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ESTIMATING THE ECONOMIC BURDEN OF CHRONIC KIDNEY DISEASE: A COST OF ILLNESS STUDY

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ABSTRACT: The study aims to estimate the cost expenditure in chronic kidney disease patients. A prospective, observational study was carried out in a tertiary care hospital in south India for around 6 months. In the 201 patients enrolled in the study, 137 were males and 64 were females, aged 18 years or older, diagnosed with 3-5 and 5D stages of chronic kidney disease included in the study. Patient data were collected from the patient medical records, and direct and indirect medical cost analyses were analyzed. Descriptive analysis was done for age, gender, stages, co-morbidities, socioeconomic status, food habits, family history and occupational status. The P value of <0.05, was considered significant. The current study reveals that the social cost, including both direct and indirect medical costs, increases in the advanced stages of CKD. Patients on HD had the highest economic burden compared to other stages patients.

INTRODUCTION: Chronic kidney disease (CKD) is defined as kidney damage with a glomerular filtration rate (GFR) < 60 mL/min/1.73 m^2 for three months or more, irrespective of the cause [1]. It is a progressive loss of kidney function that requires renal replacement therapy (dialysis or transplantation). Kidney damage refers to pathological abnormalities suggested by imaging studies or renal biopsy, abnormalities in urinary sediment, or increased urinary albumin excretion rates [2]. In general, CKD is a global health threat, but mainly for developing countries, because the treatment options are expensive and lifelong. In India, ~90% of patients cannot afford the cost.

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Even today, over 90% of patients requiring Renal Replacement Therapy (RRT) in India die because of their inability to afford care. Even those who start RRT, 60% stop due to financial constraints. Among those who undergo kidney transplantation, unexpected complications directly cause many financial hardships.

Around 130,000 patients are receiving dialysis, and the number is increasing by about 232 per million, which correlates with longevity. India is estimated to have about 120,000 patients on HD (Hemodialysis) and 8500 patients on PD (Peritoneal dialysis). Every year 1,00,000 newly diagnosed end-stage renal disease (ESRD) patients start dialysis in India [3].

Cost-Of-Illness Study: Cost-of-illness studies (COIs), or burden of disease (BOD), remain the first economic evaluation tool in a healthcare system that contains important information to inform the healthcare sector about the cost-

effectiveness of treatments and economic burden of disease. COIs are used to assess the economic impact of a disease and identify the associated costs to inform decision-makers about the economic burden of the illness [4].

COI studies often document the economic burden of specific disease and its risk factors. COI studies provide a comprehensive assessment of the associated costs and can include direct costs, indirect costs, and losses in economic productivity related to morbidity and mortality [5].

COI studies measure the maximum amount that could be saved if a disease were eradicated. Many of these studies have potentially impacted public health policy debates as they indicate the magnitude of an illness or disease's impact on society [6]. A COI study aims to identify and measure all the costs of a particular disease, including the direct, indirect, and intangible dimensions. The output estimates the total burden of a particular disease to society.

Cost-of-illness studies can be carried out in two methods. They are,

Prevalence Based: The Amount spent to care for a person with a specific disease or injury each year.

Incidence Based: The Amount spent over a person's lifetime for a specific disease or injury first occurring within a particular period [7].

Direct Cost: Direct medical costs include medical care expenditures for diagnosis, treatment, continuing care, rehabilitation and terminal care, as well as non-medical expenditures occasioned by illness or disease. It includes the cost of hospitalization, outpatient clinical care, nursing home care, home health care; services of primary physicians, specialists, dentists and other health professionals; drugs and drug sundries and rehabilitation counselling and other rehabilitation costs, such as those for prostheses, appliances, eyeglasses, hearing aids, speech devices, *etc*., to prevent or overcome illness-related impairments.

Direct non-medical costs - include transportation cost to health care providers; relocation expenses; and the cost of making changes to one's diet, house, car, or related items [8].

Indirect Cost: Indirect cost covers the loss of resources incurred due to morbidity and mortality in a particular disease, which ultimately has monetary value on the value of life. There are three primary ways to quantify indirect cost: the human capital method, the friction cost method, and the willingness to pay method.

