Assessment of Quality of Life and Drug Usage Among Haemodialysis Patients at A Tertiary Care Hospital

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ABSTRACT

Objectives: To analyse the prescribing trends in haemodialysis patients and to assess QOL in haemodialysis patients with reference to their physical, psychological, social and environmental health dimension. Material and Methods: After taking approval from the Institutional ethical committee, a cross-sectional study was conducted in patients undergoing haemodialysis at Dialysis centre of tertiary care teaching hospital, over a period of three months. Rationality of prescription was analysed by comparing with WHO core drug prescribing indicators. WHOQOL-BREF questionnaire was used to assess the different domains of quality of life of haemodialysis patients. Data was analysed using statistical methods such as Kolmogorov-Smirnov (KS) test, unpaired t-test and Analysis of Variance, Pearson correlation coefficient, SPSS version 18 and 20. Results: A total of 84 cases were analysed during the study, of which 65 were males and 19 were females with a 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 4.73, percentage of drugs prescribed by generic name was 39.62%, percentage of patients with an injection prescribed was 100%, percentage of drugs prescribed from essential medicine list was 41.5% and none of the patient was prescribed with antibiotic. Anticoagulant agent (100%) was the most commonly used drug, followed by antihypertensive drugs (94%), ulcer protective, calcium salt, multivitamins, erythropoietin, insulin, antiplatelet, oral hypoglycaemics and statins. Patients on haemodialysis had a poorer QOL in all domains except for domain 4 (environment). Domain 1 was highly correlated with domain 2 and moderately correlated with domain 3 and 4 with significant P value at 0.01. Conclusion: 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.

Key words: Chronic Kidney Disease, Drug Utilization Studies, Hemodialysis, WHO core prescribing indicators, WHOQOL-BREF

INTRODUCTION

Drug utilization studies are conducted frequently all over the world. In developing countries with the constraint of health budget for drugs, it becomes even more meaningful to prescribe drugs rationally. These studies can thus help to set priorities for the rational allocation of health care budgets and can ascertain the role of drugs in society.¹¹
In 1985, World Health Organization (WHO) defined that rational use of drugs requires that patients receive medication appropriate to their clinical needs, in doses that meet their own individual requirement for an adequate period of time and at the lowest cost to them and their community.[3]

Drug utilization study is defined as “the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences” and has the principal aim of facilitating the rational use of drugs. Irrational use of drugs may lead to ineffective & unsafe treatment, exacerbation or prolongation of illness, distress & harm to patient, increase in the cost of treatment.[3]

These studies can increase our understanding of how drugs are being used. It helps to estimate the numbers of patients exposed to specified drugs within a given time period, describe the extent of drug use at a certain moment and/or in a certain area, estimate to what extent drugs are properly used, over used or under used.[4]

Chronic kidney disease (CKD) is defined as the presence of kidney damage or a reduction in the glomerular filtration rate (GFR) for three months or longer. The degree of renal insufficiency and the severity of kidney disease are generally reflected in the decline of GFR. Many diseases can lead to CKD such as diabetes and hypertension which account for the majority of cases.[5]

As per recent Indian Council of Medical Research data, prevalence of diabetes in Indian adult population has risen to 7.1% and in urban population (over the age of 40 years) the prevalence is as high as 28%. Likewise the reported prevalence of hypertension in the adult population today is 17% (14.8% from rural and 21.4% from urban belt). With rising prevalence of these diseases in India, prevalence of chronic kidney disease (CKD) is expected to rise, and obviously this is the key target population to address.[4]

Haemodialysis (HD) is the most preferred treatment modality for end stage renal disease (ESRD) in India. Haemodialysis improves serum creatinine, albumin and prealbumin, normalises the protein catabolic rate (n PCR) as well as increases the dietary intake of patients.[7]

ESRD patients who are on haemodialysis have complex drug regimens and receive nearly 10 to 12 medications daily, many of which requires multiple doses per day.[8] Due to reduction in glomerular filtration rate (GFR), the elimination rate of medications or their metabolites is decreased which in turn causes accumulation of drug if prescribed in the normal, standard dosage, which may lead to exaggerated pharmacologic effects or adverse drug reactions.[9] Therefore, dosage may need to be modified to achieve the target therapeutic range.[10]

Apart from its advantages, HD also has disadvantages like malnutrition and lower quality of life (QOL). It is reported that, among HD patients approximately 4.6% - 19% patients are suffering from severe malnutrition and 72% - 90.9% are mildly malnourished.[11-13]

