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Pharmacoeconomic evaluation of chronic kidney disease patients: A study on cost of illness

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ABSTRACT

Chronic kidney diseases (CKD) is an important public health problem due to its high prevalence , morbidity and mortality. It is associated with high expenditure among indian patients. Higher stages of CKD have higher economic burden especially on the lower middle class. Hemodialysis, patients habits like alcohol consumption and smoking, treatment support by employer and patients with co morbid conditions and ESRD was found to effect the direct cost of the treatment.. Although CKD is generally Progressive and irreversible patients are advised regarding nutrition, life style changes and compliance with treatment might slow progression, enabling patients to live longer without complication and need for renal replacement therapy**.** Major barrier in the successful treatment of CKD is high cost of hemodialysis and medication which is difficult for the patient to afford. The main objective is to analyse the direct cost involved in treating Chronic Kidney disease patients in tertiary care hospital. Reimbursement, patients dialysis , social habits and comorbid conditions were found to have a significant effect on the direct cost of treatment.

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INTRODUCTION

Chronic Kidney Disease (CKD) is a condition defined as a , irreversible kidney damage which decreases estimated glomerular filtration rate or evidence of kidney damage from at least 3 months which is also progressive in nature. According to KDIGO (The Kidney Disease Improving Global Outcome) guidelines 2012 CKD is defined "an abnormality of kidney function or structure, present for more than 3 months, with implications for health". CKD is classified based on, Glomerular Filtration Rates and albuminuria category [1–3].

High blood pressure and diabetes mellitus are major causes of chronic kidney disease. Kidney disease is a public health issue and problems faced by kidney Worldwide. The Kidney Disease: Improving Global Outcomes (KDIGO) started in 2003, with a aim to improve care and outcomes of kidney disease patients worldwide by promoting, coordination, collaboration, and integration of initiatives. KDIGO is managed by the National Kidney Foundation (NKF) [4].

Epidemiology

Chronic kidney disease is one of the public health problem where 1 in 10 people estimated to be suffering from some form of kidney disorders. Report says 1,75,000 new cases of kidney failure(stage v CKD) comes up in India each year, severe enough to need dialysis [1]. The reported prevalence of CKD in different regions ranges from

1% to 13%, and recently, data from the International Society of Nephrology's Kidney Disease Data Center Study reported a prevalence of 17%.

In 2016: 417 million females and 336 million males. [1] In 2015 it caused 1.2 million deaths, up from 409,000 in 1990. [5] [6] The causes that contribute to the greatest number of deaths are high blood pressure at 550,000, followed by diabetes at 418,000, and glomerulonephritis at 238,000. As per recent Indian council of medical research data, prevalence of diabetes in Indian urban population has raised to 7.1% and in rural population the prevalence is as high as 28% [7].

Pathophysiology

While discussing the pathophysiology of CKD, structure and physiology of the renal system, and also about the renal tissue injury and its repair should be taken in consideration.

400ml/100g of tissue per minute is the approximate renal blood flow rate which is greater than other well per fused vascular organs like heart, brain, and liver. As a result of this renal tissues might be exposed to harmful circulating substances or agents.

Glomerular filtration depends up on trans and intra glomerular pressure. This makes glomerular capillaries more vulnerable to hemodynamic injuries. According to the work done by Brenner and other Coworkers states that Glomerular hypertension, hyper filtration contributes majorly in chronic renal disease progression.

Glomerular filtration membranes are molecules having negative charges which acts as a barrier which hold backs anion molecules. Resulting in the Glomerular injury, plasma protein gains access to the glomerular filtrate due to disruption in the electrostatic barrier

The organization of the nephrons and the tubuli's downstream position with reference to glomeruli, maintains glomerulo-tubular balance as well as helps in the spreading of glomerular injury to tubule-interstitial compartments. Due to over flow of few mediators of glomerular inflammatory reactions to peritubal circulation which results in interstitial inflammatory reaction in glomerular disease.

Peritubular blood flow will be depleted due to reduced preglomerular or glomerular perfusion which also depends on the degree of hypoxia, entails tubule-interstitial injury and tissue remodeling. Therefore it is important to consider nephron as functional unit not only to renal physiology, but also in renal disease pathophysiology [8].