The substantial social economic burden of CKD in pre-dialysis and dialysis stages has not been widely investigated in the scientific literature. A limited number of studies aimed at quantifying the social cost of a patient with CKD are available with a high level of heterogeneity and incompleteness in cost estimates. In most studies, the direct medical costs have been estimated, while direct non-medical and indirect costs have been reported with insufficient or missing estimates.

An economic burden has been used to describe the self-care practices and work carried out by patients due to engaging in treatment for one or more chronic illnesses. It entails the patient's engagement with providers, the health care system, their family or social support network, and personal self-care regimens [8].

Literature Review: Thai Quang Nguyen *et al.*, (2018) conducted a study on Socioeconomic Costs of CKD. The results of this study showed the economic burden of CKD was considerable at all levels of the disease, and the progression of CKD might cause direct costs to increase sharply. The direct medical costs in HD patients were significantly higher than in those not on dialysis (p-value <0.001). As to the CKD 1–3 group, the annual cost per patient was significantly affected by factors like age, residence, BMI, education level, exercise, and comorbidities. Of the total costs in each group, direct medical costs contributed the most [9].

S. Fathima *et al.;* (2018) conducted a study to analyze the healthcare costs of hemodialysis (HD**)** patients in a charitable hospital Mangalore, Karnataka. It was a prospective observational study done for 8 months in an outpatient HD unit. A total of 39 outpatients were included in the study. Of 39 patients, the majority of the HD patients were males (66.2%) followed by females (33.8%). Most patients underwent HD twice a week (89.7%)

followed by thrice a week (10.3%). The study revealed that the total median direct cost was found to be uppermost for the age group of 41–60 years when compared to all other age groups, and it was also observed that the total median direct cost for males was higher than females (1,03,170.7 INR). The factors such as type of co-morbidities, age, and number of HD per week may affect the cost of illness [10].

Giuseppe Turchetti *et al.,* (2016) carried out a study to evaluate the social cost of CKD in Italy. It was a multi-center, cross-sectional study done for a period of 1 year on 484 patients, of whom 279 had CKD in stage 4 and 205 were in stage 5 pre-dialysis. 268 patients with CKD in stage 4 and 193 in stage 5 had comorbidities. The authors concluded that direct non-medical costs and indirect costs represent the main component of the social cost of CKD [11].

Marion Kerr *et al.,* (2012) estimating the financial cost of chronic kidney disease in England. In this study, Economic modeling was used to estimate the annual cost of Stages 3–5 CKD to the National Health Service (NHS) in England, including CKD-related prescribing and care, renal replacement therapy (RRT), and excess strokes, myocardial infarctions (MIs) and Methicillin-Resistant Staphylococcus Aureus (MRSA) infections in people with CKD. The study shows that the financial impact of CKD is large, with particularly high costs relating to RRT and cardiovascular complications [12].

Objective: The study aims to estimate the cost expenditure in CKD patients.

Primary Objective: To estimate the economic burden of disease.

Secondary Objective: To assess the functional status in CKD patients.

MATERIALS AND METHODS: This was a prospective observational study conducted in a 750 bedded multispecialty hospital (Vijaya group of hospitals) located at Vadapalani, Chennai, for the period of 6 months (April to September 2019). The study was approved (Ref No: EC/LTR/2019/049(C) by the Institutional Ethics Committee of the Vijaya group of hospitals. Patients were included in the study based on the inclusion and exclusion criteria after getting the patient consent, and the required data was collected in a specially designed data entry form.

Study Population: Outpatients of the nephrology department diagnosed with stage 3-5 and 5D CKD.

Study Population Size: 201 CKD patients were included in this study based on inclusion and exclusion criteria after getting the patient consent (Annexure -2), and the required data was collected in specially designed data entry form (Annexure - 1).

Patient Selection:
Inclusion Criteria

- ✓ Gender: both male and female.
- ✓ Subjects who are diagnosed with 3,4,5 and 5D stages of CKD.

Exclusion Criteria:

- Renal transplant recipients.
- Pregnant and lactating women.
- Patients who are not interested participate in the study.

