



Review Article

PHARMACOECONOMIC EVALUATION IN END STAGE RENAL DISEASED PATIENTS

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ABSTRACT:

Aim : The purpose of this project is to evaluate the economic evaluation of End Stage Renal Diseased patients within the context of continued economic uncertainty and pressure on healthcare resource use.

Objective : These findings are important to find out the impact of cost of haemodialysis on patients suffering from ESRD. Further studies related to costs and outcome, otherwise known as pharmacoeconomic studies, are needed to analyse the cost evaluation in End Stage Renal Dialysis patients

Methodology : A prospective observational study was conducted for a period of Eight months (December 2015 to July 2016) at a tertiary care hospital in the Inpatient Nephrology Department. Patients coming on outpatient basis were selected for the study. Patients were allotted in different shifts either in morning, afternoon or evening, based on their preferences. The patients were followed up for a period of 8 months. The patient sociodemographics, cost details of dialysis, hospital costs, comorbidities diseases and their cost, adverse reactions occurred during dialysis, cost to manage such adverse reactions, regularity, affordability, outcome and patient satisfaction to dialysis, etc. were collected prospectively

Result : The total cost per session was found to be around INR 4500. Fifty six percent contributes direct medical cost whereas 20% contributes direct non medical cost. Twenty four percent cost was due to indirect costs. Since the patients are paying from their own pocket, only the upper or upper middle class patient can undergo haemodialysis regularly.

Keywords: *Cost Analysis, End Stage Renal Disease, Haemodialysis, Pharmacoeconomics.*

Received on : 07-12-2016

Revised on : 01-02-2017

Accepted on : 04-02-2017

INTRODUCTION

Chronic kidney disease (CKD) is a serious condition associated with premature mortality, decreased quality of life, and increased healthcare expenditures¹. CKD refers to an irreversible loss of renal function that develops due to a multi factorial

etiology over a period of a few years. Initially it starts as a biochemical abnormality and progresses in stages. Earlier stages of CKD can be detected through routine laboratory measurements. Loss of renal function happens progressively leading to loss of excretory, metabolic and endocrine functions.

Chronic kidney disease is a worldwide public health problem, a social calamity and an economic catastrophe. In the year 2000, in India about 30 million people were diagnosed with chronic kidney disease (CKD). It is estimated that by 2010, six million worldwide would need renal replacement therapy (RRT) costing 28 billion dollar².

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The exact burden of CKD in India still remains undefined with only limited data from the three population-based studies^{3,4,5,6&7}.

It is hoped that the CKD registry, recently established by the Indian Society of Nephrology, may provide useful epidemiological data in the future. In the prevention study done in Chennai, the prevalence at the community level is 8600 per million populations (pmp) in the study group and 13900 pmp in the control group. The second study based in Delhi⁴ revealed a prevalence of CKD (serum keratinize more than 1.8 mg %) at 7852 pmp. The third study from Bhopal revealed an incidence of 151 patients per month suffering from end stage renal disease (ESRD)⁵.

The most common cause of Chronic Kidney Disease is:

- Diabetes mellitus
- Hypertension.
- Diabetes
- Hypertension Glomerularnephritis
- Polycystic kidney disease
- Tubulointerstitial disease
- Bilateral kidney stones

Pharmacoeconomic evaluation

Pharmacoeconomics is an important tool in the socio economic studies of healthcare system over the world especially in developing countries^{8,9}. The exact detail of the total cost of hemodialysis in India according to the patient perspective was not found in any literature. The burden of end stage renal disease can be realized only if the costs are analyzed in patient perspective. This is the study to analyze the direct as well as indirect cost of hemodialysis in a tertiary care hospital of South India. Since renal replacement therapy is an expensive treatment modality, it is very essential to assess the outcome of therapy in terms of quality of life, since this may be influenced by various factors such as comorbid conditions, age, dialysis frequency, infection/inflammation, etc. This study gives the complete details of the cost associated with hemodialysis in a private sector on patient perspective².

METHODOLOGY

Study Design:

1. Prospective observational study.

2. Place: Multi Care Unit in a tertiary care hospital.

3. Period of data collection: January-August (8 months)

4. Data collection source:

- Patient allotment and data collection
- Sociodemographic variable

Exclusion criteria : Patients whose circumstances or illnesses could interfere with the development of the study.

Inclusion criteria : Patients admitted in the dialysis ward in nephrology department are selected for the study and their haemodialysis sessions are noted.

