A Study on Drug Utilization Evaluation and Health-Related Quality of Life in Hemodialysis Patients

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ABSTRACT

Introduction: Hemodialysis patients have specific medical needs and challenges due to their renal failure and the need for regular dialysis treatment. These patients often experience significant physical, emotional, and social burdens associated with their condition. Studying this population can provide useful insights on the impact of drug use and its effects on their quality of life. Researchers can identify opportunities to optimise prescription regimens, eliminate side effects, and improve overall well-being by analysing the impact of drug use on their guality of life. Materials and Methods: Over the six-month period from May 2022 to October 2022, we conducted an observational and cross-sectional study on 100 patients who were admitted to the hemodialysis unit of a tertiary care teaching hospital. A well-designed data collecting form was used in conjunction with the KDQoL-36 questionnaire to record all the necessary information. Results: In a study involving 100 hemodialysis patients, it was found that 96% had co-morbidities. A total of 761 medications were prescribed, with 22.87% for female patients and 77.13% for male patients. Adverse drug reactions were observed in 52% of cases, with hyponatremia, hypokalemia, and hypoglycemia being the most common. Patients generally had an average quality of life, but some experienced below-average quality. There was a significant difference between men and women in the Physical Health component. Dry mouth and anorexia were prevalent, and adherence to food and drink limits was challenging. Cramping occurred in 62% of patients after dialysis. Patients scored worse in the physical component compared to the mental component. Conclusion: This study recognized the diversity of medications in hemodialysis patients. In conclusion, this study found that hemodialysis patients had a significant prevalence of co-morbidities, with the majority having an average quality of life. Adverse medication reactions were widespread, including hyponatraemia and hypokalaemia. Gender disparities in the physical health component were discovered. The findings of this study urge the hemodialysis unit's practioners to create educational initiatives to raise standard of living.

Keywords: Prescribing pattern, Health-related quality of life, Hemodialysis, Drug Utilization Evaluation.

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INTRODUCTION

End-stage renal disease is defined by a Glomerular Filtration Rate (GFR) of fewer than 15 mL/min. Renal replacement therapy, also known as hemodialysis, supplements the kidney's function of purifying the blood by utilizing artificial machinery to remove excess water, solutes, and toxins. Dialysis is used to maintain homeostasis (a stable internal environment) in both Acute Kidney Injury (AKI), which causes a sudden loss of kidney function, and Chronic Kidney Disease (CKD), which causes a long, constant loss of kidney function.



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Diabetes mellitus, hypertension, glomerular disease, tubulointerstitial disease, urinary tract obstruction or dysfunction, and some medications, including Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), calcineurin inhibitors, and antiretroviral, can all cause End-Stage Renal Disease (ESRD). Comorbid conditions such as hypertension, cardiovascular disease, anaemia, mineral and bone disorders, nutrition and electrolyte, and gastrointestinal problems are usually connected with chronic kidney disease. Hemodialysis has been demonstrated to have a negative psychological impact on end-stage renal disease patients. Some of the most common psychological issues are an increased risk of suicide, sadness, anxiety, exhaustion, and a decline in quality of life.1

Patients undergoing dialysis for End-Stage Kidney Disease (ESKD) are prone to polypharmacy. Polypharmacy in this population reflects the high prevalence of comorbidities as well as the many side effects of renal failure and dialysis treatment.

According to previous research, these individuals use at least 8 to 12 various medications on a daily basis. In dialysis patients, negative drug interactions and side effects are more likely. Cardiovascular medications, anti-diabetic, anti-hypertensive, gastro-intestinal pharmaceuticals, vitamins and minerals, blood and blood-forming agents, and other types of pharmaceuticals may be recommended to patients.

Health-related quality of life, or HRQoL, is the perceived physical and mental health of an individual or a community over time. It is more important than ever to evaluate the Quality of Life (QoL) of people with end-stage renal disease in order to gauge how the disease affects individuals. Past research has indicated that hemodialysis patients typically face mental health concerns as a result of their medical diseases, which may impair QoL. The fact that hemodialysis patients had lower QoL scores in the environmental domain may be due to expensive medical care, primarily drugs, transportation challenges during follow-up appointments, and safety-related concerns.² A higher QoL influences both a longer lifespan and a better response to therapy.³

We wish to evaluate the prescribing trends and health-related quality of life in hemodialysis patients.