Method: A data collection form was designed per the study requirements. The details such as age, gender, stages of CKD, occupation status, marital status, socioeconomic status, food habits, and social history, co-morbid conditions were obtained from the patient's medical records.

The Pharmaco-economic related direct medical costs like medicines, HD, laboratory investigations, consultations, hospitalization and miscellaneous costs and non-medical costs like transportation to visit HD unit and food expenses during HD were collected from the patient records, medical bills, hospital accounts section and interviewing the patients or from patient parties. From the data obtained, the total cost for 6 months was calculated.

Data Analysis: The collected data and the cost analysis were done.

Statistical Analysis: All the data collected were tabulated and analyzed statistically using Microsoft Excel and statistical software SPSS version 17.0.

Descriptive analysis was done for age, gender, stages of CKD, *etc*. Continuous variables were represented as Mean (SD). The P value of <0.05, was considered significant.

RESULT: 201 patients from the outpatient nephrology department were randomly selected in the study based on the inclusion and exclusion criteria. Among 201 patients, 137 were males, followed by 64 females. Their demographic and treatment details were collected.

Stage Wise Classification: Table 1 & **Fig. 1** represents the prevalence of CKD in the study population according to the stages of CKD as per the National Kidney Disease Foundation classification as follows:

62 (31%) patients were in CKD stage 3, 52 (26%) were in CKD stage 4, 10(5%) were in CKD Stage 5 without HD, and 77 (38%) were in HD.

TABLE 1: DISTRIBUTION OF PATIENTS WITH STAGES OF CKD

Stages	No. of Patients (n=201)	Percentage
Stage 3	62	31%
Stage 4	52	26%
Stage 5	10	5%
HD	77	38%
All	201	100%

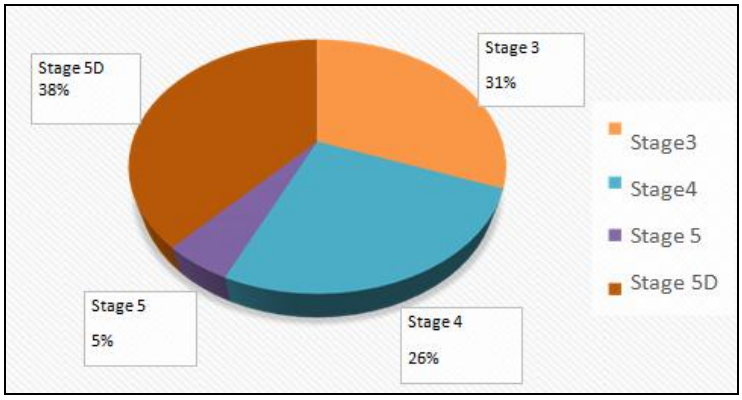

FIG. 1: DISTRIBUTION OF PATIENTS WITH STAGES OF CKD

Age Distribution of CKD Patients: Table 2 & **Fig. 2** represents the age of the study population, the maximum number of patients were in the age group of 61-80.

TABLE 2: AGE-WISE DISTRIBUTION OF THE STUDY POPULATION

Age Interval (years)	No. of Patients (n = 201)			
	Stage 3	Stage 4	Stage 5	Stage 5D
18 – 40	12	4	2	5
41 – 60	21	14	3	25
61 – 80	26	25	5	43
> 80	3	9	0	4

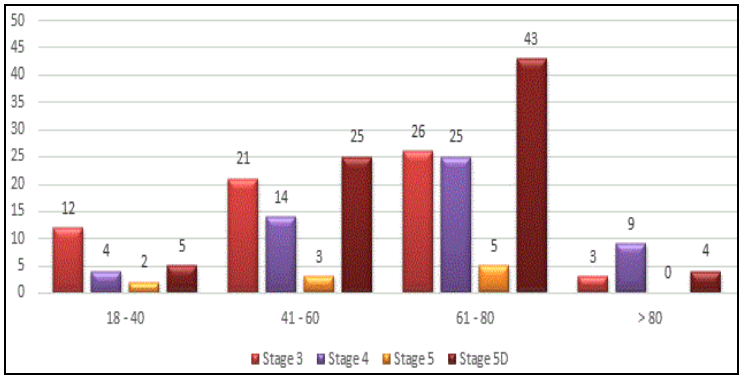

FIG. 2: AGE DISTRIBUTION OF PATIENTS

Gender-wise Distribution of the Study Population: Among 201 patients, 137 were males, followed by 64 females, as shown in **Table 3** & **Fig. 3.**

