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## COST OF ILLNESS AND ITS IMPACT ON QUALITY OF LIFE OF PATIENTS ON MAINTENANCE HEMODIALYSIS

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#### **ABSTRACT**

In India, majority of patients with End stage renal disease (ESRD) can afford only hemodialysis and the cost of maintenance hemodialysis (MHD) differs across the country. A study was conducted in 108 patients aged 18 years or older, on MHD to assess the cost of illness and its impact on quality of life of patients on MHD. The medical costs were collected from various units of the hospital and the prescription was analyzed to assess the cost factor involved in the medications. Non- medical costs and indirect costs were collected from the patients directly. The Quality of Life (QOL) was assessed using Short form 36 questionnaire. The data collected was analyzed with SPSS 17.0 version. Paired t-test was used to find the significant difference and Pearson's correlation was used to assess the relationship between the variables. A probability value of  $P \le 0.05$  was considered as statistically significant. The average cost per session was found to be Indian Rupee (INR) 1500, this included the dialysis session cost only excluding all other costs. The mean total annual cost of dialysis per patient was estimated to be INR 5, 42,299. The cost factor for direct medical expense amounted to INR 52,420 per month, direct non-medical cost amounted to INR 6,856 per month and the indirect cost amounted to INR 6,759 per month. Apart from this monthly cost, there were additional expenses in direct medical cost which included ICU admissions costs for major complications, hospitalization costs for access procedures and for other complications. Erythropoietin contributed to 81% of the total drug cost spent by MHD patients. The physical component showed a higher score compared to the mental component of health related OOL. There was a significant correlation between cost of illness and physical/mental components of health related QOL. This study identified that direct costs were momentous when compared to indirect costs. This information can form a basis for further pharmacoeconomic studies.

**KEYWORDS:** End stage renal disease, chronic kidney disease, maintenance hemodialysis, renal replacement therapy, quality of life.

#### INTRODUCTION

Chronic kidney disease (CKD) and end-stage renal disease (ESRD) are emerging public health problems in developing countries. [1] Chronic renal failure is a devastating medical, social and economic problem for patients and their families. [2]

The worldwide incidence of chronic renal failure has doubled in the last 15 years, [3] and its progression to end stage disease has been expected to be doubled during next 15 years. [4] It is evident from the worldwide data that more than one million end stage renal disease patients are on Renal Replacement Therapy (RRT) where as two more million patients are in need of that. [5]

There is an increase in the incidence of end stage renal disease in India and the options for the treatment of

ESRD is dialysis or transplantation. The affordability of the ESRD patients towards transplantation is very low due to the cost of treatment in the present scenario. As majority of them can afford only hemodialysis and there exists a marked variability in the cost of hemodialysis across the country, the average cost of hemodialysis needs to be evaluated. It would be interesting to know that the incidence of chronic kidney disease in India, which is a densely populated country with low income, different food, cultural traditions and lifestyle habits, is 7.85 million Chronic Renal Failure (CRF) patients of its one billion populations and the prevalence rate is 0.78%. [7]

As per the December 2007 index, the per capita income in India is Indian Rupee (INR) 20,734 per annum. The total population is 113 crores, of which 26% live Below

Poverty Line (BPL) where the daily earning is INR 10, in comparison, the international standard BPL is US \$1 per day that is, 65 per day. By this parameter, in India, 70% of the population would be BPL. The government spends barely US \$8 per capita on health with priorities more on infectious disease, sanitation, nutrition etc. <sup>[7,8]</sup>

### NEED FOR ECONOMIC EVALUATION IN HEMODIALYSIS

Most of the dialysis units are in the private sector and the average hemodialysis cost anywhere in India range between INR 1200 and INR 2000 per session. When calculating the cost of hemodialysis in private hospitals, it comes around INR 12,000 per month and INR 1, 40, 000 per year. [9] In addition to this they have to pay for erythropoietin, lab test, consultation fee, etc. This becomes a nightmare for the common Indian people who cannot afford the expense. Many of them purposefully quit the sessions and their condition worsens terribly. [10]

There is a direct relationship between the number of dialysis centers and per capita gross national income of developing nations. The high cost of hemodialysis (HD) puts it unreachable for the low and middle income group and maintenance HD is the exclusive preserve of private hospitals. Such endeavors affect entire families by resulting loss of income of other family members too. [2]

Chronic hemodialysis patients have multiple complications that require pharmacologic therapy. These patients often require 12 medications to treat 5 to 6 co morbid conditions. [11] The administration of multiple medications simultaneously, consecutively, or both further contributes to the cost factor significantly.