Quality of life is an important indicator of health and well-being.[10] In patients who are on haemodialysis, health-related QOL is usually poorer than that in the age-matched general population, because of the typically high burden of comorbidity and complications of ESRD.[14]

The World Health Organisation (WHO) defines 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”.[15]

Quality of life is a difficult variable to define. Two basic characteristics can be distinguished in the concept of QOL: subjectivity and multidimensionality. Subjectivity should be distinguished because the QOL is a unique perception for each individual, which reflects the patient’s self-assessment about their own health, defined by medical and nonmedical aspects of their lives.[16,17]

An abbreviated 26-item version of WHOQOL-BREF has been used in numerous studies to evaluate perceptions of health. This questionnaire, developed using data from 30 inter- national field centres, has been found to be an effective cross- cultural assessment of QOL with good to excellent psychometric properties of reliability and validity. [18] The same questionnaire method is used to assess the QOL in our institutional dialysis centre.

The main objective of the study was to assess QOL in haemodialysis patients with reference to their physical, psychological, social and environmental health dimension, and to analyse the prescribing trends in haemodialysis patients.

**MATERIALS AND METHODS**

This was a cross-sectional study conducted in patients undergoing haemodialysis at Dialysis centre of tertiary
care teaching hospital, over a period of three months. Institutional ethics committee approval was obtained, written informed consent was taken from the patients.

**Inclusion criteria**

- Patients between age group of 18-70 years of either sex and on maintenance haemodialysis for more than 3 months.

**Exclusion criteria**

- Patients with recent history of hospitalisation for co-morbid illness and impaired sensory or motor functions that may affect scheduled assessment was excluded.
- Illiterate patients, who have major hearing impairment (inability to hear loud speech even with a hearing aid) and who is not able to speak.
- Patient not consenting for the study.

Haemodialysis subjects satisfying the study criteria were recruited in the study. Demographic data of patient along with drug data was collected. Data was collected from each subject and documented in suitably designed proforma.

Rationality of prescription was analysed by comparing with following WHO core drug prescribing indicators: average number of drugs per encounter, percentage of drugs prescribed by generic name, percentage of encounters with an antibiotic prescribed, percentage of encounters with an injection prescribed, percentage of drugs prescribed from essential drugs list or formulary.

WHOQOL-BREF questionnaire which was translated to regional language of Kannada was used to assess the different domains of quality of life of haemodialysis patients. This questionnaire contains 26 questions which were mainly based on noise annoyance, health effects, sleep quality, perceived stress, life- style behaviours and prevalent chronic disease.[9]

It generates a profile and score for each of the four QOL domains; The Physical Health domain, Psychological domain, Social relationships domain, Environment domain. Questions are centred on the meaning respondents attribute to each aspect of life and how problematic or satisfactory they perceive them to be.

Physical domain mainly measures the activities of daily living, energy, pain and discomfort, sleep and work capacity. Body image and appearance, negative and positive feelings, self-activities, spirituality, thinking and concentration were assessed in the psychological domain. Social domain included personal relationship, social support and sexual activity. Financial resources, health and social care, home environment and participation in leisure activities were covered in the environmental domain.

**Data Analysis**

Descriptive statistics SPSS (version 18) was used to analyse the drug usage in hemodialysis patients. WHO core drug prescribing indicators like average number of drugs per encounter, percentage of drugs prescribed by generic name, percentage of encounters with an antibiotic prescribed, percentage of encounters with an injection prescribed, percentage of drugs prescribed from essential drugs list or formulary were assessed.

Data entry and analyses were done using the Statistical Package for Social Sciences (SPSS) for Windows software (version 20.0; SPSS Inc, Chicago). Descriptive statistics such as mean and standard deviation (SD) for continuous variables, and frequency and percentage for categorical variables were determined. Raw Scores and transformed Scores were calculated for all four domains using WHO Manual. Normality of data was first checked by using Kolmogorov Smirnov (KS) test. Unpaired t Test and ANOVA (Analysis of Variance) respectively were used to show the associations between predictor and outcome variables for two categories and more than two categories. Pearson correlation coefficient was calculated between all four domains. The level of significance was set at 0.05.