TABLE 3: GENDER-WISE CLASSIFICATION

Stages	Males	Females	Total
Stage 3	40	22	62
Stage 4	43	9	52
Stage 5	1	9	10
HD	45	32	77
All	137	64	201

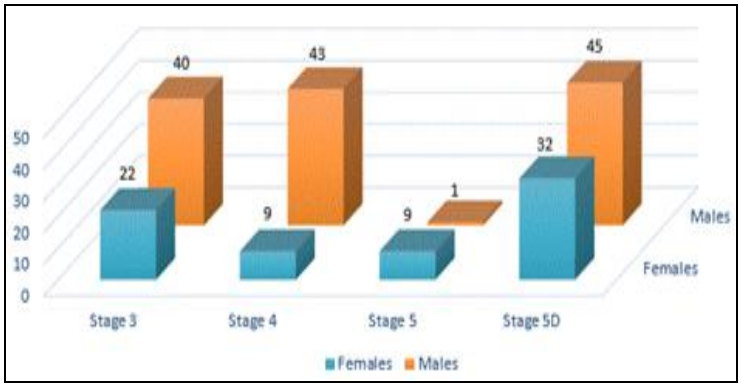

FIG. 3: GENDER DISTRIBUTION IN CKD PATIENTS

Occupation Status of the Study Population: Out of 201 patients, (40.29%) 81 were retired, 33.33% (67) were employed and 26.36% (53) were unemployed as shown in **Table 4** and **Fig. 4.**

TABLE 4: OCCUPATIONAL STATUS OF THE STUDY POPULATION

Occupational status	ALL (n=201)	Stage 3 (n=62)	Stage 4 (n=52)	Stage 5 (n=10)	Stage 5D (n=77)
Employed	67(33.33%)	25(40.32%)	17(32.69%)	5(50%)	20(25.97%)
Un Employed	53(26.36%)	15(24.19%)	8(15.38%)	2(20%)	28(36.36%)
Retired	81(40.29%)	22(35.48%)	27(51.92%)	3(30%)	29(37.66%)

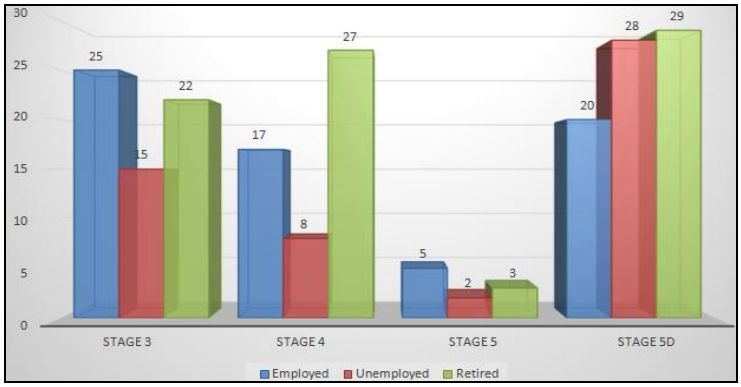

FIG. 4: OCCUPATIONAL STATUS OF THE STUDY POPULATION

Baselin Demographics and Clinical Characteristics of CKD Patients: Table 5 represents marital status, literacy status, socioeconomic background, food habits, and social history among the study population.