Since diabetes and hypertension are the major contributing factors of renal failure that has to be managed properly in its initial stage. The lifelong treatment of renal failure along with diabetes and hypertension significantly increases the economic burden on patient and their whole family. [5]

The costs of therapy in patients treated by hemodialysis are three times higher compared with those in the pre-dialysis phase. In addition to this, hemodialysis is associated with a large number of medical, psychic and social complications. The financial expenses coinciding with drug costs (direct loads) are significant and represent a major part of the pharmacoeconomic complexity. The burden of end stage renal disease can be realized only if the costs are analyzed on patient perspective. [12]

Cost of Illness (COI) is an important tool in the pharmacoeconomic studies of healthcare system over the world especially in developing countries. COI analysis measures the economic burden of disease and illness on society which is often called as burden of illness (BOI). The components of pharmacoeconomic analysis include costs and consequences. Costs can be divided into direct and indirect costs. Direct medical costs are those related to providing medical services such as hospital stay, physician fees for outpatient visits and drug costs (including the cost of medication itself and any downstream adverse events that may arise as a result of drug administration). Direct nonmedical costs are those related to expenses such as transportation costs, that are a direct result of the illness. Indirect costs are lost time from work (absenteeism) and unpaid assistance from a family member. In addition, intangible costs such as pain and suffering may be included in the analysis (Table 1).

COI analysis is used to aid in policy making; resource allocation, that is prioritizing resource use for disease treatment and prevention and as baseline research from which to determine the potential benefit of new therapies.<sup>[13]</sup>

Table 1: HEALTH CARE COST CATEGORIES

THE COST CATEGORIES			
COST CATEGORY	COSTS		
	Medications		
	Supplies		
Direct medical costs	Laboratory tests/Diagnostic tests		
Direct medical costs	Health care professional's time		
	Hospitalization		
	Physician consultation		
	Transportation		
Direct nonmedical costs	Food		
	Family care		
Indirect costs	Lost wages (morbidity)		
mun'ect costs	<b>Income forgone due to premature death (mortality)</b>		
	Pain		
Intangible costs	Suffering		
	Inconvenience		
	Grief		
0	Lost opportunity		
Opportunity costs	Revenue forgone		

Adapted from www.cdc.gov.

#### **QUALITY OF LIFE**

Quality of life (QOL) is a multidimensional concept that focuses on how disease and its treatment affect the individual. Quality of Life is a phrase used to refer to an individual's total wellbeing. This includes all emotional, social and physical aspects of the individual's life. However, when the phrase is used in reference to medicine and healthcare as Health Related Quality of Life (HRQOL), it refers to how the individual's wellbeing may be impacted over time by a disease, a disability, or a disorder.

Little is known about the quality of life and survival in the patients on Maintenance Hemodialysis (MHD) in India. Poor nutrition and dialysis noncompliance is common. The existing Chronic Kidney Disease Registry of India has 154 contributing centers as of 2008 and less than 50% of them contribute data regularly. It does not collect the morbidity, mortality and quality of life (QOL) data. [14-16]

#### MATERIALS AND METHODS

A prospective, observational study was conducted in108 patients comprising of 70 males and 38 females, aged 18 years or older with chronic kidney disease who were on twice or thrice weekly maintenance hemodialysis. The study was conducted with the approval of institutional ethics committee and informed consent of the study participants. Patients with major illness such as severe neurological problems like Stroke, Epilepsy etc. were excluded.

