

**ASSESSMENT OF DRUG USE PATTERNS AND QUALITY OF LIFE IN
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ABSTRACT

Patients on hemodialysis are highly dependent with several comorbid conditions who often have unsatisfactory rehabilitation, poor prognosis and suffer additional burdens including invasive interventions and time commitment. Patients suffer from further losses in professional, social, sexual and psychological contexts, in addition to physiological and emotional shocks felt at the time of diagnosis and during the course of treatment. Hence a study is conducted to assess the drug use patterns and QoL (SF-36) in HD patients (n=105). Hypertension (100%) was found to be the most common comorbid condition followed by anemia (85.71%), DM (60%), CAD (33.33%), hyperlipidemia (26.67%) and hypothyroidism (14.8%). Among drug use patterns antihypertensives (100%), anticoagulants (100%) and erythropoietin (100%) were most commonly prescribed. The present study revealed that the study sample undergoing hemodialysis had lower health related QOL scores for all the 8 domains for the first assessment compared to the second assessment. But there was no significant difference between the two assessments. After the follow up, in both males and females, all the domain scores were found to be significantly improved. In males, after follow up, bodily pain was more improved followed by vitality, general health, role physical, social functioning, role emotional and mental health. In females, after follow up, bodily pain was more improved followed by general health, vitality, social functioning, mental health and physical functioning.

KEYWORDS: Chronic Kidney Disease, Quality of life, Hemodialysis, Prescription patterns, Renal Replacement Therapy.**INTRODUCTION**

Chronic kidney disease (CKD) of stage-5 is also called End stage renal disease (ESRD) which is characterized by both structural and functional abnormalities in the kidney due to decrease in the glomerular filtration rate (GFR) that persists for more than 6 months^[1]. The decline of GFR is generally reflected by the degree of renal insufficiency and the severity of kidney disease^[5]. CKD is a progressive decrease in the normal function of kidneys overtime^[15] and presents in the form of injuries to renal parenchyma^[22]. It is non-curable condition^[18] which is often progressive, irreversible, persists throughout the patient's life time and affects all the aspects of life^[2].

CKD has been recently included in the group of lifestyle diseases of 21st century^[1]. According to epidemiological studies CKD affects 6-15% of the worldwide population i.e.; approximately 600 million people^[2]. The elderly patients are the fastest increasing subgroup in dialysis population in developed countries^[14]. Incidence and prevalence of CKD is increasing worldwide^[5]. CKD prevalence in all over the world was predicted to be 8-16% of the populations^[11]. As per the global burden of

disease study in 2010, in the list of causes of total number of global deaths, CKD rose from 27th in 1990 to 18th in 2010. With a prevalence of 11.9% in Taiwan and 10.8% in Mainland China, CKD is a significant problem in Asia. In 2005-2006, in Asia over 90% of dialysis patients in China and Taiwan were on HD^[10]. Every year an estimation of 1,00,000 persons suffer from ESRD of which about 20,000 only get treated^[20].

Patients with ESRD can undergo either renal replacement therapy (RRT) or kidney transplantation. Renal replacement therapy includes hemodialysis (HD) and peritoneal dialysis (PD) that would either be intermittent or continuous based on treatment modalities^[1]. The count of the patients receiving RRT is increasing constantly due to reasons such as high quality in treatment, high disease detection rate and improved patient life expectancy^[2]. The available treatments are complex, costly and lasts lifelong^[7]. The number of the ESRD patients has continued to climb since dialysis and kidney transplantation began to be used as treatment strategies^[12]. Compared to dialysis, renal transplantation has more efficacy because only one treatment makes the patients avoid dialysis procedure which usually takes

place relatively in long duration; meanwhile, dialysis is used to treat CKD^[11]. Patients who cannot tolerate PD or who have medical contraindications towards PD, HD is preferred as the best option^[10].