Damage to one will effect in part due to different mechanisms, direct cell-cell connections (e.g., gap junctions), soluble mediators such as chemokines, cytokines, growth factors, and changes in matrix and basement membrane composition [2].

Treatment

Goal of therapy

The goal of therapy for early stages is to reduce the progression of CKD, thereby minimizing development or severity of complications including cardiovascular disease and ultimately limiting the progression to ESRD, but in later stages (4-5) progression to ESRD is almost inevitable, the process may be delayed if appropriate therapy is initiated.

Medications used to treat CKD are as follows

Anti hypertensive therapy among CKD patients

ACEI'S/ARB'S are especially given when proteinuria or e-GFR<60ml/min. These drugs have a well-established safety profile, even in patients with serum creatinine level in range of 3-4mg/dl.

Management of hypertension in CKD patients with DM requires combination therapy, Dual therapy is most effective than mono or triple therapy.

Diuretics, and calcium channel blockers are mostly prescribed to reduce cardiovascular morbidity and mortality progression of ESRD.

1. Dual therapy in CKD with HTN: CCB+Diuretics
2. Dual therapy in CKD with HTN, CAD:CCB+Diuretics
3. Triple therapy : CCB+Beta blockers+Diuretics

Oral hypoglycemic used in treatment of DM among CKD patients

Metformin

Used in low doses in patients with GFR 30-60ml/min. It should not be used in patient with GFR below 30ml/min as there is risk for lactic acidosis, better to avoid metformin once serum creatinine concentration rises above 1.5mg/dl in men,1.3mg/dl in women.

Sulphonyl urea and meglitinides

Glipizide (2.5mg/day) or glimepiride (1mg/day), an alternative agent is repaglinide, starting with a dose of 0.5mg/day, can be used in low doses.

For most haemodialysis patients with type 2 diabetes, initial treatment with insulin, rather than oral agents can suggested, several different insulin regimens can be used to reduce glucose condition. Twice daily intermediate acting insulin, with regular insulin should be taken before breakfast, long acting

insulin with 2 or 3 times daily supplemental regular insulin given 2 or 3 times per day before meals.

Diuretics

These drugs act by elimination of water and salts therefore it is used to control high blood pressure, edema and potassium levels in body. Loop diuretics (furosemide, torsemide), thiazides (hydrochloro thiazide, chlorthalidone) and potassium sparing diuretics (spiranolactone, amiloride), are the drugs belongs to this class [9].

To treat anaemia

Erythropoietin stimulating agents are used. CKD patients often develop anemia due to a lack of erythropoietin produced by the kidneys. After excluding other causes of anemia, erythropoiesis-stimulating agents such as erythropoietin, darbepoetin, peginesatide are used in treating anemia.

To treat hyperphosphatemia

Phosphate binders are used.. When these drugs are taken with meals, binders combine with dietary phosphate and allow for elimination without absorption into the bloodstream. Binders are divided into large classes, including calcium-based binders such as calcium carbonate, calcium acetate and non-calcium based binders like (lanthanum carbonate), sevelamer hydrochloride and sevelamer carbonate [10].

Vitamin D

Vitamin D deficiency is seen in most of the patients with chronic kidney disease. Vitamin -D supplements are used based on patients vitamin –D level.

Antibiotics

CKD patients are having more chance to prone into infections, usually antibiotics like Cephalosporin's, Flouroquinolones and Penicillin's are commonly used drugs in CKD treatment.

To treat acidemia

Decreased capacity to excrete hydrogen and generate bicarbonate is often called as metabolic acidosis. Sodium bi carbonate and potassium citrate are used to treat acidosis monitoring of sodium and potassium levels is necessary.

Dialysis

It is a process of separating elements in a solution by diffusion across a semi-permiable membrane down a concentration gradient.

Hemodialysis

The Process for removing waste products like creatinine and urea and free water from the blood and the kidneys [10].

Types of Hemodialysis

Conventional hemodialysis

In this technique patient blood will be drawn out through a tube at a rate of 3-400cc per minute. This process will be carried out for3-4 hours thrice in a week, for each treatment, During the process, the patient's entire blood circulates through the machine for every 15 minutes.

Daily hemodialysis

Used by patients who do their dialysis at home. Usually done for 2 hours, 6 days a week.