Patient data was taken for the analysis of cost component and the details collected by direct patient interview. The costs collected from the billing section of dialysis unit were the hemodialysis cost, physician consultation cost and dialyzer cost. The blood transfusion cost was collected from blood bank. The Laboratory investigation costs, diagnostic procedures like X –ray, Echocardiogram (ECHO) costs etc. were collected from the central laboratory and the drug costs from the pharmacy. Non- medical costs and indirect costs were collected from the patient directly.

The data was collected using the special patient data collection proforma (Annexure1) by direct patient interview. Cost of illness was calculated in Indian rupees (INR) from the expenditures. Cost analysis sheet for hemodialysis patients was prepared as in (Annexure 2).

Direct medical cost included cost of hemodialysis, physician consultation, dialysis disposables, laboratory investigation, hospitalization for any complications and ICU admissions, Erythropoietin, AV (Arterio -venous) fistula — access, Blood transfusion, Vaccination, Diagnosis and Medications.

Lab. investigations included cost of tests on Hemoglobin, PCV (Packed cell volume), BUN (Blood urea nitrogen), Serum(S) creatinine, Serum(S) albumin, Serum(S) ferritin, Sodium, Potassium, calcium, Phosphorus, Bicarbonate, Uric acid, Blood grouping etc. and Initial includes dialysis screening tests Human immunodeficiency virus (HIV), Hepatitis B antigen (HBsAg), Hepatitis C virus (HCV) and antibody screening. Diagnostic test includes cost of X-ray, ECHO etc. as required. The direct non-medical costs included cost of food, transportation, nutrition (Renal diet), telephone and extra family care.

Indirect cost included cost of lost wages (morbidity) and income forgone due to premature death (mortality). Indirect costs were calculated based on the number of missed working hours and the percentage of current income compared to the income that the patients had before they entered the dialysis procedure. Intangible costs included pain, suffering, inconvenience and grief. An opportunity cost included lost opportunity and revenue forgone.

Patients demographics, socioeconomic status, co-morbid conditions, regularity and affordability of hemodialysis were documented in the data collection proforma. Consultation from physician, nursing staff and dialysis staff was taken whenever necessary.

#### **OUALITY OF LIFE**

The Quality of Life (QOL) was assessed using SF -36 questionnaire. The SF-36, a well-documented, self-administered QOL scoring system includes eight independent scales and two main dimensions, which has been widely used and validated. It consists of 36 questions, 35 of which are compressed into eight multi-item scales:

- 1) Physical functioning is a ten-question scale that captures abilities to deal with the physical requirement of life, such as attending to personal needs, walking and flexibility;
- 2) Role-physical is a four-item scale that evaluates the extent to which physical capabilities limit activity;
- 3) Bodily pain is a two-item scale that evaluates the perceived amount of pain experienced during the previous four weeks and the extent to which that pain interfered with normal work activities;
- 4) General health is a five-item scale that evaluates general health in terms of personal perception;
- 5) Vitality is a four-item scale that evaluates feelings of pep, energy and fatigue;
- 6) Social functioning (SF) is a two-item scale that evaluates the extent and amount of time, if any, that physical health or emotional problems interfered with family, friends, and other social interactions during the previous four weeks;

- 7) Role-emotional (RE) is a three-item scale that evaluates the extent, if any, to which emotional factors interfere with work or other activities; and
- 8) Mental health is a five-item scale that evaluates feelings principally of anxiety and depression.

SCORING METHOD FOR SF-36 QUESTIONNAIRE: The methodologies of the scoring were available free for download online (<a href="http://www.rand.org/health/">http://www.rand.org/health/</a>). [15]

The scales are assessed quantitatively, each on the basis of answers, two to ten multiple choice questions and a score between 0 and 100 is then calculated, with a higher score indicating a better health related quality of life. The scores from these questions address each specific area of functional health status, which is averaged together for a final score within each of the 8 dimensions measured (eg., pain, physical functioning). The questionnaire was translated into regional language in a user friendly style for the patients and the language translation was validated by linguistic scholars. All the data collected finally was analyzed comprehensively and scored as per the afore mentioned scoring method.