MATERIALS AND METHODS

A single-center cross-sectional observational study was conducted at a tertiary care teaching hospital's hemodialysis unit from May 2022 to October 2022. The institutional ethics committee (Reference number: FMIEC/CCM/252/2022) authorised prior approval. Participants in the study ranged in age from 18 to 80, had been on dialysis for at least 4 months, and had agreed to sign an informed consent form. Pregnant and lactating women, patients on dialysis for substance poisoning, and people with cancer as a comorbidity were all excluded from the study.

We calculated our sample size using the danial ($n \ge [Z\alpha^2 p(1-p)]/d^2$) (Z α =1.96 at 5% level of significance, p= 21.03% (from reference study),⁴ d= margin of error at 10%) sample size formula. We began with a sample size of 256. However, because the study is being conducted in a single location, each patient having a dialysis schedule of twice or three times per week, and a few patients not satisfying the inclusion criteria, we were limited to a sample size of 100 (at 8% margin of error). Patients' socio-demographic information, such as age, gender, education level, and marital status, was gathered. A well-designed data collecting form was used to record comorbid disorders, test findings, and medications.

The Kidney Disease Quality of Life-36 (KDQoL-36) questionnaire was used to assess health-related quality of life. KDQOL-36 includes Physical Component Summary (PCS), Mental Health Component Summary (MCS), Kidney Disease Burden (BKD), Kidney Disease Symptoms and Problems (SPKD), and Kidney Disease Impact (EKD). The latter three subscales evaluate issues particular to patients with ESRD while the first two subscales measure HRQoL generally. All elements on each kidney-focused KDQoL-36 scale are linearly transformed to a possible range of 0-100 before being averaged to determine the scale's score. Higher KDQoL-36 scores correspond to better HRQoL. The differences and correlations between various parameters were evaluated using the Fischer's exact test and the Pearson's correlation test.

RESULTS

The socio-demographic information of 100 hemodialysis patients was collected from the hemodialysis ward, and the results are as follows. (Table 1). Of the total 100 patients in the study 96 patients (96%) had comorbidities. The details of the comorbidities are summarized in Chart 1.

A total of 761 medicines were prescribed for the study's hemodialysis patients, with 175 (22.87%) of those prescriptions going to female patients and 586 (77.13%) going to male patients. Chart 2 provides a summary of the recommended medication information.

52 cases (52%) of adverse drug reactions were observed, with hyponatraemia (33%) and hypokalemia (21%) being the most common, followed by hypoglycemia (12%).

Patients who completed the survey were classified into three groups based on Mean SD (standard deviation) values from each of the five areas of the KDQL-36 questionnaire: above average, average, and below average. The majority of patients reported an average quality of life, whereas a small fraction had a below-average quality of life. We identified a significant difference between men and women in the Physical Health component category using Fisher's exact test (p = 0.036 at the 0.05 level of significance). Furthermore, using the same test, there was no discernible difference between male and female patients from different areas (p > 0.05) of the questionnaire.

According to our findings, 80% of patients have dry mouth, 70% have anorexia, and some have difficulty adhering to food and drink limits. After a dialysis session, 62% of patients experienced cramping. In our study, dialysis patients scored much worse on the physical component than on the mental component, with a statistically significant difference between the two (*p*-value 0.001 at the 0.05 level) (Chart 3).

Chart 4 depicts the association between QoL and drug usage, whereas Chart 5 depicts the relationship between QoL and the number of hemodialysis sessions.