**RESULTS**

Total number of patients diagnosed as CKD undergoing dialysis during the study period was 84, of which 65 were males and 19 were females with their mean age of 53.89 ± 13.34 years and 39.05 ± 8.45 years respectively. 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 (84%) followed by diabetes mellitus (34.5%) and nephropathy (3.5%). Other causes like haemorrhagic dengue fever in two patients and polycystic kidney disease in one patient was seen.(Figure 1)

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%), ulcer protective (specially proton pump inhibitors), calcium salt, multivitamins, erythropoietin, insulin, antiplatelet, oral hypoglycaemics and statins were used.

The average number of drugs prescribed per patient was 4.73.

Among antihypertensive agents, calcium channel blockers (80.9%) were the most predominantly used drugs followed by beta blockers (26.1%), alpha blockers (25%), central sympatholytic (22.6%), ACE (Angiotensin Converting Enzyme) inhibitors (3.5%) and beta and alpha blocker (2.3%). (Figure 3)

An injection was prescribed in all the 84 patients as an injectable anticoagulant agent or in the form of IV fluids. Thus the percentage of patients with an injection prescribed was 100% in our study. None of the patient was prescribed with antibacterial agents. In our study we found that out of 53 different drugs, 21 drugs were prescribed by generic name (39.62%) and remaining 32 drugs were prescribed by brand name (60.37%).

Out of 53 different drugs prescribed, 22(41.5%) were from the Essential Medicines WHO Model List (2015) and 31 (58.4%) were from Non-Essential Medicines WHO Model List.

Distribution of patients according to QOL is shown in Table 1. 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.

In the current study, we found that the patient age of more than 60 years had lower transformed score of Physical health (20.6), Psychological (29.8), social (42) and Environmental (40) domains when compared to patients who are age group of less than 40 years and between 40-60 years. But the significance difference in the P-value was not seen. We also found that female patients had better QOL score in physical (29.4) domain than male patients (20.7) with significant P-value 0.007. Similarly the score of psychological, social and environmental domains in female patients (41.1, 48.2, and 46.3 respectively) had better score than the male patients (30.5, 42.4, and 42.8 respectively) with significant P values (0.016, 0.462, and 0.027 respectively).

Table 3 shows Pearson Correlation Coefficient between various domains of QOL scores. Domain 1 is highly correlated with domain 2 and moderately correlated with domain 3 and 4 with significant P value at 0.01.

**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 fails to clean the blood, excess fluid, minerals, and harmful wastes build up in the body, which may result in raise in blood pressure, oedema and decrease in erythropoesis.

The two main causes of chronic kidney disease are diabetes mellitus and hypertension, which are responsible for up to two-thirds of the cases.

In our study, more males (77.3%) were undergoing haemodialysis than female (22.6%). This finding was similar to study done by Tamil selvan et al, where 62.85 % were male subjects.

The reason behind the male predominance is non-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. The mean age of male and female was 53.8 and 39 y respectively; this finding was similar to findings of study carried out by Tamil selvan et al (53.26 ±15.69 years).

In study done by Bajait CS et al, 55% were hypertensive and 31% were diabetic patients, which was lower than our study where it was 84 % (hypertension) and 34.5% (diabetes mellitus).

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. The Average number of drugs utilized was 4.73 which was lower to the study done by Santra et al.
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**Figure 1:** Co-morbid conditions associated with renal failure (n=84).

**Figure 2:** Categories of drugs used.

**Figure 3:** Percentage of Antihypertensive drugs used.
Among all the prescribed drugs, antihypertensive agents were the most predominantly used drugs. Followed by ulcer protective drugs which were used in 63% of the patients to prevent stress ulcers and for the symptomatic relief of dyspepsia. Haematinics were extensively used along with other multivitamin supplements (36.9%) including calcium (44%). The diabetic patients were managed with insulin (16.9%) and oral hypoglycaemic agents (15.5%) like metformin, gliclazide and glimepiride. Statins and antiplatelet drugs were used in 9.5% and 16.7% of patients respectively to maintain the normal lipid profile of the patient. Haematopoetic agents like erythropoietin was used only in 17.8% of the patients because most of the patient could not afford it.