#### STATISTICAL ANALYSIS

The collected data was analyzed with Statistical package for social sciences (SPSS) 17.0 version. The frequency analysis has been done to find the distribution of data. Descriptive statistics (Mean, Standard deviation) for the bivariate analysis has been done. Paired t-test was used to find the significance difference between variables. To assess the relationship between the variables, Pearson's correlation was used. The Probability value  $P \leq 0.05$  was considered as significant.

#### RESULTS

A total of 108 (65% males and 35% females) patients of either sex, aged 18 years, attending the hemodialysis unit of a tertiary care teaching hospital in South India were included in the study. Patients and above were included. The mean age of the patients was  $52 \pm 11.86$  years, the age range being 18-75 yrs. The duration of dialysis of the patients was found to be less than 6 months for 23(21%) patients, 6 - 12 months for 33 (31%) patients, 1-2 years for 25(23%) patients, 2 - 3 years for 11 (10%) patients, 3 - 4 years for 6 (6%) patients and above 5 years for 8 (8%) patients. Of the 108 patients, 85 (79%) patients were on thrice weekly and 23 (21%) were on twice weekly maintenance heamodialysis. The mean dialysis vintage was found to be  $36 \pm 21$  months. The mean dialysis adequacy (Kt/V) was found to be  $1.28 \pm 0.26$ . The etiology of ESRD were as follows: diabetes &

hypertension (42%), hypertension (18%), diabetes (22%) and others included Pyelonephritis, Renal calculi, IgA Nephropathy, Renal anemia, Ectopic kidney, Glomerulonephritis and Non Steroidal Anti-Inflammatory Drugs abuse, which summed up to 19%.

The direct medical cost spent by each patient per month amounted to INR 52, 420 which included cost of dialysis, dialyzer disposable, consultation fees, AVF access procedure, medications, erythropoietin, diagnostic test, laboratory tests, dialysis screening, blood grouping, vaccination, antibody screening etc. excluding the hospitalization cost for complications/graft and ICU admissions. The direct non-medical cost spent by each patient per month was INR 6,856 which included cost of transportation, food, nutrition, telephone and attendee company (extra family care) etc. The indirect cost was found to be INR 6,759 and it included cost of lost wages owing to dialysis and income forgone due to premature death. The direct medical cost contributed to 93.74%, direct non-medical cost contributed to 3.15% and indirect cost contributed to 3.11% of the total cost (Tables 2-5). Erythropoietin contributed to 81% of the total drug cost spent by MHD patients. The cost of illness had a strong positive correlation with the duration of dialysis. As the duration of dialysis increased, the cost of illness increased (r = 0.682; P<0.01) as shown in table 6. The duration of dialysis also had a negative correlation with quality of life. As the duration of dialysis increased, the quality of life decreased (r=-0.214; P<0.0001).

The SF-36 score range was found to be 0-20 for (39%) of patients, followed by 21-40 for (49%), 41-60 for (10%), 61-80 for (1%) and 81-100 for (1%) of patients. Majority of patients were found to be in the SF-36 score range of 21- 40. The physical component of health showed a higher score compared to the mental component of health. There was a significant correlation between physical and mental component of health in the quality of life assessment. In physical component of health, the pain scale scored higher and role limitation due to physical health scored the least. In mental component of health, the emotional well-being scale scored higher and the role limitation due to emotional problems scored the least. There was a strong positive correlation between the physical and mental components of the QOL (r= 0.651; P = < 0.0001).

The cost of illness and quality of life were negatively correlated as depicted in table 7. As the cost of illness increased, the quality of life decreased and the difference was statistically significant (r = -0.241; P < 0.01).

TABLE - 2: COST ANALYSIS OF HEMODIALYSIS PATIENTS

COST CATEGORIES	COST OF HD/SESSION (INR)	MONTHLY COST (INR)	PERCENTAGE
DIRECT MEDICAL COST	1500	52,420	24.10%
DIRECT NON-MEDICAL COST	800	6,856	3.15%
INDIRECT COST	1,000	6,759	3.11%

DIRECT MEDICAL COST (with AV-GRAFT and other complications)	60000*+31463	91,463	42.05%
DIRECT MEDICAL COST (with ICU admissions)	60000 (for 3 days)	60,000	27.59%

<sup>(\*</sup>If Fistula fails, then additional cost towards graft); INR Indian Rupee.

