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Direct Cost for Treating Chronic Kidney Disease at an Outpatient Setting of a Tertiary Hospital: Evidence from a Cross-Sectional Study

Rajiv Ahlawat, MPharm[1], *Pramil Tiwari, PhD*[1,*], *Sanjay D'Cruz, MD, DNB, DM, MAMS, FISN*[2]

[1]*Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research (NIPER), Mohali, Punjab, India;*
[2]*Department of General Medicine, Government Medical College and Hospital, Chandigarh, India*

ABSTRACT

Background: Chronic kidney disease (CKD) has a high morbidity and mortality in developing countries. And this burden is also increasing rapidly in India. Unaffordability due to high cost of medication and hemodialysis remains one of the major barriers in the successful treatment of CKD. **Objectives:** To determine the direct cost involved in treating CKD at an outpatient department of a public tertiary care hospital. **Methods:** This cross-sectional study was carried out at a public tertiary care hospital. Patients diagnosed with CKD by a physician were included in the study after obtaining a written informed consent. All the relevant data were collected on a predesigned case record form. **Results:** The results are based on data obtained from 150 patients. The average age of the patients was 55.7 ± 10.1 years. The average number of drugs per prescription was found to be 6.5 ± 1.7. The annual average costs of treatment for patients on medication only and for patients on hemodialysis plus medication were Rs 25,836 (US $386) and Rs 2,13,144 (US $3181), respectively (Rs = Indian rupee). Treatment cost was found to be statistically significantly higher in patients on hemodialysis, treatment support by employer, patients with a smoking habit, patients with comorbidities, and patients with end-stage renal disease. Calcium tablets, vitamin D sachets, iron supplements, torsemide, and amlodipine were the top five medications prescribed. **Conclusions:** Reimbursement, patient's dialysis status, habits, and comorbidities were found to have a significant effect on the direct cost of treatment.
Keywords: chronic kidney disease, costs and cost analysis, direct cost of therapy, India, kidney disease.

Introduction

The increasing burden of chronic kidney disease (CKD) is a matter of great concern because it leads to high levels of morbidity and mortality. Various researchers who have assessed this in India have reported a prevalence of up to 6% [1–7]. Diabetes has been found to be the most common risk factor for patients with CKD in India [8–11]. With the estimated increase in elderly population in India, the burden of diabetes (and indirectly CKD) is also likely to increase [10].

CKD has enormous economic impact too. It severely affects the patient's physical health and quality of life. It also has disruptive effects on lifestyle, relationships, family, emotions, and employment. The disease is known to affect not only the patients but also the caretaker [12]. CKD has a huge economic burden on health care systems [13]. The cost of hemodialysis varied from Rs 150 (US $2) in public facilities to as high as Rs 2000 (US 30) in private facilities (Rs = Indian rupee) [14]. Only a limited number of public-funded dialysis and kidney transplant centers are available in India. These are restricted to health care facilities in urban areas. According to the Planning Commission Report of the Government of India, 22% of the population in India is below the poverty line [15] and cannot afford the high cost of treatment associated with CKD. According to data from the World Bank, 1.267 billion people fall in the "lower middle" income status, whereas the per capita gross national product of India is US $5760 (Rs 385920) [16]. According to data from the World Health Organization (2013), the gross national income per capita on the basis of purchasing power parity is US $5 (Rs 335) [17]. Patients have high out-of-pocket (OOP) expenditure in India. To our knowledge, India does not have a reimbursement policy covering all its citizens for health care expenditure. According to the latest available data from the World Bank, the Indian government is spending only 4% of the gross domestic product on health [18]. Only 32% of the total health expenditure is public [19].

According to the estimates of March 2014 on health insurance coverage by the Insurance Regulatory and Development Authority, only 17% of the population (21.62 crore people) is covered by health insurance in India. Out of the total, 15.5%, 3.4%, and 2.7% are sponsored by government, nongovernment, and individual

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* *Address correspondence to:* Pramil Tiwari, Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research (NIPER), Sector 67, Mohali, Punjab 160062, India.

E-mail: ptiwari@niper.ac.in

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covers, respectively [20]. The access of this health care insurance is restricted to public employees and some selected groups of people who can afford to have insurance. A large number of patients in India do not have access to insurance. A large number of patients with CKD belong to the elderly group, who do not have any source of income and therefore cannot afford the treatment cost.

Patients with CKD often present with several coexisting comorbidities that require multiple medications. Other than the high number of medications, patients with end-stage renal disease (ESRD) also require dialysis. This increased pill burden and dialysis along with other factors increase the cost of treatment. Lack of a reimbursement/insurance mechanism continues to be a challenge in the treatment of CKD. The inability to afford the cost of erythropoietin for treating anemia in patients with CKD has been reported [14]. High cost of dialysis is the most common reason for nonadherence to dialysis in India [11]. It is fair to believe that a large number of patients could die because of their inability to afford the treatment.

Satyavani et al. [21] and Kumpatla et al. [22] have estimated the annual OOP expenditure in CKD caused by diabetes only [21,22]. Ramachandran and Jha [23] have estimated the OOP expenditure to be US $7881 in patients with CKD undergoing transplantation. Suja et al. [24] have reported the cost for patients with ESRD undergoing hemodialysis for a period of 6 months (Rs 318822; US $4759).

