Assessment of Pharmacoeconomics and Drug Usage Among Haemodialysis Patients, Baptist Hospital, Bangalore

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Abstract

Objective: To analyses the prescribing pattern in haemodialysis patients and Pharmacoeconomics to assess QOL in haemodialysis patients. Methodology: This was a cross-sectional study conducted in patients undergoing haemodialysis at Dialysis center of tertiary care teaching hospital at Bangalore Baptist hospital (BBH) Hebbal, over a period of six months. Data was analyzed using statistical methods such as Kolmogorov Smirnov (KS) test, unpaired t-test and Analysis of Variance, Pearson correlation coefficient, SPSS version 18 and 20.Result:Total number of patients diagnosed as CKD undergoing dialysis during the study period was 50, of which 34(68%) were males and 16 (32%) were females with their mean age of 53.89 ±13.34 years and 39.05 ± 8.45 years respectively. Analysis of WHO core drug prescribing indicators showed that the average number of drugs prescribed per patient was 5. CKD was most commonly seen in males with significant statistical difference (P-value<0.001). Most common co-morbid condition associated with CKD was hypertension (16%) followed by diabetes mellitus (20%) and IHD (20%). Anticoagulant agent (100%) was the most commonly used drug, followed by antihypertensive drugs (94%), ulcer protective, calcium salt, multivitamins, erythropoietin, insulin, antiplatelet, oral hypoglycemic and statins. Patients on haemodialysis had a poorer QOL in all domains except for domain 4(environment). Conclusion: Current study provides valuable insight about the overall pattern of drug use profile in haemodialysis population. heparin and amlodipine has the highest cost among all commonly used drugs. In haemodialysis patient the lowest QOL score was observed with social domain (8.2) followed by physical (13.2) and psychological (13.9) domain. Highest score was seen with environmental (21.5) domain.

Key words: Prescribing Pattern, Chronic Kidney Disease, Haemodialysis Patients, Pharmacoeconomics.

Introduction

haemodialysis, commonly called kidney dialysis or simply dialysis, is a process of purifying the blood of a person whose kidneys are not working normally. This type of dialysis achieves the extracorporeal removal of waste products such as creatinine and urea and free water from the blood when the kidneys are in a state of kidney failure. Hemodialysis is one of three renal replacement therapies (the other two being kidney transplant and peritoneal dialysis). An alternative method for extracorporeal separation of blood components such as plasma or cells is apheresis. Hemodialysis can be an outpatient or inpatient therapy. Routine hemodialysis is conducted in a dialysis outpatient facility, either a purpose built room in a hospital or a dedicated, stand-alone clinic. Less frequently hemodialysis is done at home. Dialysis treatments in a clinic are initiated and managed by specialized staff made up of nurses and technicians; dialysis treatments at home can be self-initiated and managed or done jointly with the assistance of a trained helper who is usually a family member.¹

Many people with chronic kidney disease (CKD) and end-stage kidney disease (ESKD) have irreversible kidney damage and require renal replacement therapy. For people with ESKD, kidney transplant is the treatment of choice because compared with haemodialysis, transplant reduces mortality risk and improves quality of life. Haemodialysis has become the default treatment for people with ESKD in developed countries, and although it sustains life, for many people it is a supportive or palliative therapy (Davison & Torgunrud, 2007). Age and co-morbidities of people receiving haemodialysis have increased. In low-risk patients, mortality is much higher compared with age-matched controls who do not have kidney failure; and for high-risk patients, haemodialysis may simply prolong the process of dying. (Vilar & Farrington, 2011).

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¹ https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/choosing-treatment

The Dialysis Outcomes and Practice Patterns Study (DOPPS) has been developed to provide data on current practice in haemodialysis management and to relate this to patient outcomes. The DOPPS is designed as a prospective, observational study of nationally representative samples of randomly selected haemodialysis facilities and patients (Young et al., 2000)

In recent decades, several important advances have been made in the treatment of end-stage renal disease (ESRD) (Davison & Torgunrud, 2007), not least the management of anemia associated with chronic kidney disease (CKD). The burden of anemia in these patients is substantial, causing considerable morbidity and dramatically reducing their quality of life (Foley ewt al., 1998; Levin et al., 1999; O'Riordan E, Foley, 20100). Until 15 years ago, the mainstay of treatment was blood transfusion, with all its associated risks. However, the management of renal anaemia has been transformed over the past decade by the introduction of recombinant human erythropoietin (rHuEpo). Over this period, rHuEpo has become accepted as an effective and well-tolerated treatment, and its clinical benefits in patients with CKD are well documented (Collins, 2000; Parfrey, 2000; Besarab et al., 1998; Pascual etal., 1991; McMahon et al., 1999; Evans et al., 1990; Canadian Erythropoietin Study Group, 1999; Painter et al., 2002; Lundin et al., 1991; Moreno et al., 1991).