TABLE- 3: DISTRIBUTION OF DIRECT MEDICAL COST

COST CATEGORIES	MEAN MONTHLY COST IN (INR) ± SD	COST PER ANNUM (INR)
HEMODIALYSIS COST *	$11750 \pm 2429$	141000
PHYSICIAN COST *	$1306 \pm 270$	15667
DIALYSER DISPOSABLE, TUBINGS *	771 ± 142	9256
DRUGS COST *	$16024 \pm 3153$	192282
LAB.INV / DIAGNOSIS COST *	915 ± 554	10977
DIALYSIS SCREENING TEST COST (OTC)	855 ± 0	855
VACCINATION (OTC)	$800 \pm 0$	800
HOSPITALIZATION COST FOR ACCESS (AV FISTULA) (OTC)	$20000 \pm 0$	20000
HOSPITALIZATION COST FOR ACCESS (AV GRAFT) (OTC)	60000±0	60000
HOSPITALIZATION COST FOR COMPLICATIONS	31463± 17275	31463
ICU ADMISSION COST	60000±0	60000
TOTAL DIRECT MEDICAL COSTS		5,42,299

OTC (ONE TIME COST); \* Recurring Costs; INR Indian Rupee.

TABLE -4: DISTRIBUTION OF DIRECT NON - MEDICAL COSTS

COST CATEGORIES	MEAN MONTHLY COSTIN (INR) ± SD	COST PER ANNUM (INR)
FOOD/NUTRITION	$2500 \pm 0$	30,000
TRANSPORTATION	$3319 \pm 522$	39,822
TELEPHONE/FAMILY CARE	$1037 \pm 163$	12,444

INR Indian Rupee.

**TABLE- 5: DISTRIBUTION OF INDIRECT COSTS** 

COST CATEGORIES	MEAN MONTHLY COST IN (INR) ± SD	COST PER ANNUM (INR)
MORBIDITY (LOST WAGES-Monthly)	$15581 \pm 7182$	186,977
MORTALITY	$20000 \pm 0$	240,000

INR Indian Rupee.

TABLE - 6: DURATION OF DIALYSIS Vs TOTAL COST OF ILLNESS

DURATION OF DIALYSIS	TOTAL COST OF ILLNESS (Rs)	PEARSON CORRELATION 'r'	SIGNIFICANCE P
0-6 MONTHS	195,242		
6-12 MONTHS	517,724		
1- 2 YEARS	832,300		
2-3 YEARS	1,603,788		
3-4 YEARS	2,123,433	0.682	< 0.01
4-5 YEARS	3,351,085		
5-6 YEARS	0		
6-7 YEARS	3,547,831		
7-8 YEARS	3,997,615		

INR- Indian Rupee; \*P <0.01 – statistical significance.

OSI OF ILLNESS VS QUALITY OF LIFE SF-30 SCORE				
	SF-36 SCORE	COST OF ILLNESS PER MONTH (INR)	PEARSON CORRELATION 'r'	SIGNIFICANCE P
	0-20	153,545		
	21-40	134,422		
	41-60	114,215	- 0.241	<0.01*
	61-80	108,400		
	81-100	107,270		

TABLE -7: COST OF ILLNESS Vs QUALITY OF LIFE SF-36 SCORE

INR- Indian Rupee; \*P < 0.01 – statistical significance.

#### DISCUSSION

In this study, a total of 108 patients were included, of which males were 65% and females were 35%. The incidence was more common in males compared to females. The reason could be the lifestyle factors, dietary and other habits. This is in conformity with the study conducted by Modi GK et al.<sup>[1]</sup>

