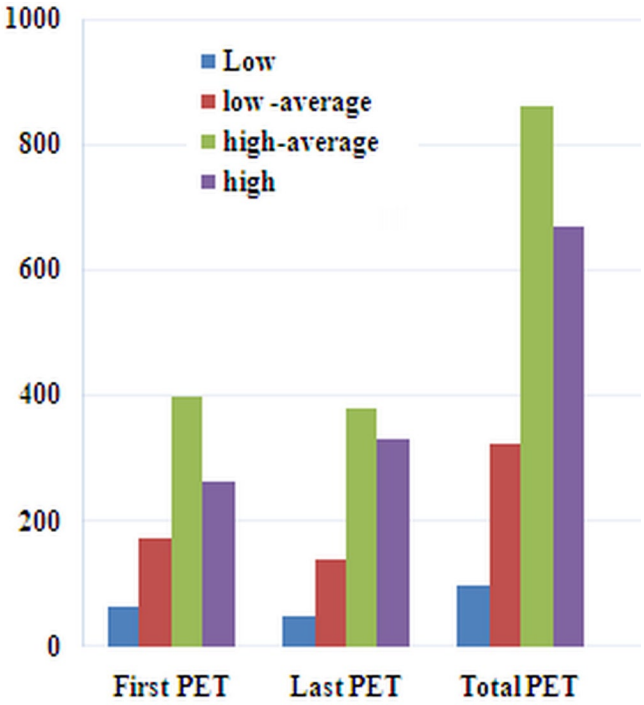

Figure 4 — Distribution of membrane transport status based on a first and last peritoneal equilibration test (PET) in peritoneal dialysis patients (Iranian Peritoneal Dialysis Registry, 2010).

hospitals affiliated to universities, physicians receive only their salary; they receive no bonus for practicing PD. In private clinics, doctors are paid directly by PD patients the same amount they would receive for a routine visit, although almost no patient would be ignored, even if they could not afford to pay the visit charge.

The mean age of our PD patients was 46 years, with 40% being in 50 – 69 age group. That age is similar to the mean age of patients in Turkey [46 years (7)] and Korea [44 years (8)] and lower than the mean age of patients in Denmark (60 years), France (53 years), the United States (63 years), and Japan (58 years) (9,10).

As is observed elsewhere in the world, hypertensive and diabetic nephropathy were the primary diseases among our PD patients. We have to emphasize that we should be cautious about hypertension and diabetes as the cause of ESRD, because these two diseases could be regarded as comorbid conditions as well. In our registry analysis, the primary diagnosis of ESRD was generally based on history and a clinical assessment without pathology confirmation. Therefore, in many cases, it would be a difficult matter to differentiate between diabetes and hypertension as primary causes or comorbidities.

Different survival rates for PD patients have been reported from various countries. Survival at 3 and 5 years in our registry was 64% and 49% respectively.

The US Renal Data System 2006 report showed a 5-year survival of 32% in the United States (11). In Asia, 3- and 5-year survival rates of 83.8% and 68.6% were reported for Turkey (7), and a 5-year survival of 69.8% has been reported for Korea (12). The reasons for these differences in survival are likely to be multifactorial, but part of the difference may reflect the varying demographic characteristics of the PD patients, especially age.

Our2010 data for 3- and 5-year survival showed improvement compared with our 2006 data. We have to emphasize that, in addition to overall improvement in our PD practice, some of the differences between the 2006 and 2010 registry results can be explained by improvement in the quality and quantity of data collection and also by enforcement of the PD registry protocol and better training of PD nurses.

As expected, our study showed that a higher number of comorbidities and the presence of diabetes were associated with lower patient survival. A high number of comorbidities could perhaps be assumed to be a marker of a medical decision to avoid transferring the patient to other modalities when short life expectancy is anticipated.

Like reports from other registries, our report shows that the main causes of death in our PD patients were cardiac events, cerebral stroke, and infection (7,13). Preventing dialysis-related infectious complications, especially peritonitis, is crucial for improving long-term outcomes. Our average peritonitis rate was 1 episode in 25 patient–months, which is higher than rates reported by the registry of the European Renal Association–European Dialysis and Transplant Association and the registries of Turkey and Japan (7,9,13). We should also emphasize that the peritonitis rate does not seem to be accurate, possibly because of a very low response rate from the centers concerning this complication. Our registry also demonstrates an unacceptably high rate of culture-negative peritonitis (more than 50%). The reported rate of negative peritonitis cultures varies significantly, from 11% in North America to 67% in Mexico (14). Culture negativity has many causes, including unskilled personnel, prior antibiotic use in the patient, inadequate sample collection, and poor culturing technique, among others (15).

The overall condition of our PD patients is evaluated by measuring the serum levels of albumin, hemoglobin, calcium, and other elements. Compared with data from other registries, including those of Turkey, Japan, the United States, and Australia (7,11,13), hypoalbuminemia, hypocalcemia, and anemia were more prevalent in our PD patients, denoting the inferior health condition of our accepted PD patients.

CONCLUSIONS

This first official report of the Iranian PD registry indicates that improvement in PD practice has been taking place nationwide in our country since the mid-1990s. Our registry represents the second-largest use of PD in the Middle East, with data almost comparable to that in the largest registry. In future, we hope to improve our shortcomings and lessen the gap in our results compared with developed countries.

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DISCLOSURES

The authors declare that no financial conflicts of interest exist.

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