HD may be debilitating because renal failure patients come across many challenges due to their condition which make them feel fatigued and depressed. Fistula or grafting done for dialysis access affects the body image; high cost of weekly treatments for dialysis and occasional admission to the emergency department due to complications affects the financial status of the patients. HD also acts as a threat to relationships and independency^[6] and contribute to malnutrition^[4]. Over 60% of the HD patients were treated in government funded hospital-based renal units^[10]. Dialysis therapy is primarily aimed at the outcome of reduction in morbidity and mortality^[19]. HD costs range between 600-2000INR per session or 5,500-20,000INR per month without including the amount spend on medication and travel. Affording capacity is generally hindered by low incomes, low reimbursement for chronic illnesses and low penetration of insurance^[20].

Dialysis patients are highly dependent with several comorbid conditions who often have unsatisfactory rehabilitation and poor prognosis and suffer additional burdens including invasive interventions and time commitment^[3]. Patients suffer from further losses in professional, social, sexual and psychological contexts, in addition to physiological and emotional shocks felt at the time of diagnosis and during the course of treatment^[23]. Patients must be encouraged to follow the discipline in eating and fluid intake and to adopt to the conditions that enable them to be active both socially and physically within their natural potential^[7]. Survival of the dialysis patients depends on the basis of delivered dialysis dose which should take into account the functional outcomes to estimate the dialysis adequacy^[16].

The stressful factors to be beared by the patient include pain, feeling unrest, limitation of food, liquid, fatigue, weakness, stress, depression, feeling of inadequacy. Appropriate coping or adaptive methods which are purposeful activities rather than the habitual behaviors that people do unconsciously are important considering the signs and symptoms of the disease. Coping methods include problem oriented methods which involve planning an active program and implementing that and emotion oriented methods which aims at controlling emotions and adapting with the opportunity like lack of concentration on that^[26].

Health Related Quality of Life (HRQoL) is an important outcome measure of RRT^[21] and one of the major challenges in the healthcare system^[31]. The collective perception of the effect of a disease or its treatment on the health and overall quality of life of an individual refers to the HRQoL^[1]. Both generic and disease-specific instruments can be used to assess HRQoL^[25].

The World Health Organization (WHO) defines Quality Of life (QoL) as: "the perception that individual makes about his position in life, within its cultural context and value system, and related to its goals and vital objectives"^[4,13].

QoL is a complex^[33] patient centered concept^[19]. Although QoL is difficult to define, it is considered as an important indicator of health and well-being^[4] as well as a parameter to calculate person's illness and survival^[15]. Subjectivity and multidimensionality are the two basic characteristics that can be distinguished in the concept of QoL^[4]. QoL involves the subjective evaluation of both positive and negative aspects of life^[13]. QoL comprises of physical, mental, social and economic components which can be influenced by many factors such as demographic, medical and psychological parameters^[9]. Better response to the treatment and longer lifespan are obtained by a better QoL^[2]. Assessment of QoL identifies the strategies to prevent the adverse outcomes^[30].

The issues which affect the QoL include age, economic status, literacy level, loss of employment and gender bias^[17]. The core components of QoL include physical, functional, psychological/emotional and work/occupational domains^[34].

A well-documented scoring system, the short form health survey with 36 questions (SF-36) has been widely used and validated as a QoL assessment tool for the patients on HD^[8]. SF-36 is a specific^[19], reliable, comprehensive, brief^[24], generic and self-administered questionnaire; suitable for general populations without reference to any disease, or condition specific or domain specific. 35 items of the SF-36 form were categorized into 8 multi-item scales: 1) physical functioning; 2) role-physical; 3) bodily pain; 4) general health; 5) vitality; 6) social functioning; 7) role-emotional; and 8) mental health^[27]. Each of these scales are assessed quantitatively based on the answers of 2-10 multiple choice questions, and a score between 0 and 100 is then calculated based on the well-defined guidelines, with the high score indicating the better health status^[27]. These 8 scales can be summarized into 2 composite scales^[14]; Physical Component Score (PCS) that summarizes physical functioning, role physical, bodily pain and general health scores and Mental Component Score (MCS) summarizes vitality, social functioning, role emotional and mental health subscales^[28]. Lower PCS and MCS of 7 and 5 respectively had a greater risk for poor outcome^[32]. Significantly impaired QoL has been observed in both incident and prevalent dialysis patients^[29].