Hemodialysis as a therapeutic procedure consumes a great proportion of financial expenses. Patients with ESRD require some form of dialysis during their lifetime due to the long waiting list of transplantation. In this study, after excluding all other costs including the onetime expenses, the average cost per session of dialysis was found to be INR 1500, which is still difficult to afford by the common people, as they have to undergo maintenance dialysis twice or thrice per week. The mean total annual cost of maintenance dialysis per patient (including all total costs, provided if they hospitalized for complications in ward/ICU, fistula failure cost etc) was estimated to be INR 5, 42,299. The cost to manage the multiple frequencies of complications has further intensified the financial load per patient. The cost to handle the co-morbid conditions like diabetes and hypertension, the major contributing factor of renal failure in this study, has additionally increased the total annual cost per patient. Thus, the lifelong treatment of renal failure along with diabetes, hypertension and cardiovascular disease significantly increased the economic load on patient and decreased the clinical outcome. This is in concurrence with the study conducted by Rao et al.[17]

Direct cost is easier to account for than the indirect cost; accounting methods are likely to vary between hospitals and even in one hospital from one year to another and this adds to the difficulties of comparisons of costs. This is in consensus with the study reported by Al Saran et al,<sup>[18]</sup> Hidai et al<sup>[19]</sup> and McFarlane et al.<sup>[20]</sup> There is a constant increase in the total expenditures for hemodialysis compared to previous years Gazdikova et al.<sup>[12]</sup>

From the data obtained, the cost factor for direct medical expense amounted to INR 52,420 per month. The direct non-medical cost amounted to INR 6, 856 per month and the indirect cost amounted to INR 6, 759 per month. Apart from this monthly cost, there were additional expenses in direct medical cost which included, ICU

admissions costs for major complications, hospitalization costs for access procedures (like AV fistula/AV Graft) and hospitalization cost for other complications. These expenditures further attributed to the total direct medical costs. Thus these costs were the highest, followed by medication cost, hemodialysis and so on. This study emphasizes, how the financial burden of MHD impacts the lifestyle and future of entire families and extracts a cost far higher than the actual amount of money spent on treatment, which is in consensus with the study of Vaiciuniene et al.<sup>[21]</sup>

The costs of medications mainly, erythropoietin contributed a major extent to the total medication expenditure apart from dialysis. The drug costs are direct load, but represent only a part of the pharmacoeconomic complexity. The erythropoietin contributed to 81% of the total drug cost used by HD patients. This is in accordance with the results reported by Gazdikova et al. [12]

Hospitalization costs for complications were another additional factor towards the total cost. An infection was a common complication for hospitalization and is an important cause for morbidity and mortality in dialysis patients. The common infections were in the AV graft, fistula line, hepatitis, broncho-pneumonia, bacteremia/sepsis etc. The bacterial and viral infections are common in long term dialysis patients. The patients with cardiovascular risk are also hospitalized for various complications, mainly cardiac arrest. The hospitalization cost for complications and access related procedures contributed significantly to the direct medical cost. This is in consistence with the study done by Jones et al. [22]

There is limited information available on the QOL in Indian dialysis patients. QOL can predict the incidence of hospitalization and mortality. Age  $\leq 65$  years, absence of catheter use and hospitalization predicted better quality of life score. Avoiding hypotension and cramps in these patients will increase the QOL and decrease the long-term complications of intradialytic hypotension in them. This is in accordance with the study reported by De Oreo et al.  $^{[23]}$ 

The quality of life assessment proved that the physical and mental component of health played a vital role in the day to today lifestyles. The maintenance hemodialysis (MHD) does affect their quality of life significantly. The

MHD affected their physical, general health and their emotional well being, which limited their overall activities. Each one point increase in PCH was associated with 2% drop in relative risk of death & hospitalization and each one point increase in MCH was associated with 2% drop in relative risk of death and 1% drop in relative risk of hospitalization.

The mental health dimension and the SF-36 score had the strongest predictive value for mortality. The results were analogous with the report of Kalantar et al. [14], which confirmed that patients on MHD often show substantial reduction in Quality of Life (QOL) and were at higher risk of morbidity and mortality. In the present study, the physical component of health showed a higher score of 26% compared to the mental component of health of 24% and the physical component is highly correlated with the mental component of health.