Health care costs

These costs were organized into four main categories:

- 1) Haemodialysis sessions,
- 2) Pharmaceutical Consumption,
- 3) Hospitalisations,
- 4) Outpatient visits.

RESULTS

During the study period, 200 prescriptions were included as per inclusion criteria, out of which 139 (69.5%) were males and 61 (30.5%) were females. Maximum number of patients, 66 (33%) were found between 51-60 years and minimum number of patients 1 (0.5%) between 11-20 years and 81-90 years. The maximum age of patients in the study population was 86 years and minimum age was 18 years.

DEMOGRAPHIC DATA:

During the study period 200 prescriptions were collected and they were divided based on gender and age which were shown in Tables-1 and 2.

Table 1: Distribution of Patients Based on Gender

S.NO.	GENDER	PATIENTS	PERCENTAGE
1.	Male	139	69.5%
2.	Female	61	30.5%

Table 2: Age wise categorisation of the patients based on Gender

Age of patients	Number of patients (n=200)	Percentage (%)
0-20	4	2
21-30	13	6.5
31-40	29	14.5
41-50	37	18.5
51-60	68	34
61-70	44	22
71-80	5	2.5
81-90	1	0.5

Biochemical data were collected from the hospital lab and the data were shown in Table-3.

Table 3: Laboratory Data of CKD Patients

Parameters	Normal Range
Urea	16.6 -48.5 mg/dl
Creatinine	Male 0.7 -1.2 mg/dl
	Female 0.5 -0.9 mg/dl
Sodium	137 -145mmol/L
Potassium	3.5 - 5.1mmol/L
Chloride	98 - 107 mmol/L

The ward cost, consultation cost and Lab cost spent by the CKD patients were taken and tabulated in Table - 4, 5 and 6.

Table 4: Ward Costs of CKD Patients

S.No	Room Services	Amount Per Day I (INR)
1.	AMCU bed charges	750
2.	Medical and allied charges	110
3.	Nursing and allied charges	100
		Total =960

Table 5: Consultation Cost of CKD Patients

S.No	Consultation Charges	Amount Per One Visit (INR)
1.	General physician and diabetologist	150
2.	Nephrologist	200
		Total = 450

Table 6: Laboratory Cost

S.No	Investigation	Test involved	Amount (INR)
1.	Biochemical Investigation	Urea	150
		Serum Creatinine	150
		Electrolytes	600
2.	Haematology investigation	• Sodium	250
		• Potassium	
		• Chloride	
		• CBP	
3.	Microbiology investigation	• Haemoglobin	250
		• RBC,PCV,WBC	
4.	Serology investigation	• Complete urine examination(CUE)	400
		• Urine culture	
		• HIV ECLIA	
		• HCV ECLIA	
5.	other	• HBSAG ECLIA	500
		• 2D ECHO	1200
6.	GIT	• Ultra sound	450
			TOTAL = 4,500

Table 7 and 8 shows the hospital cost per patient and number of drugs prescribed per prescription.

Table 7: Hospital Cost per Patient

S.No	Hospitality Services	Quantity	Amount Per Day (INR)
1.	Admission charges	1	375
2.	Bed charges	1	170
3.	Folycatherisation charges	1	750
4.	GRBS (glucometer random blood sugar)	1	5
6.	Nebulization charges	1	35
7.	Oxygen charges upto 24 hours	1	1150
			Total = 1,735

Table 8: Number of Drugs per Prescription

S. No. Per	Range of Drugs Prescription	Number of 200) Prescriptions (n=)	Percentage Distribution
1	0-5	49	24.5
2	6-10	93	46.5
3	11-15	47	23.5
4	16-20	11	5.5

Many antihypertensive and gastro intestinal drugs were prescribed to the CKD patients. The details and cost of those drugs were given in Tables-9, 10 and 11

Table 9: Antihypertensives prescribed in patients with Chronic Kidney Disease:

S.No.	Antihypertensives	Frequency	Percent
1	Calcium channel blockers	85	39.53
2	Diuretics	54	25.12
3	ACE inhibitors	3	1.40
4	Alpha blocker	17	7.91
5	Beta blocker	21	9.77
6	Alpha and beta blocker	6	2.79
7	Centrally acting antihypertensives	22	10.23
8	Vasodilators	7	3.26

Table 10: Cost Effectiveness Analysis of Antihypertensives

Antihypertensive class	Number of prescription	Cost of drugs per 1 Month (INR)	Cost of drugs per year (INR)
Calcium channel blocker	43	177.48	2,130
Diuretics	10	317.2	3,804
β blocker	5	307.14	3,684
α agonist	5	88 62	1 170