TABLE 5: BASELINE DEMOGRAPHICS OF THE STUDY POPULATION

Demographics	ALL (n=201)	Stage 3 (n=62)	Stage4 (n=52)	Stage 5 (n=10)	Stage 5D (n=77)
Marital Status					
Married	194(96.51%)	60(96.77%)	51(98.07%)	10 (100%)	73(94.80%)
Un Married	4(1.99%)	2(3.22%)	0	0	2(2.59%)
Separated	1(0.49%)	0	1(1.92%)	0	0
Widow	2(0.99%)	0	0	0	2(2.59%)

Literacy Status					
College	124(61.69%)	41(66.12%)	32(61.53%)	7(70%)	44(57.14%)
High	65(32.33%)	18(29.03%)	18(34.61%)	2(20%)	27(35.06%)
Middle	12(5.97%)	3(4.83%)	2(3.84%)	1(10%)	6(7.79%)
Socioeconomic status					
Low	16(7.96%)	2(3.22%)	4(7.69%)	1(10%)	9(11.68%)
Moderate	178(88.55%)	57(91.93%)	46(88.46%)	9(90%)	66(85.71%)
High	7(3.48%)	3(4.83%)	2(3.84%)	0	2(2.59%)
Food Habits					
Veg	12(5.97%)	1(1.61%)	4(7.69%)	9(90%)	71(7.79%)
Mixed	189(94.02%)	61(98.38%)	48(92.30%)	1(10%)	6(92.20%)
Social History					
Alcohol	34(16.91%)	11(17.74%)	10(19.23%)	2(20%)	11(14.28%)
Smoking	54(26.86%)	17(27.4%)	16(30.76%)	6(60%)	15(19.48%)
Family History of CKD	18(8.95%)	5(8.06%)	4(7.69%)	1(10%)	8(10.38%)

Co-morbidities: Among the study population, the major co-morbidities were DM 190(94.52%) followed by HTN 195(97%), CVD 89(44.27%), Hypothyroidism 26(12.93%), Rheumatoid Arthritis 20(9.95%), Arthritis 5(2.48%), Hyperuricemia 5(2.48%), Liver disease 2(0.99%) as shown in **Table 6.**

TABLE 6: CO-MORBID CONDITIONS IN THE STUDY POPULATION

Conditions	ALL (n=201)	Stage 3(n=62)	Stage 4 (n=52)	Stage 5 (n=10)	Stage 5D (n=77)
Diabetes Mellitus	190(94.52%)	50(80.64%)	45(86.53%)	8(80%)	87(87.01%)
Hypertension	195(97%)	60(96.77%)	50(96.15%)	9(90%)	76(98.70%)
Cardiovascular disease	89(44.27%)	21(33.87%)	26(50%)	5(50%)	37(48.05%)
Rheumatoid Arthritis	20(9.95%)	7(11.29%)	3(5.76%)	1(10%)	9(11.68%)
Liver disease	2(0.99%)	1(1.61%)	1(1.92%)	0	0
Arthritis	5(2.48%)	2(3.22%)	0	0	3(3.89%)
Hypothyroidism	26(12.93%)	7(11.29%)	7(13.46%)	1(10%)	11(14.28%)
Hyperuricemia	5(2.48%)	3(4.83%)	2(3.84%)	0	0

The Social Cost of Chronic Kidney Disease:

TABLE 7: SOCIAL COST OF CKD IN EACH STAGES AND HEMODIALYSIS

Cost Component	Stage 3	Stage 4	Stage 5	Stage 5D
Direct medical cost				
Consultation Fee	609.72±260.17 (8.577USD)	792.85±399.84 (11.153USD)	791.66±400.52 (11.137USD)	924.59±437.95 (13.00USD)
Laboratory Test	2286.66±798.17 (32.168USD)	2480.42±835.09 (34.894USD)	3479.16±757.36 (48.944USD)	3404.68±1397.96 (47.896USD)
Medication for CKD	2416.44±1477.9(33.99USD)	4374.14±2747.0(61.53 USD)	7071.66±4060. 67 (99.48USD)	8735.87±5125.90 (122.89USD)
Medication for co-morbidities	1087.5±662 (5.29USD)	1658.25±1598.3 (23.32USD)	1604.16±792.53 (22.56USD)	2909.55 ±2348.99 (40.93USD)
Alternative Treatment	0	1030±174.10 (14.46USD)	0	0
Dialysis Cost	0	0	0	24985.25±6937.33 (351.48USD)
Medical Supplies	0	0	1000±1095.44 (14.04USD)	380.32±791.58 (5.34USD)
Total	6400.32±3202. 49 (90.03USD)	10332.68±5754.64 (145.10USD)	13946.64±7106.52 (196.19USD)	41340.26±17039.71 (581.56USD)