Pharmacoeconomics centers on the economic evaluation of pharmaceuticals, and can use cost-minimization analysis, cost-benefit analysis, cost-effectiveness analysis or cost-utility analysis. Quality-adjusted life years have become the dominant outcome of interest in Pharmacoeconomics evaluations, and many studies employ a cost-per-QALY analysis. Economic evaluations are carried out alongside randomized controlled trials and using methods of decision-analytic modeling. Pharmacoeconomics is a useful method of economic evaluation of various treatment options. As more expensive drugs are being developed and licensed it has become imperative especially in context of developing countries where resources are scarce to apply the principles of Pharmacoeconomics for various drugs and treatment options so that maximum improvement in quality of life can be achieved in minimum cost.(Deepak et al., 2017).

The main objective of the study was to assess QOLY (quality-adjusted life year or quality-adjusted life-year) in hemodialysis patients with reference to their physical, psychological, Pharmacoeconomics dimension, and to analyses the prescribing trends in hemodialysis patients.

Materials and Methods

This was a cross-sectional study conducted in patients undergoing haemodialysis at Dialysis center of tertiary care teaching hospital at Bangalore Baptist hospital (BBH) Hebbal, over a period of six months. The hospital has various departments like medicine, surgery, pediatrics, gynecology and obstetrics, orthopedics, ear nose throat (ENT), nephrology psychiatry and dermatology. written informed consent was taken from the patients.

All dialysis inpatient medication charts will be reviewed and noted down in a predefined data collection form. The basic demographic details along with clinical diagnosis, history, comorbidities, allergies, past surgeries and socioeconomic status will be noted. The reason for the prescription of each medication will be identified. The pattern of the drugs prescribed in the dialysis patients will be analyzed.

The therapeutic inappropriateness such as selection of the drug, dose, frequency and duration of the treatment will be analyzed separately and the occurrence of number of medication related problems under each criterion will be noted. The follow-ups with an intention of identifying the occurrence of medication related problems such as ADR, drug interactions, renal impairment and liver impairment will be carried out for all the patients under this study. Furthermore, the patients increased hospital stay, additional drug management and their variable costs involved will be correlated with all medication related problems. The inappropriateness is further confirmed with treating consultant, appropriate literature survey and information provided based on the concept evidence based medicine. The prevalence of the inappropriateness will be documented. The data analyzed using statistical methods such as Kolmogorov Smirnov (KS) test, unpaired t-test and Analysis of Variance, Pearson correlation coefficient, SPSS version 18.

Result and Discussion

Chronic kidney disease (CKD), also known as chronic renal disease, is progressive loss in kidney function over a period of months or years. It slowly progresses to End Stage Renal Disease requiring haemodialysis or renal transplantation. Haemodialysis restores the intracellular and extracellular fluid levels which is similar to the function of normal kidney. When kidneys fail to clean the blood, excess fluid, minerals, and harmful wastes build up in the body, which may result in raise in blood pressure, edema and decrease in erythropoiesis. (Feder et al., 2015) The two main causes of chronic kidney disease are diabetes mellitus and hypertension, which are responsible for up to two-thirds of the cases.

Total number of patients diagnosed as CKD undergoing dialysis during the study period was 50, of which 34(68%) were males and 16 (32%) were females with their mean age of 53.89 \pm 13.34 years and 39.05 \pm 8.45 years respectively. This finding was similar to study done by Tamil selvan et al, where 62.85 % were male subjects. (Dheepan et al., 2015). The reason behind the male predominance is no

communicable diseases like hypertension and diabetes are more common in males which cause damage to kidney over period of time leading to chronic kidney failure.

Among the study patients,8% were between 20-29 years' age, 12% were in 30-39 years' age, 32% were in 40 -49 years' age, 28% were in 50-59 years' age, 12% were in 60-69 years of age and 8% were in 70-79 years' age group. this finding was similar to findings of study carried out by Tamil selvan et al $(53.26 \pm 15.69 \text{ years})$. (Selvan et al., 2014).

CKD was most commonly seen in males with significant statistical difference (P-value<0.001). Most common co-morbid condition associated with CKD was hypertension (16%) followed by diabetes mellitus (20%) and IHD (20%). (Figure 1)

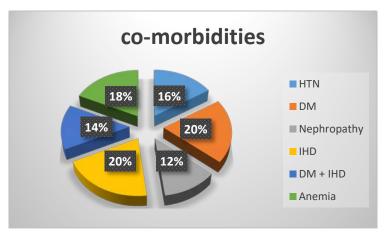


Figure 1: Schematic representation of co-morbidities distribution of study patients

Anticoagulants, commonly referred to as blood thinners, are chemical substances that prevent or reduce coagulation of blood, prolonging the clotting time.

figure 2 shows prescription pattern in patients undergoing haemodialysis. Anticoagulant drugs (100%) were used in majority of the patients. Heparin was the most commonly used anticoagulant agent which was given by intravenous route followed by antihypertensive drugs (94%), ulcerprotective (specially proton pump inhibitors), calcium salt, multivitamins, erythropoietin, insulin, antiplatelet, oral hypoglycemic and statins were used. Heparin and amlodipine was the most commonly used drugs for study patients. Heparin, also known as unfractionated heparin (UFH), is medication which is used as an anticoagulant (blood thinner). The average number of drugs prescribed per patient was 5.1. Polypharmacy or use of more than 5 or more drugs at a time is an unavoidable predicament faced while managing CKD patients due to the prevalence of co-existing illnesses.