Nocturnal hemodialysis

Performed 6 nights a week and 16 hours per session while the patient sleeps.

Economics

CKD burden is a great concern due to its high level of morbidity and mortality rate

Most of the CKD patients often present with many co existing comorbidities that leads to poly pharmacy. Other than the high number of medications , Dialysis is required in patient with ESRD Cost of the treatment and dialysis cost increases the burden of patient [11].

Delayed or lack of reimbursement or insurance is a major drawback in the treatment of CKD for pocket out patient.

In India non adherence to dialysis is due to high cost of the treatment which even resulted in many deaths.

Existing schemes covering dialysis

It is important to compare our findings with dialysis service packages being offered by existing health insurance schemes in India.

Aarogyasri (Rajiv Arogya Sri)

Is a healthcare programme, started by Dr.Y.S.Rajashekar reddy chief minister of AP in 2007.

The new government of AP renamed the scheme in 2019to Dr.YSR Arogyasri. It covers those patients with below poverty line. The government will provide Arogyasri card and the beneficiary can use it at government and private hospitals to obtain services free of cost .

EHS

Employees health scheme provide free of cost treatment to most of the government employees, pensioner and to their family members through a hospitals which covers this scheme.

MATERIALS AND METHODS

Study site

IP & OP Department in Nephrology ward at teritary care hospital.

Study population

All Patients of age 20 to 90 years diagnosed with CKD.

Study duration

Six months.

Sample size

200

Inclusion criteria

All patients of age 20-90 years diagnosed with CKD.

All patients with comorbidities like Hypertension, diabetes, Anemia , Bone mineral disorders, Cardiovascular diseases, Thyroid disorders, Respiratory problems, Hyperlipidemic diseases.

Exclusion criteria

1. Pregnant women.
2. Excluding patients with other neuro-degenerative disorders.
3. Patients with cancer.
4. Pediatrics.
5. Patients who are not willing to participate in the study.

Study procedure

Step 1

An Observational Cross sectional study was conducted out in the hospital with prior permission from both IP & OP department of nephrology.

Step 2

The patient visiting the department was enrolled in the study considering the study criteria after taking their consent to participate in the study.

Step 3

From the enrolled patients the data was collected from the case sheets, and other relevant resources in a suitably designed data collection form.

Step 4

We conducted various educational programs to all patients and their attenders

in the nephrology department regarding preventing measures and reducing the progression of CKD.

Step 5

From that collected data cost of illness of treatment was analyzed by using statistical tool.

Data collection method

Data has been collected from, case sheets of the patients.