Drug utilization is defined as marketing, prescribing, distribution and use of drugs in the society with a special emphasis on resulting medical and social consequences^[37,46] with a primary aim of facilitating the rationalized drug use^[46]. Drug use indicators specified by WHO can be adopted in drug utilization studies. WHO

defined that rational use of drugs requires that the patients should receive appropriate medications to their clinical needs at appropriate doses for an adequate time period at lowest cost. Drug utilization studies should be based on socio medical and economic health for healthcare decision making^[37].

Dialysis patients have at least 5-6 chronic medical conditions^[36] who are often managed clinically by treating the multiple comorbid conditions, in which patients are prescribed on an average of 9-10 oral and 2-3 parenteral medications^[35] on an average of 17-25 doses per day^[39]. Complex therapeutic regimen has a negative impact on QoL of HD patients^[41] and therefore needs frequent monitoring and dosage adjustments^[38]. High medication burden,^[39] poor compliance and drug interactions^[40] results in frequent medication related problems such as adverse drug events and inappropriate under- and overuse of drug therapy,^[39] medication dosing errors^[41]. Rational drug therapy in CKD patients is a difficult task^[47].

The prescription medications of CKD patients include those that alter the rate of progression of decline in kidney function, and those used to treat hypertension, lipid disorders, diabetes, anemia and osteodystrophy^[42]. Electronic medical records can be used as reminders for the prescribing physicians^[43]. In order to increase the effectiveness of prescribing patterns the following step-wise procedure is essential: 1) Have a detailed initial assessment 2) Evaluate the degree of renal impairment 3) Review the medication list 4) Choose the drug that has no or minimal nephrotoxicity 5) Select loading dose and a maintenance regimen 6) Monitor drug levels^[44]. The evidence on the prescribing trends in CKD patients from India is very limited^[45].

MATERIALS AND METHODS

Study design

This was a single-center, prospective observational study conducted at hemodialysis unit of Nephrology department in a multispeciality tertiary care teaching hospital. Between January 1, 2017 and June 30, 2017 all consecutive patients with the following criteria were recruited: (a) age ≥ 18 years of either gender at the time of hospitalization; (b) confirmed diagnosis of CKD; (c) on maintenance HD for atleast 3 months and more; (d) able to answer questions; (e) having provided written informed consent. The following criteria were excluded: (a) Patients with a history of kidney transplantation; (b) who are not willing to participate in the study; (c)

Pregnancy or lactating women. Patient medication lists and comorbidities were obtained from the patient's medical records. This protocol was approved by the Ethics Committee at our institution.

Data collection method: An approval of ethical clearance has been obtained from Institutional Ethical Committee prior to the initiation of study. Patients who were admitted in the department of medicine were screened based on the inclusion and exclusion criteria, subjects who met the inclusion criteria were enrolled for the study. Informed consent was obtained from the patient or attenders of patient. Follow up was done in the study. Details regarding the past medical history, medications, current therapy and the QOL by using questionnaires were obtained by patient interview and by observing case notes. Patient therapy was monitored by using patient data collection for medication history, present and discharge medication to obtain combination and single drug therapy to find out prescribing pattern and it was documented.

Assessment of health-related quality of life: According to study design, health related quality of life for CKD patients was measured by using SF-36 scale. The QOL was assessed for the first time and then follow up was done after 2 months.

Assessment of drug use patterns: Drug use patterns in CKD patients was assessed by reviewing the patient profile forms and drug chart. All the medications were classified according to the pharmacological and therapeutic use.

Statistical methods: Descriptive statistical analysis (frequencies, means, standard deviations and ranges) were used to describe the characteristics of the study population.

RESULTS

Drug use patterns: A total of 105 patients were enrolled in the study to assess the drug use patterns. Out of the 105 patients included in the study, 61.90% were males and 42.85% were females showing that males were dominant in the study. According to the age group in this study, the least number of patients undergoing dialysis were found to be within the age range of 16-25 years and the moderate and high number of patients undergoing dialysis were found to be within the age range of 46-55 and 56-65 years respectively.

Table-1: Age distribution.