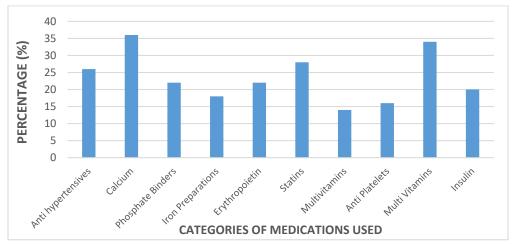


Figure 2 categories of medication used for study patients

Among all the prescribed drugs, antihypertensive agents were the most predominantly used drugs. Followed by ulcer protective drugs which were used in 65% of the patients to prevent stress ulcers and for the symptomatic relief of dyspepsia. Haematinics were extensively used along with other multivitamin supplements (42%) including calcium (45%). The diabetic patients were managed with insulin (25%) and oral hypoglycemic agents (12%)like metformin, gliclazide and glimepiride. Statins andante platelet drugs were used in

8% and 16.9% of patients respectively to maintain the normal lipid profile of the patient. Haematopoetic agents like erythropoietin was used only in 19.1% of the patients because most of the patient could not afford it.

Impact of patient counseling for six months was remarkable. While comparing the slightly declining or constant QOL in control group; patients under counseling (test group) have shown a trend of improving the QOL. The study shows that patient counseling can improve health related QOL by improvement awareness and removing the misconceptions about the disease process and its management from the patients. Dietary compliance was observed to be a key factor in improving QOL of patients undergoing chronic hemodialysis. Patients were given a minimum fifteen minutes of unstructured counseling at least once on every alternative visit. Specific questions were noted and answered on their next visit. Available materials or books were given to the patients who requested for reading it.

Table 1: Distribution of patients according to QOL Transformed Scores (N = 50)

Domain	Mean	SD	SEM	Minimum	Maximum
I (Physical)	13.29	3.5	0.38	7	23
II (Psychological)	13.96	3.96	0.43	6	22
III (Social)	8.23	2.17	0.23	3	13
IV (Environmental)	21.56	3.16	0.34	14	31

The Physical, Psychological, Social and Environmental domains of QOL score were found to be 13.29, 13.96, 8.23 and 21.56 respectively Table 1. The scores were low when compared to findings of study carried out by (Sathvik BS et al.,2008) The low physical health score in haemodialysis patients clearly indicates that daily activities were disturbed in ESRD patient as they were more dependent on renal replacement treatment for their survival. All most all patients had sleep disturbance because of generalized body ache, weakness and anxiety. In this study, highest score was seen with environmental (21.5) domain when compared to study carried out by (Anees et al., 2011)

Distribution of patients according to QOL is shown in Table 2. In haemodialysis patient the lowest QOL score was observed with social domain (8.2) followed by physical (13.2) and psychological (13.9) domain. Highest score was seen with environmental (21.5) domain. Table 2 shows transformed score of different domains. The patients showed very low score with physical, psychological and social domains than environmental domain. Table 2

Table 2 parameters counseling for study patients

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Parameter	Before Counseling	After Counseling			
Dietary compliance	Poor and weak built	Improved			
Risk factors	Unaware	Patients developed cautiousness			
Medication management	Missing doses, irregularity in medication therapy	Improved			
Dialytic complications	Patients were worried and tensed before counseling	Managing ability improved			
Awareness and improving misconceptions	Patients were unaware of stages of kidney disease	Improved			
Disease process and its management	Emotional status, physical status were worsened	Emotional status, physical status Improved			
Regularity on dialysis	Patients were irregular to dialysis center	Regularity Improved			

It is interesting to note that the majority of our study patients did not have adequate financial security and suffered a loss of income while being on hemodialysis. The education status of the most patients was poor, they are illiterate (42%). Education status and medication adherence are closely related. Our study results also show their family income is also very low.

Conclusion

Total number of patients diagnosed as CKD undergoing dialysis during the study period was 50, of which 34(68%) were males and 16 (32%) were females with their mean age of 53.89 ± 13.34 years and 39.05 ± 8.45 years respectively. Pharmacoeconomics attempts to measure the benefit of one intervention is worth the cost of that intervention. This is very much important in making any critical pharmaceutical interventions regarding cost of health care. This study is aimed to investigate the Pharmacoeconomics aspects of treatment in CKD patients. This study was also assessed that how Pharmacoeconomics is affecting the quality of life of CKD patients.

Pharmacoeconomics analysis shows that CCBs were having high cost than other antihypertensive in CKD patients when compared to other treatment modalities.

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It is interesting to note that the majority of our study patients did not have adequate financial security and suffered a loss of income while being on hemodialysis. An increase in no of comorbidities may worsen the QOL of patients due to physical, psychological and emotional reasons. So low education level low family income and high cost of drugs will cause the medication adherence and ultimate it will affect the quality of life of the patient.

Current study provides valuable insight about the overall pattern of drug use profile in haemodialysis population. Heparin and amlodipine was the most commonly used drugs. We also found that QOL was very poor; especially low score was seen with physical and psychological domains.

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