Statistical analysis

Student t- test

RESULTS

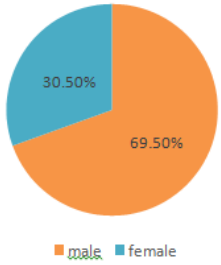

Figure 1: Gender categorization

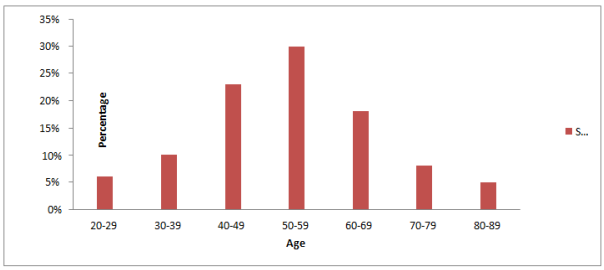

Figure 2: Age distribution among CKD patients

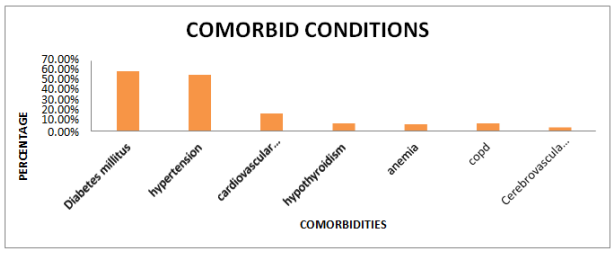

Figure 3: Comorbidities among CKD patients

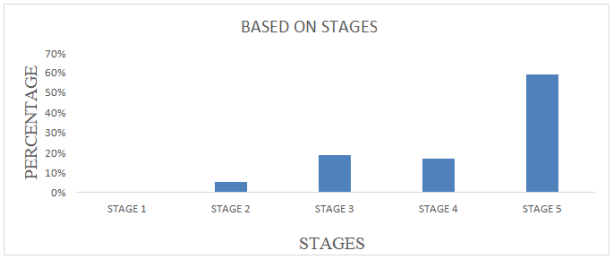

Figure 4: Categoriz ation based on stages of CKD

Table 1: Based on BMI

BMI	No. of patients (N=200)	Percentage (%)
Normal weight	104	52%
Under weight	12	6%
Over weight	70	35%
Obese	14	7%

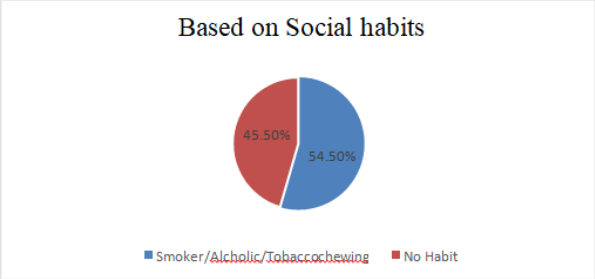

Figure 5: Categorization based on social habits

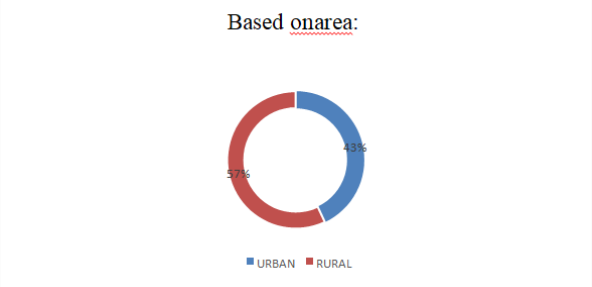

Figure 6: Categorization based on area

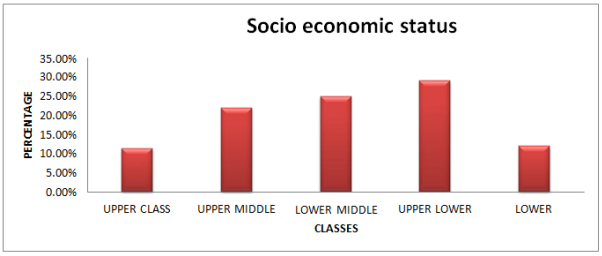

Figure 7: Categorization based on socioeconomic status

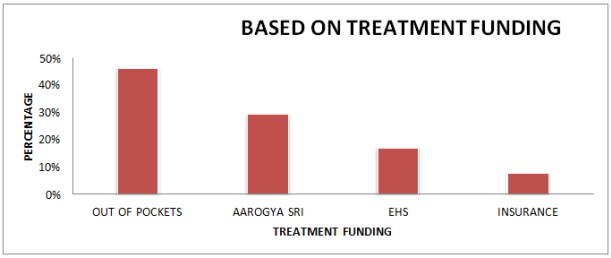

Figure 8: C ategorization based on treatment funding

Table 2: Cost of commonly prescribed medicine

Drugs	Cost(Rs) MEAN±SD	Range
Torsemide	1387±250	468-1872
Sevelamer	3987±850	1749-5724
Iron tablets	1250±225	990-1980
Vitamin-D	2732±454	3096-8514
Metoprolol+Amlodipin	2936±637	990-3960

Table 3: Pattern of direct cost involved in CKD treatment

Type of treatment	Cost (Rs), Mean±SD	P-value
Dialysis dependent patients (n=161)	165188±89399	0.361
Non dialysis Dependent (N= 39)	34224 ±30552	

Table 4: Catezorization of direct cost based on HD/week

Tyoe of treat-ment	Cost (Rs) Mean±SD	P value
Dialysis-weekly twice (n=92)	72706±38185	0.382
Dialysis-weekly trice (n=69)	93482±83026	

Table 5: Categorization of cost based on three most common comorbidities in CKD patients

Comorbidities	Cost (Rs) Mean±SD	P value
HTN(n=58)	33245±29828	0.42
DM(n=9)	16741±12412	
HTN+DM(n=85)	86607±34261	
HTN+DM+CVD (n=22)	121804±69298	