Among the anti-hypertensives, most commonly prescribed drug were calcium channel blockers (80.9%) like amlodipine, nifedipine and clindipine followed by β blockers (26.1%) which included atenolol and metaprolol and α blocker (25%) like prazosin. Centrally acting drugs (22.6%) like clonidine, ACE inhibitors (3.2%) like enalapril and alpha + beta blocker (2.3%) were also used. A similar antihypertensive prescription was found in study done by Bhanu Priya B et al.[25]

In the present study, we found that 60.3% of the drugs were prescribed by brand name and remaining 39.6% of the drugs were prescribed by generic name which was quite low when compared to the study done by Ahlawat R et al.[26] Non availability of generics in hospital pharmacy and physician trust in the quality of branded medicine might be the reasons for high number of drug prescribed by brand name in present study. Drug prescribed from the Essential medicine list in present study was found to be 41.5% which was much lower to the study carried out by Ahlawat R et al (81%).[26]

The cost and pain associated with parenteral drugs is likely to reduce adherence. However, there are certain medicines like insulin, heparin and erythropoietin that are available only as parenteral form. The number of drugs prescribed as parenteral dosage form was found to be 7.5% of the total number of medicines which was similar to the study done by Ahlawat R et al (11%).[26] This might be due to smaller number of diabetic patients on insulin therapy in the present study.

The Physical, Psychological, Social and Environmental domains of QOL score were found to be 13.29, 13.96, 8.23, and 21.56 respectively.

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Table 1: Distribution of patients according to QOL Raw Scores (N = 84)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mean</th>
<th>SD</th>
<th>SEM</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (Physical)</td>
<td>13.29</td>
<td>3.50</td>
<td>0.38</td>
<td>7</td>
<td>23</td>
</tr>
<tr>
<td>II (Psychological)</td>
<td>13.96</td>
<td>3.96</td>
<td>0.43</td>
<td>6</td>
<td>22</td>
</tr>
<tr>
<td>III (Social)</td>
<td>8.23</td>
<td>2.17</td>
<td>0.23</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>IV (Environmental)</td>
<td>21.56</td>
<td>3.16</td>
<td>0.34</td>
<td>14</td>
<td>31</td>
</tr>
</tbody>
</table>

Table 2: Distribution of patients according to QOL Transformed Scores (N = 84)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mean</th>
<th>SD</th>
<th>SEM</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (Physical)</td>
<td>22.74</td>
<td>12.53</td>
<td>1.36</td>
<td>0</td>
<td>56</td>
</tr>
<tr>
<td>II (Psychological)</td>
<td>32.93</td>
<td>16.91</td>
<td>1.84</td>
<td>0</td>
<td>69</td>
</tr>
<tr>
<td>III (Social)</td>
<td>43.68</td>
<td>17.98</td>
<td>1.96</td>
<td>0</td>
<td>81</td>
</tr>
<tr>
<td>IV (Environmental)</td>
<td>43.77</td>
<td>9.99</td>
<td>1.09</td>
<td>19</td>
<td>75</td>
</tr>
</tbody>
</table>

Table 3: Correlation between various Domains of QOL Raw Scores (N = 84)

<table>
<thead>
<tr>
<th>Domain 1</th>
<th>Domain 2</th>
<th>Domain 3</th>
<th>Domain 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain 1</td>
<td>-</td>
<td>0.814</td>
<td>0.496</td>
</tr>
<tr>
<td>Domain 2</td>
<td>0.814</td>
<td>-</td>
<td>0.506</td>
</tr>
<tr>
<td>Domain 3</td>
<td>0.496</td>
<td>0.506</td>
<td>-</td>
</tr>
<tr>
<td>Domain 4</td>
<td>0.454</td>
<td>0.419</td>
<td>0.344</td>
</tr>
</tbody>
</table>

Correlation is significant at the 0.01 level
8.23 and 21.56 respectively. The scores were low when compared to findings of study carried out by Sathvik BS et al.[1] 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 generalised 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 M et al.[27]

In the current study, it was found that physical domain is strongly associated with psychological domain and moderately associated with social and environmental domain which was different from the study done by Abraham S et al, in which they found that there was a positive relationship between socioeconomic status and QOL domains, especially physical, psychological and environmental domains of haemodialysis patients with different socioeconomic status.[28]

Early detection of renal disorders and the adoption of multifactorial interventions targeting the main risk factors like hypertension, hyperglycaemia may delay the progression of renal disease besides reducing the cardiovascular morbidity and mortality.

Combination therapy of drugs was prescribed because of multifactorial aetiology and pathogenesis of the disease. Improving the QoL of haemodialysis patients is as important as increasing the length of their lives. For this reason patients need to be considered together with their families in a family-centered approach, and regular individual or group education needs to be given to them about maintaining QOL and sleep quality.[29]

Further, large scale studies carried out at other tertiary care centres would help to compare, analyse and rationalize prescribing trends in chronic renal failure, giving a broader perspective to these findings.

REFERENCES