DISCUSSION

A compelling aspect of our study was the observation that nearly all (96%) of our hemodialysis patients had additional co morbidities beyond kidney disease. The presence of such extensive comorbidity underscores how multi-dimensional their healthcare needs are. Additionally, it heightens awareness about potential drug interactions and other unforeseen complications that clinicians need to consider when devising treatment plans. To provide optimal care for patients with such diverse diagnoses would require a careful consideration by providers as they navigate intricate clinical scenarios regarding medication use and overall management plans.

Erythropoietin Stimulating Agents (87.07%) constituted majority of the hematopoietic agents prescribed unlike the results of the study conducted by Chakraborty *et al.*⁴ Erythropoietin production is reduced in hemodialysis patients, who frequently have compromised kidney function, resulting in anemia.

Table '	1:	Socio-demographi	c distribution o	f the	patients.
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Characteristics	Number of Patients
Sex	
Male	76
Female	24
Age Distribution	
18-30	7
30-60	57
>60	36
Married Status	
Married	88
Unmarried	12
Level of Education	
Degree	38
High School	41
< High School	21

Erythropoietin drugs enhance red blood cell formation by mimicking the activity of natural erythropoietin.

All of the GI medications provided were alkalinizing agents, H2 receptor antagonists, and proton pump inhibitors. Hemodialysis patients are prone to gastrointestinal problems such as Gastroesophageal Reflux Disease (GERD), peptic ulcers, gastritis, constipation, and gastrointestinal bleeding. Uremia, dietary restrictions, or drug adverse effects can cause these diseases. Several aspects must be considered while providing GI medicines for hemodialysis patients. Renal function is important because poor kidney function might alter drug pharmacokinetics and clearance.

Some GI drugs must be dosed differently or are not appropriate for use in patients with renal impairment. As a result, choosing GI medicines that are predominantly removed via non-renal routes or that have clear dose guidelines for renal impairment is critical. Antacids, such as aluminium hydroxide or calcium







Chart 2: Percentage distribution of drugs prescribed.



Chart 3: Relationship between the elements of physical and mental health.



Chart 4: Relationship between Drug Use and Quality of life.

carbonate, can be used to relieve symptoms temporarily. For long-term therapy of acid-related illnesses, acid suppressants such as histamine-2 receptor antagonists (H2 blockers) or Proton Pump Inhibitors (PPIs) can be administered.

Due to a variety of causes, hemodialysis patients are at an elevated risk of developing vitamin deficiencies. First, there are dietary restrictions. Secondly, the dialysis treatment itself can result in the loss of water-soluble vitamins during the ultrafiltration process. Finally, impaired renal function can alter vitamin metabolism and excretion. By inhibiting RAAS, vitamin D treatment may reduce proteinuria. The balance of calcium and phosphorus levels is another benefit of Vitamin D. Vitamin supplementation for hemodialysis patients should be tailored to their individual needs, nutritional state, and laboratory results. Regular monitoring of vitamin levels via blood tests is essential for guiding proper supplementation.



Chart 5: Correlation between Quality of life and Hemodialysis session.

Despite being on the expensive side, Sevelamer, a non-calcium phosphate binder, outperformed all of the Phosphate Binders (PB) recommended. This finding contrasts with the findings of other research, when calcium carbonate was found to be the Phosphate Binder that was most frequently recommended, followed by calcium acetate and sevelamer.⁴ Utilizing Sevelamer provides benefits all on its own. Compared to calcium-based PB, it is associated with less cardiovascular calcification because to its non-absorbable and calcium-free nature. According to a recent meta-analysis, calcium-free PBs reduce all-cause mortality in CKD patients by 46% compared to calcium-based PBs.⁵

Only 29 of the 50 diabetes patients received anti-diabetic medicine prescriptions. These data lend support to the idea that CKD reduces the demand for insulin, resulting in a decrease in the prescription of anti-diabetic drugs. Our findings differ from earlier trials in which insulin was the sole anti-diabetic medication utilized and no oral anti-diabetic medications were used at all.⁴ Oral anti-diabetic medicines have a history of inducing hypoglycemia and metabolic acidosis in CKD patients.