Evidence on the direct cost of treatment in patients with CKD is available in India. No evidence is available about the impact of different sociodemographic and clinical characteristics on the direct cost of treatment in different stages of CKD. This present study was carried out to determine the direct cost involved in treating CKD at an outpatient department of a public tertiary care hospital.

Methods

This cross-sectional study was carried out at a renal clinic of medicine in the outpatient department of the Government Medical College and Hospital, Chandigarh, which is a multispecialty hospital with 440 beds. All patients who were diagnosed with CKD, older than 18 years, and willing to participate were included in the study. Patients unable to complete the interview were excluded from the study. A written informed consent was obtained from the patients for participation in the study. Data from patients with cognitive impairment and those unable to complete the interview were excluded. The relevant data were captured in case record forms. A case record form consisted of information related to a patient's age, sex, weight, height, diagnosis, dialysis status, education status, occupation, family income, source of funding, habits, residential area, caretaker, transport expenses, presence and duration of comorbidities (diabetes, hypertension, anemia, and hyperlipidemia), biochemical parameters, and medications prescribed. Patients' demographic details were collected from clinical records and interviews. Anthropometric measurements including weight and height were taken from the patients' records. Biochemical parameters were captured from the latest laboratory investigation reports documented in the clinical records. The Kuppuswamy Scale was used to assess the socioeconomic status of the patients [25]. Data regarding source of funding were obtained through interviews.

The Kidney Disease Improving Global Outcomes definition of CKD was used. *CKD* is defined as abnormalities in kidney structure or function (albuminuria, urine sediment abnormalities, electrolyte and other abnormalities due to tubular disorders, abnormalities detected by histology, structural abnormalities detected by imaging, history of kidney transplantation, and a glomerular filtration rate [GFR] $<$60 ml/min/1.73 m^2) present for more than 3 months, with implications for health. It is classified on the basis of cause, GFR category, and albuminuria category. Patients with CKD were classified into five stages: G1 ($\geq$90 ml/min/1.73 m^2), G2 (60–89 ml/min/1.73 m^2), G3a (45–59 ml/min/1.73 m^2), G3b (30–44 ml/min/1.73 m^2), G4 (15–29 ml/min/1.73 m^2), and G5 ($<$15 ml/min/1.73 m^2) [26]. On the basis of body mass index (BMI), patients were classified as underweight ($<$18.50 kg/m^2), normal weight (18.50–24.99 kg/m^2), and overweight ($\geq$25.00 kg/m^2) [26,27]. The participants were considered hypertensive if they were on antihypertensive medication (as documented in clinical records and diagnosed by the physician) or had a systolic blood pressure of 140 mm Hg or higher or a diastolic blood pressure of 90 mm Hg or higher. Blood pressure was measured in sitting position after a 10-minute rest [28]. Confounding and erroneous reading were handled by rechecking of the blood pressure by the physician.

Direct medical costs included physician fees for outpatient visits, drug costs for CKD treatment, and charges for laboratory test(s). The direct cost of medicines was calculated by using the online version of the Current Index of Medical Specialities. The maximum retail price as mentioned in the current issue of the index was used. The cost of the prescribed brand was included whenever applicable. In case of drugs prescribed by the generic name, the highest cost was considered. The annual cost of treatment was calculated. All the calculations were reported in Indian rupee only.

The study was approved by the research and ethics committee of the clinical site. It was carried out in compliance with the ethical standards provided by the Indian Council of Medical Research for biomedical research [29].

Data were presented as mean with SD or as median with interquartile range and numbers with percentages, as applicable. The Student *t* test (unpaired) and analysis of variance were used to assess the differences between means of independent categorical variables and dependent continuous variables. A *P* value of 0.05 was considered statistically significant. All analyses were done by using IBM SPSS Statistics version 20.0 (SPSS Inc., Chicago, IL).

Results

Data from 150 patients included in the present study were analyzed. The response rate was 92.6% (150 of 162). The mean age of the patients was 55.7 $\pm$ 10.1 years. The male-to-female ratio was 1.17. Different characteristics of male and female patients were compared (Table 1). There was no statistically significant difference between the characteristics of the two sexes, except for the BMI and the GFR. Median BMI was found to be statistically significantly different between males and females (23.4 and 27.1, respectively; $P < 0.05$). Mean GFR was found to be lower in male patients than in female patients (17.3 and 19.5, respectively; $P < 0.05$; Table 1). Patients were categorized on the basis of their sociodemographic characteristics (see Table 2). They were also categorized on the basis of their clinical characteristics (see Table 3). The mean number of drugs was found to be 6.5 $\pm$ 1.7.

The mean annual cost of treatment was found to be statistically significantly higher in patients on hemodialysis and medication than in patients on medication only (Rs 2,13,144 vs Rs 25,836; US $3181 vs US $386; $P < 0.001$). Mean OOP expenditure was found to be statistically significantly higher when the treatment was funded by the employer (Rs 65,664 vs Rs 48,600; US $980 vs US $725; $P < 0.05$).

The mean cost was also studied with reference to the BMI of the patients. It was found to be statistically significantly lower in