AGE	NO. OF PATIENTS(n=105)	MALE	FEMALE
16-25	2	2	0
26-35	9	5	4
36-45	16	9	7
46-55	25	15	10
56-65	36	24	12
>65	17	11	6

As per hemodialysis duration, the patients with duration of dialysis <2 years were found to be 39.04%, and the patients with hemodialysis duration of 2-4 years and >4 years were found to be 45.71% and 15.23% respectively. The prevalence of co-morbidities includes the following hypertension (100%) followed by anemia (85.71%), diabetes mellitus(60%), CAD(33.33%), hyperlipidemia(26.66) and hypothyroidism (14.28%).

Drug use patterns in hemodialysis patients

Dialysis patients were prescribed several drugs for their co-morbidities like AntiHypertensives-105 (100%), Anticoagulants-105 (100%), Erythropoietin-105 (100%), Calcium preparations-85 (80.95%), Phosphate binders-78 (74.28%), Proton pump Inhibitors-75 (71.42%), Antiplatelets-48 (45.71%), Multivitamin Tablets-46 (43.80%) and Statins-35 (33.33%). Dialysis patients having diabetes mellitus were most commonly

prescribed with Oral-Hypoglycaemic Agents-45 (42.85%) compared to Insulin-18 (17.14%).

Drug use patterns of anti-hypertensives

Dialysis patients with hypertension were prescribed with Anti Hypertensives like calcium channel blockers-78 (74.28%), Beta blockers-65 (61.90%), Loop diuretics-55 (52.38%), Vasodilators-27 (25.71%), Alpha blockers-35 (33.33%), Angiotensin Receptor blockers-21 (20%) and Angiotensin converting enzyme Inhibitors-14 (13.33%).

Drug use patterns of combination drugs

In the present study, combination of drugs was also prescribed for the dialysis patients such as Calcium carbonate and Vitamin D - 70 (66.66%) being the most commonly prescribed combination followed by Metoprolol and Amlodipine - 41 (39.04%).

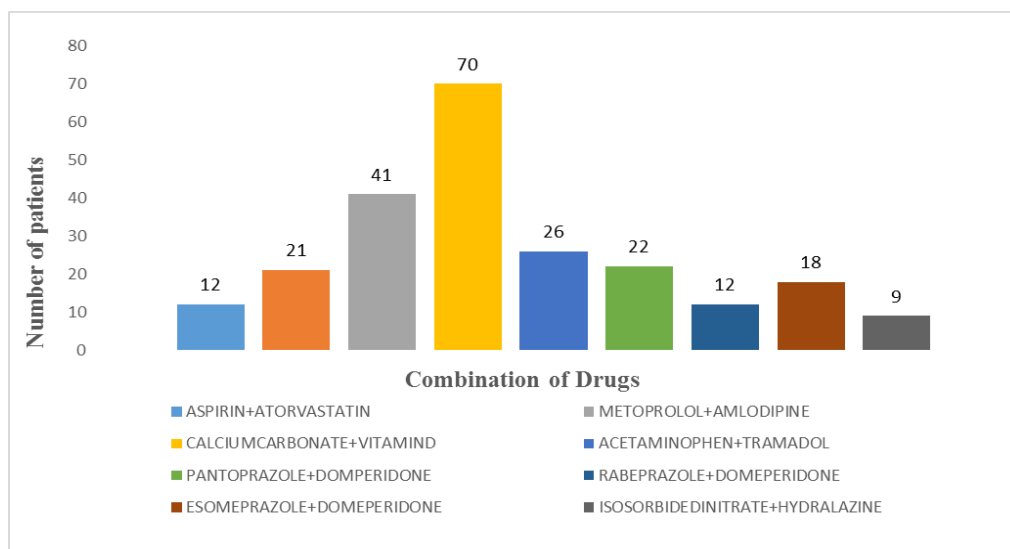


Fig. 1: Drug use patterns of combination drugs.

Quality of life

A total of 105 patients were included in the study. The patients were assessed for their QOL for 2 times for a time gap of 2 months by using SF-36 scale. The scores of the SF-36 domains which were assessed before and after

2 months were shown in table-3. The table-3 indicates that there was a slight improvement in the QOL domains particularly after 2 months after their initial assessment was done.

Table-2: Scores of the SF-36 domains before and after 2 months.