According to the socioeconomic status of the patient, only upper and middle class people can afford the hemodialysis service offered by the private sector. In this study, majority of patients were in upper middle II and lower middle III, followed by upper I and upper lower IV. Patients on low economic status take pain for the regular dialysis and to manage the complications. The larger parts of patients were regular for hemodialysis and the source of funding were self, insurance and from relatives' financial support. Majority were self-funded compared to other sources. This finding is in consensus with the study reported by Suja et al. [6]

Patients from the middle income family face difficulty in affording the costs for the management of co morbid conditions along with the dialysis cost. This will affect the clinical outcome as well as the satisfaction with the treatment. Upper class patients' experiences better clinical outcome as well as patient satisfaction when compared to middle class people because they were able to manage the cost without affecting much to their daily life. There is no significant difference in the regularity as well as affordability even though the middle class people face a lot of problems. This is in accordance with the study reported by Nick et al. [24]

This study has compared the cost of dialysis and perceived quality of life, as well as morbidity and mortality outcomes in patients. Many studies have reported the need for comparison of cost and QOL, as well as morbidity /mortality outcomes. The studies reported were Roderick et al<sup>[25]</sup> and De Vecchi et al. <sup>[26]</sup>

True differences in the cost of HD provision between different studies obviously ensue as a result of various factors, namely, different management protocols, variable standards of care, differences in the methodologies used, the differences in countries in which the analyses were carried out and finally the number of dialysis sessions as well as the nurse/patient

and physician/patient ratios. Direct comparisons may not be particularly informative.

The use of dialysis to treat patients with ESRD remains one of the most resource-intensive therapeutic interventions. This is in conformity with the reports of Tediosi et al,<sup>[27]</sup> Sennfalt et al, and Lysaght et al.<sup>[29]</sup>

The cost for renal replacement therapy (RRT) has been described to be enormous. However, national and international population-based cost studies are scarce. All countries, even industrialized ones, were facing the problem of diminishing financial resources to deal with the increasing health care costs brought on by this lifesaving modality of RRT. This is reported in the studies of Icks et al, [30] Romao et al [31] and Straube et al. [32]

This study has established that cardiovascular risk is the major cause of poor outcome along with other co-morbid conditions in dialysis patients. This is in consistence with the study done by Jones et al. [22] The non availability or less availability of dialysis unit in public sector compared to private sector and also lack of reimbursing or insurance scheme to the dialysis patients are the major concerns in a country like India. Only the upper or upper middle class people can afford hemodialysis. The cost of maintenance hemodialysis therapy at the public sector needs quantification and studies focusing on evaluating the cost and clinical outcome of hemodialysis patients approaching public versus private hospitals are in dire need. If the patients achieve better clinical outcome and quality of life at an affordable cost in the public sector, government has to take initiative to commence more dialysis centers at the public level. Various nongovernmental organizations as well as charity trusts are coming forward to provide more cost-effective maintenance hemodialysis. Supply of drugs by the public sectors mainly for hypertension and diabetes at free of cost will also help the patients to reduce the overall cost.

# STRENGTHS AND LIMITATIONS OF THE STUDY STRENGTHS

- This is the first study which analyzed the direct medical costs of hospitalization for complications and co-morbid conditions of dialysis patients from a patients' perspective. The analysis was done comprehensively regarding the direct as well as indirect costs of hemodialysis in a tertiary care hospital setting. Most of the other studies have reported the cost factor from hospital perspective.
- From this observational study, it was found that 93.74% of the cost was due to direct medical costs, 3.15% of the cost was due to direct non-medical costs and 3.11% were due to indirect costs. This information can be a strong basis for future studies of pharmacoeconomic evaluations.

#### **LIMITATIONS**

- ➤ The main limitation of the study is its duration. This analyzes the data of one year only and not extrapolated.
- Another major limitation is that this data is obtained from a single center. A multicentric study design is more valuable and the data obtained also would be more accurate.

#### CONCLUSION

The study findings revealed the real impact of cost of hemodialysis in patients suffering from ESRD and the compromised quality of life led by the patients. There is higher economic burden associated with maintenance hemodialysis. The financial expense coinciding with drug costs (mainly erythropoietin), hospitalization costs for access, complications and ICU admissions are significant. From this observational study, it was found that direct costs (direct medical and non-medical costs) was momentous compared to indirect costs. This information can be a basis for future studies of pharmacoeconomic evaluations.

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