Careful medication and dose selection is required for antibiotics because the majority of them are nephrotoxic and are removed through the kidneys. Our findings also go counter to those of another study, whose findings showed that antibiotics were prescribed in about 82.05% of cases despite there being no obvious need for doing so.⁴

The observation of adverse drug reactions in 52% of the patients emphasizes the need for vigilant monitoring and management of medication-related risks in hemodialysis patients. These findings highlight the importance of closely monitoring electrolyte and glucose levels during drug therapy, particularly in this vulnerable population with compromised renal function. Only a small number of research have been done on dialysis patients, although several have used the KDQOL-36 to evaluate HRQOL in individuals with chronic renal disease. The study evaluated the quality of life of hemodialysis patients using a questionnaire. The majority of patients reported an average quality of life, indicating that they were able to maintain a reasonable level of functioning and well-being despite their health challenges. However, a small fraction of patients reported below-average quality of life, suggesting the need for targeted interventions and support for these individuals.

Fisher's exact test revealed a significant difference between men and women in the Physical Health component category. This finding suggests that there may be gender-specific variations in the physical well-being of hemodialysis patients. Further research is warranted to explore potential factors contributing to this difference, such as variations in disease progression, treatment response, or social and cultural factors. The study participants scored significantly lower on the physical component than on the mental component. In other words, despite the worsening physical health status, the mental health of dialysis patients is somewhat preserved. Male patients had greater physical health than female patients. The results of this study also suggest that quality of life is generally connected to age. The fact that older patients frequently experience physical and mental impairments or have lower expectations than younger patients is a probable explanation.

The study identified several common symptoms and challenges faced by hemodialysis patients. Dry mouth and anorexia were prevalent among the majority of patients, highlighting the potential impact of renal failure and its treatment on oral health and appetite. Additionally, adherence to dietary restrictions appeared to be a challenge for some patients, indicating the importance of patient education and support in promoting adherence to prescribed food and drink limits. Moreover, post-dialysis cramping was experienced by 62% of patients, emphasizing the need for effective management strategies to alleviate this discomfort.

Age and length of dialysis were found to be associated to quality of life in our study, while male gender was revealed to be a negative predictor. In contrast to past findings, we did not detect a significant link between education level and quality of life. Furthermore, our study found that individuals getting 4-5 medications had a higher quality of life than those using 10-12 medications, implying that there is a point beyond which an excessive medication regimen may negatively affect quality of life.

CONCLUSION

In conclusion, our study sheds light on the critical issues of adverse drug reactions and polypharmacy among hemodialysis patients, underscoring the need for improved pharmaceutical management in this population. By gaining a comprehensive understanding of the factors influencing their quality of life, healthcare practitioners can develop targeted interventions that address individual needs more effectively. These findings provide valuable insights into drug utilization patterns, adverse reactions, and quality of life, empowering healthcare providers to optimize medication regimens, implement gender-specific considerations, enhance symptom management, and adopt holistic approaches that prioritize the overall well-being and quality of life for hemodialysis patients.

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DECLARATION OF PATIENT CONSENT

Before starting the study, approval from the Institutional Review Board was sought.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

GFR: Glomerular Filtration Rate; AKI: Acute Kidney Injury; CKD: Chronic Kidney Disease; NSAIDs: No Steroidal Anti-Inflammatory Drugs; ESKD: End Stag Kidney Disease; HRQoL: Health-Related Quality of Life; KDQoL-36: Kidney Disease Quality of Life; RAAS: Renin Angiotensin Aldosterone System.

SUMMARY

Hemodialysis patients, facing unique medical challenges due to renal failure and regular dialysis, endure physical, emotional, and social burdens. Investigating their drug use's impact on quality of life offers insights for optimizing prescriptions, curbing side effects, and enhancing well-being. A six-month study on 100 patients revealed 96% with co-morbidities, 761 prescribed medications (22.87% for females, 77.13% for males), and 52% experiencing adverse drug reactions. Despite an average quality of life, gender disparities and challenges in adherence were noted. The study underscores medication diversity, prevalent co-morbidities, adverse reactions, and gender disparities, emphasizing the need for enhanced patient education.

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