DOMAINS	BEFORE 2 MONTHS	AFTER 2 MONTHS
PHYSICAL FUNCTIONING	15.95±15.70	16.30±14.85
ROLE PHYSICAL	8.57±1.09	11.66±4.14
BODILY PAIN	9.84±2.74	26.03±9.05
GENERAL HEALTH	28.33±2.97	33.00±1.84
VITALITY	42.89±10.15	48.22±8.67
SOCIAL FUNCTIONING	42.57±11.85	46.30±11.95
ROLE EMOTIONAL	21.85±0.67	22.90±0.60
MENTAL HEALTH	12.19±19.83	13.66±19.90

Based on gender, males have higher QOL scores than females. Table-4 shows the QOL scores for before and after 2 months based on the gender. There was slight

improvement found for the latter assessment for both males and females.

Based on age, the QOL scores were assessed for patients with age ≤ 60 years and > 60 years. It was observed that the QOL scores for most of the domains were low for the patients with age > 60 years compared to those with ≤ 60 years. Table-5 shows the influence of age on QOL domains.

Based on hemodialysis duration, QOL scores were assessed for before and after 2 months for hemodialysis duration of ≤ 2 years and > 2 years. The QOL scores for duration of > 2 years were observed to be low when compared to those for ≤ 2 years. Table-6 shows the influence of hemodialysis duration on the QOL scores.

Table-3: Influence of gender, age and duration of dialysis on HRQoL.

DOMAINS	MALES		FEMALES		AGE ≤ 60 YEARS		AGE > 60 YEARS		DURATION ≤ 2 YEARS		DURATION > 2 YEARS	
	BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER
PHYSICAL FUNCTIONING	17.53±15.61	17.91±14.87	17.32±16.66	18.15±16.06	17.32±16.66	18.15±16.06	7.35±8.57	8.82±11.09	16.11±14.28	16.48±15.66	15.39±15.82	16.51±15.5
ROLE PHYSICAL	8.58±2.23	12.68±2.58	7.95±1.85	11.07±3.51	7.95±1.85	11.07±3.51	11.76±6.79	14.70±7.59	16.66±2.13	22.68±8.05	5.88±1.60	6.86±0.56
BODILY PAIN	9.95±0.86	29.85±10.44	9.09±2.27	28.78±9.11	9.09±2.27	28.78±9.11	11.76±10.18	13.72±8.98	19.13±5.34	30.24±11.31	5.88±1.95	21.56±7.06
GENERAL HEALTH	28.13±1.84	33.88±3.27	29.20±1.46	34.48±2.62	29.20±1.46	34.48±2.62	23.82±11.17	25.32±7.01	28.98±3.57	34.90±1.72	27.64±2.40	30.99±2.72
VITALITY	44.89±11.44	51.46±9.69	42.54±9.54	48.31±7.97	42.54±9.54	48.31±7.97	44.70±13.74	47.76±13.24	47.33±11.94	51.92±10.05	38.19±8.52	44.31±7.50
SOCIAL FUNCTIONING	40.44±11.39	44.77±12.13	42.69±11.12	46.44±11.45	42.69±11.12	46.44±11.45	41.91±15.59	45.58±14.55	43.98±12.43	49.07±12.43	41.07±11.23	43.38±11.43
ROLE EMOTIONAL	22.91±0.84	24.29±1.00	23.35±0.16	24.46±1.16	23.35±0.16	24.46±1.16	14.11±3.32	14.85±2.28	21.01±0.91	22.40±0.26	22.74±0.41	23.43±1.52
MENTAL HEALTH	12.46±19.92	14.17±20.18	12.15±19.59	13.86±19.68	12.15±19.59	13.86±19.68	12.35±21.35	12.64±21.30	12.68±20.36	14.25±20.23	11.66±19.26	13.03±19.56

DISCUSSION

Drug use patterns: The present study enrolled 60 males and 45 females to assess their drug use patterns. When compared to females, males were found to be more dominant in the study due to chronic co-morbid conditions like hypertension and diabetes mellitus. In this study, more number of patients underwent hemodialysis after fourth decade of their life due to chronic comorbid conditions. More number of patients were found to be participating in dialysis between a hemodialysis duration of 0-4 years. The worsening of condition was observed in patients with highest hemodialysis duration. Hypertension (100%) and diabetes mellitus (60%) were the most common co-morbid conditions observed in many patients.