TABLE 8: SUMMARIZES THE TOTAL COSTS ASSOCIATED WITH CKD. THE OVERALL COST IN STAGE 3 CKD PATIENT WAS 9512.82±4375.99 (133.58USD), STAGE 4 CKD WAS 14259.1±7197.86 (200.24USD) STAGE 5 WAS 15638.3±8671.43 (219.99USD) AND STAGE 5D WAS 44910.57±23238.57 (631.79USD)

Direct non-medical cost				
Transport of patient and	1112.5±6281	1301.42±1004.3	1358.33±959.38	3209.18±3737.21

caregiver	(15.65USD)	(18.30USD)	(19.10USD)	(45.14USD)
Caregivers	0	1000±169.03 (14.04USD)	0	0
Total	1112.5±628.41 (15.65USD)	2301.42±1003.97 (32.311USD)	1358.33±959.38 (19.10USD)	3209.18±3737.21 (45.14USD)
		Indirect costs		
Loss of productivity of patient	1500±345.9 (21.06UD)	875±312.48 (12.28US)	333.33±605.53 (4.68USD)	426.22±1383.94 (4.68USD)
Loss of productivity of caregivers	500±199.0 (7.02UD)	750±126.77 (10.53USD)	0	204.91±1077.71 (2.88USD)
Total	2000±545.09 (28.08USD)	1625±439.25 (22.81USD)	333.33±605.53 (4.68USD)	361.13±2461.65 (5.08USD)
Over all	9512.82±4375. 99(133.58US)	14259.1±7197.6 (200.24USD)	15638.3±8671.43 (219.99USD)	44910.57±23238.57 (631.79USD)

1USD = 71.21 INR (September 2019)

DISCUSSION: The economic evaluation has been performed for the direct medical cost component using laboratory tests, diagnostic exams, and first and follow-up visits. Progression of the disease results in an increase in cost. That is, as the stages of CKD increase, the healthcare cost per patient also increases. The majority of patients in the study population belong to stage 5 on HD (n=77) 38%, stage 3 (n=62) 31%, stage 4 (n=52) 26%, and stage 5 without HD (n=10) 5%.

In the current study, most of the patients were 61-80 years old. A study conducted by S Fathima *et al.* [10], Al Saran K *et al.* [13], has also reported that CKD is predominantly seen more in male patients, are in accordance with our study.

Eighty-one patients with CKD were retired, and sixty-seven patients were employed.

In our study, the patients who were in moderate economic status, considering that the patient had an annual income of 5-10 lakhs per annum were in higher percentage 178(88.55%) followed by low economic status (90,000 per annum) were 16(7.96%) and higher economic status (10 lakhs per annum), had a least percentage of 7(3.48%).

This study observed that Hypertension 195(97%) and Diabetes mellitus 190 (94.52%) were the major comorbid conditions. Similar results were found in the studies conducted by S Fathima *et al.* [10], Suja *et al.*[14], Mushtaq *et al.* [15] and Shyamala *et al.*[16], where diabetes and hypertension were the leading causes in compared to other disease states. The unadjusted estimated social cost of patients with CKD were 9512.82 ± 4375.99 (133.58USD for stage 3, 14259.1 ± 7197.86 (200.24USD) for stage 4, 15638.3±8671.43 (219.99USD) for stage 5 and 44910.57±23238.57 (631.79USD) for HD patients. This demonstrates that cost increases exponentially with advancing the stages of CKD. Similar results were found in the study conducted by Ladan Golestaneh *et al.* [17].

CONCLUSION: The conclusion of the current study reveals that the social cost including both direct and indirect medical costs, increases in the advanced stages of CKD. Analyzing all cost items in each stage affected direct medical costs the most. Patients on Hemodialysis had the highest economic burden compared to other stages patients. So we are concluding that it is important for the policymakers to decide health policy strategies and resource allocation suitably with the stages of CKD to ensure that healthcare services are sufficient for all patients.

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