Table 6: Categorization of cost based on health care scheme

Health care scheme	Cost (Rs) Mean±SD	P value
OOP(n=92)	116475±68851	
Arogya sri(n=59)	38397±2116	0.429
EHS(n=34)	84212±58646	
Insurance (n=15)	70412±43413	

Table 7: Categorization of cost based on social habits

Social habits	Cost (Rs) Mean±SD	P Value
Alcoholic/ Smoking/ Tobacco chewing (n=109)	111085±72289	0.326
No habit (n=91)	85516±67671	

Table 8: Categorization of cost based on stages

Stages of CKD	Cost (Rs) Mean±SD	P value
Stage 2(n=11)	39398±212	0.320
Stage 3(n=37)	49424±27470	
Stage 4(n=34)	93312±39272	
Stage 5(n=118)	132169±75439	

DISCUSSION

An observational cross-sectional study was conducted in CKD patients who were diagnosed with CKD to estimate the spending on managing CKD. CKD is a global public health concern with increased morbidity and mortality. [Figures 1 and 2]

It is associated with high expenditure because persons with CKD have significantly higher rates of hospitalizations, health care utilization also factors like dialysis and presence of co morbidities (like DM, HTN, CVD, Anaemia), further add the cost and this increasing financial burden directly effects the patients compliance. [Figure 3]

In this study out of 200 CKD patients, most of the patients belong to age group 40-60 years which include 106(53%)this is in concordance to the findings of the study by S. Fathima et.al . The gender wise distribution shows more male subjects 139 (69.5%) than females 61(30.5%) and several comorbidities were found among study population, which includes DM119(59.5%), HTN 112 (56%) and CVD 35(17.5%)respectively. [Figures 4 and 5]

Another study was also cofnducted on categorization of cost based on three most common comorbidities in CKD patients which reported that HTN , DM , CVD are the major comorbid conditions in CKD. In patient with co morbid condition the average cost for the treatment was significantly higher. [Figures 6, 7 and 8]

In the study, majority of the patients were in stage-5 118(59%) , of which =109 (56.5%) subjects have social habits. The majority of subjects n=114 (57%) in our study are from rural area and lower socioeconomic status. [Tables 1 and 2]

The total Cost of treatment for 6 months in patients who were on dialysis was found to be 165188±89399 INR. Average direct cost of treatment was found to be similar in comparison with results of S. Fathima et.. al.

The cost of illness for patients in G2 (n=11) is INR39398±2127, G3(n=37) is INR49424±27470, G4(n=34) is INR93312±39272 and G5(n=118) is INR 132169±75439 respectively. [Tables 3 and 4]

In the same time the patient who weren't under dialysis treatment dialysis had spent (n=39) INR 34224±30552 over 6months. The cost of HD patients (n=92) who underwent twice a week was INR 72706±38185 and (n=69) thrice a week is INR 93482±83026. [Tables 5 and 6]

It was found that the mean direct cost were highest in patients on thrice- weekly HD sessions. The total mean cost was high in patients without scheme as they were not getting any concessions and they had to spend more. [Tables 7 and 8]

Strengths

(i) Patients with different socio-demographic and clinical characteristics were included in the study.

Limitations

1. The study was conducted in private tertiary care hospitals thus this findings cannot be generalized for patients who were treated in public tertiary care hospitals.
2. Cost related to hospitalization was not included in the study.

CONCLUSION

CKD with its high prevalence, morbidity and mortality is an important public health problem. It is associated with high expenditure among Indian patients. Higher stages of CKD have higher economic burden especially on the lower middle class.

High OOP expenditure among Indian patients was found with CKD. Hemodialysis, treatment support by employer, patients with habits such as smoking and alcohol effected the direct cost of treatment. Patients with comorbidities and patients with ESRD. Although CKD is generally Progressive and irreversible patients are advised regarding nutrition, life style changes and compliance with treatment might slow progression, enabling patients to live longer without complication and need for renal replacement therapy. We finally conclude that early recognition of disease and lifestyle modifications might decrease the progression of the disease into ESRD and also reduces the pharmacoeconomic burden of disease on the patients.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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