Anemia (85.71%) was the commonly associated risk in hemodialysis due to bleeding at the time of dialysis session, insufficient production of erythropoietin hormone and imbalance of folic acid and iron supplements in our body.

Coronary artery disease (33.33%), hyperlipidemia (26.6%) and hypothyroidism (14.28%) were also observed in the study. Antihypertensives (100%) were most commonly prescribed drugs in order to treat the hypertension. Among Antihypertensives, calcium channel blockers (78%) and Betablockers (65%) were widely used. Amlodipine was mostly preferred in aged patients. Metoprolol was the best choice of drug due to its action on renin angiotensin activating system and sympathetic activity to decrease hypertension. Loop diuretics were used in high percentage due to their low mortality rates and their pharmacological action is shown to treat hypertension and edema conditions. Heparin (100%) was widely used for treating coagulation because of bleeding at the time of dialysis session.

Erythropoietin (100%) was also administered in all patients for every 15 days because the kidneys lose their function of producing erythropoietin hormone. Folic acid supplements and Iron preparations were together included in hematinics (85.71%) and they were prescribed mostly in anemic patients.

Phosphate binders (74.28%) was prescribed to treat hyperphosphatemia conditions among which calcium acetate and sevelamer were widely used in dialysis patients. Calcium acetate was highly used when compared to sevelamer because of its low cost and affordability.

Proton pump inhibitors (71.42%) were used to treat gastric problems that occur due to calcium preparations and common problems associated with dialysis. These drugs are of high cost and reduces the symptoms very fast.

Oral hypoglycemic agents (42.85%) and Insulin (17.14%) were used to treat diabetes mellitus. Insulin

was observed to be used at a very low percentage in the study because of the reason that kidney is the main site for the degradation of insulin.

Statins (33.33%) and antiplatelets (45.71%) were used to treat coronary artery disease. Multivitamins (43.80%) and Other drugs (52.38%) were prescribed for replacing vitamins and mineral supplements.

Combination of drugs were prescribed mostly due to more benefits such as low severity of adverse reactions and less doses were prescribed when given in combination.

Quality of life: The study findings showed that majority of the ESRD patients enrolled in the study were males and the present study revealed that the study sample undergoing hemodialysis had lower health related QOL scores for all the 8 domains for the first assessment compared to the second assessment. But there was no significant difference between the two assessments.

After the follow up, in both males and females, all the domain scores were found to be improved to some extent. In males, after follow up, the domain namely bodily pain was more improved followed by vitality, general health, role physical, social functioning, role emotional and mental health. In females, after follow up, bodily pain was more improved followed by general health, vitality, social functioning, mental health and physical functioning.

In patients with age ≤ 60 years, there was more improvement found in bodily pain after follow up followed by vitality, general health, role physical, social functioning, physical functioning, role emotional and mental health. In patients with age > 60 years, social functioning was more improved followed by vitality, role physical, bodily pain, general health and physical functioning. But this improvement was not found to be significant. The study revealed that as age of the patient increases their QOL scores decreases which was found to be consistent with the study conducted by Havva Tel.

Based on hemodialysis the QOL scores were observed to be more for patients with hemodialysis duration ≤ 2 years when compared to those with hemodialysis duration > 2 years.

Drug use pattern study concluded that

- Hemodialysis patients often have different co-morbid conditions due to which they were prescribed with a wide variety of drugs.
- The most commonly used categories of drugs for different co-morbidities include anti-hypertensives, anti-coagulants, hematinic, proton pump inhibitors.
- Among anti-hypertensives, calcium channel blockers and beta blockers are the most commonly used drugs.
- Among diabetic co-morbid patients, oral hypoglycemics were mostly preferred than insulin.

- Combinational drugs are mostly preferred due to decrease in the drug doses and less adverse effects. The QOL study concluded that:
- There was a slight improvement found in the QOL after follow up.
- Male QOL were high compared to those with females.
- Patients with age > 60 years have very low QOL.
- Patients with hemodialysis duration ≤ 2 years have better QOL compared to those with hemodialysis duration > 2 years.

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DISCLOSURES AND CONFLICT OF INTEREST STATEMENTS

The authors have no conflict of interests to disclose.

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