Table 11: Pattern of Gastrointestinal Drugs used in Chronic Kidney Disease

S.No.	Category of the drug	Generic name	Dose	Cost/dose (INR)	Cost/day (INR)
1.	Drugs for peptic ulcer H2-antihistamines	Ranitidine	40mg	1.00	1.00
		Ranitidine	20mg	1.50	1.50
		famitidine	40mg	5.00	5.00
2.	Drugs for proton pump inhibitors	Pantoprazole	70mg	7.20	7.2
		Pantoprazole	40mg	6.20	6.20
		Rabeprazole	20mg	4.00	4.00
		Omeprazole	20mg	3.00	3.00
3.	Antiemetics	Domperidone	40mg	18.50	18.5
		Domperidone	20mg	13.00	13.0
		Ondansetron	20mg	4.00	4.00

Table 12: Pattern of Anemic and Dietary Supplements used in CKD

S.No	Category of the drug	Generic name	Dose	Cost/dose (INR)	Cost per day (INR)
1.	Haematinics	Ferrous fumarate	150mg	2.00	4.0
		Folic acid	5mg	2.50	5.0
		Cyanacobalamin	50mg	1.00	2.0
3.	Anticoagulants	Heparin	5000U	175.0	350
4.	Antiplatelets	Aspirin	150mg	1.00	2.00
		Clopidogrel	75mg	0.50	1.00
5.	Erythropoietic factor	Erythropoietin	1000U	750	750
		Erythropoietin	4000U	1450	145
		Erthropoietin	4000U	2000	2000

Table 13: Drugs used for Anemic and Dietary supplements in CKD

S.No	Category	No of Patients	Percentage (%)
1	Phosphate binders	53	26.5
2	Erythropoietin	69	34.5
3	Levocarnitine	24	12
4	Vitamins and Minerals	33	16.5
5	Iron sucrose	21	10.5

To counter act anemia and to provide energy to the CKD patients anti anemic drugs and dietary supplements were prescribed to the patients. The details were shown in Table 12 and 13.

The CKD patients were also having other co morbid diseases. The details were shown in Fig.1. Among 200 patients 104 were having Cardiovascular diseases.

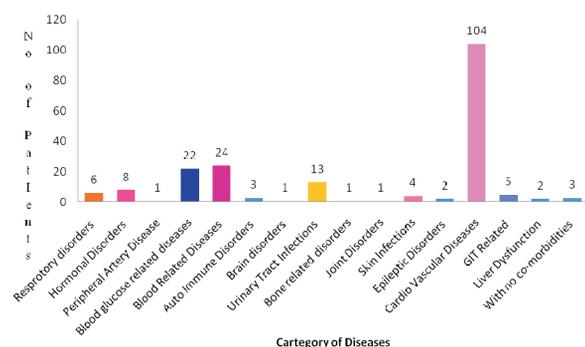


Fig. 1: Co- morbidities in Patients with Chronic Kidney Disease

The direct medical and non medical components among CKD patients were given in Table-14.

Table 14: The direct medical and non-medical cost components (per patient) among CKD patients:

Cost Components	Pre-dialysis patients Costs (INR, \$) and IQR (INR) (n=98)	Dialysis patients Costs (INR, \$) and IQR (INR) (n=102)
Direct medical cost components		
Medications costs	INR 4,489.75 (INR 1,821.67–INR 8,074.49)	INR 12,763.58 (INR 4992.18 – INR 19,446.57)
Dialysis costs	–	INR 3,100, UD \$5.10 (INR 2,300–INR 4,500)
Laboratory Investigations costs	INR 2,710	INR 6,500
Consultation charges	INR 730 (INR 425–INR 2635)	INR 3,469.20 (INR 1745–INR 5482.50)
Surgical procedure costs	INR 5,400 (INR 157.50–INR 5,437.50)	INR 2,580 (INR 1,000–INR 6,400)
Nursing services costs	INR 600 (INR 300–INR 900)	INR 1200 (INR 750–INR 1,650)
Hospitalization costs	INR 450	INR 830
Direct non-medical costs		
Transportation costs to the hospital	INR 450 (INR 100–INR 600)	INR 200 (INR 200–INR 600)
Food costs	INR 400 (INR 300–INR 700)	INR 700 (INR 400–INR 1,000)
Median total direct costs	INR 1,143.02	INR 2,628.31

Table-15: Cost of 700 dialysis done in one month in nephrology unit

Items	Per dialysis (INR)	Per day	Monthly Expenses (INR)
Formalin	2	50	1,500
Hypochloride	1	25	750
Hydrogen Peroxide	0.7	17.5	525
Acetic Acid	1.6	40	1,200
Dialyzers (118 no)	86	2,000	60,000
Bicarb Cans (303 can)	64	1,600	48,000
Tubing Set (32 sets)	6	150	4,500
A-V Fistula Needles (1400)	42	1,050	31,500
Normal saline (1 Liter 707 bottles)	20	500	15,000
Ns 500 MI 350	6.5	162.5	4,875
Gloves (Per day 2box × 26 Days)	13	325	9,750
Heparin (250 Vials Of 25000 Units)	10	250	7,500
Gauze (40packs)	14.4	360	10,800
Syringes (20ml 707)	8	200	6,000
Micropore Sticking Plaster	2.3	57.5	1,725
Neosporin Powder	3.5	87.5	2,625
IV Set (707 pieces)	8	200	6,000
Material Total expenses	289	7,225	2,16,750

Discussion:

Dialysis is an expensive therapy. The cost per session was found to be INR 4428, which is difficult to afford by the common people.

The mean age was found similar to the results of Devi *et al*¹⁰. and Al-Ramahi *et al*¹¹. This is higher than reported by Bajait *et al* (51 years)^{12,13}.

The number of male patients was higher than the number of female patients in the study. This finding is in concurrence with the results of Bajait et al and Devi *et al*.

In this study, maximum number of the patients (62%) had the end stage renal disease are male, these findings were similar to that of the results of Bajait *et al* (62%).

In the present study, hypertension was found to be the most commonly occurring co-morbidity (55% of the cases) followed by diabetes, anemia, coronary artery disease and hyperlipidemia¹³. These findings were found similar to that of study by Bajait *et al*.

Only 18% of the patients were found to be on hemodialysis. The main reason for this might be that patients in this study belonged to lower socioeconomic class and they could not afford the cost of hemodialysis.

The study by Al-Ramahi *et al*. reported over 50% of the patients on hemodialysis. Most of the patients in the present study belonged to lower middle socioeconomic class of status (40%)

The haemodialysis cost range between INR 1200 and INR 2000 per session. Patient's undergoes weekly thrice that costs INR 3,600 per week, and INR14,400 per month.

The haemodialysis cost range between INR1, 40,000 to INR1,72,000 per year. In addition to this they have to pay for erythropoietin, lab test, consultation fee, etc.

Erythropoietin cost INR 1500 which will be administered weekly thrice (INR4, 500/week). This excludes the cost of erythropoietin, which is approximately INR16,000 INR per month (the majority of patients receives 4000 to 6000 units of erythropoietin every week).

The cost of an AV fistula construction is INR 6,000 to INR 2,0000. The average cost of erythropoietin per month is INR 4,000 (bio similar) to INR 10,000 (the pioneer brand).

The cardiovascular class was the most commonly utilized class of drugs (33.9%). This was found higher than the study carried out by Devi et al and Bajait et al which reported it to be 28% and 22% respectively. Cost of diuretics was found to be INR 33/day, cost of Antihyper-tensives was found to be INR 120/day cost of phosphate binders was found to be INR 80/day, cost of gastrointestinal drugs INR 80/day, cost of anaemic and dietary supplements found to be INR 3,337/month, cost of antimicrobials was found to be INR 179/month, cost of antidiabetic drugs was found to be INR 362/month, cost of CAD management drugs was found to be INR 40.72/day similar to the studies carried out by Devi et al and Bajait *et al*.

CONCLUSION

The total cost for the haemodialysis (INR 1,143,02) and peritoneal dialysis (INR 2,628.3) patients differed significantly the number of medications per prescription and length of hospitalisation had asignificant impact on the total cost among the haemodialysis patients only the upper and upper middle class people can afford the haemodialysis due to its high cost.

Analysis of 200 prescription revealed the cost of maintenance of haemodialysis for a single session varies INR 1500 to 2000. The total cost per session was found to be around INR 4500. Since the patients are paying from their own pocket, only the upper or upper middle class patient can undergo

haemodialysis regularly. The most important factor is to reduce the number of patients with ESRD this can be achieved by preventing the progression of renal disease.

Early detection and treatment of these diseases plays a vital role in the prevention the progression of renal failure.

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