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(RESEARCH ARTICLE)

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To monitor the quality of life and degree of improvement in the stages of chronic kidney disease patients

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Abstract

Chronic kidney disease (CKD) is a global burden on healthcare systems and is recognized as a major threat to population which resulted in reduced quality of life. The key objectives of the research were to evaluate the compliance of prescribing medication patterns with standard treatment guidelines and to utilize standard questionnaires for the assessment of the quality of life. This study demonstrates that with disease progression, quality of life gets deteriorated in advanced stages. The questionnaire used in this study results that the majority of the patients were from stable economic backgrounds following renal diet plans and taking medications on time. Since the treatment course was as per the standard treatment guidelines, which showed a significant impact on the quality of life of patients with chronic renal disease.

Keywords: CKD; Quality of life; Prescribing patterns; Grades of CKD

1. Introduction

Chronic kidney disease (CKD) is defined as the presence of renal impairment or an estimated glomerular filtration rate (eGFR) usually less than 90mL/min from 3 months, regardless of cause.

It is a progressive loss of kidney function that eventually requires renal replacement therapy (dialysis or transplantation). Renal injury refers to pathological abnormalities suggested by either imaging studies or renal biopsy, abnormal urinary sediment, or increased urinary albumin excretion. In 2023, the detailed causes of CKD based on glomerular filtration rate were divided into six categories (G1 to G5, G3 divided into 3a and 3b).

Chronic kidney disease is responsible for inadequate health outcomes, low quality of life (QOL), and excessive health care costs. The increased prevalence of CKD is being acknowledged as a hazard to public health on a global scale. According to statistics, 8.9% of the world's population has CKD in stages 1-3, with prevalence rates being greater in low-income countries like Bangladesh (21.33%) and India (15.6%). The initial stage of chronic kidney disease is generally asymptomatic, and diagnosis is usually made through serum creatinine and albumin-to-creatinine ratio tests. If left undetected and untreated, it can proceed to end-stage renal disease, which requires expensive renal replacement therapy such as dialysis or kidney transplantation to save the patient's life.

Most CKD patients are reported to originate from middle-aged and elderly populations. Most CKD cases are diagnosed with other chronic non-communicable diseases such as hypertension and diabetes's impact several aspects, including, a decrease in individual quality of life, family income, and contribution to social and national development. Patients with

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chronic renal failure and especially end-stage renal disease (ESRD) are at increased risk of mortality, particularly from cardiovascular disease and diabetes.

The actual burden of ESKD (End-stage kidney disease) in India is not known, with few dedicated centres for care, lack of universal access to RRT (Renal replacement therapy), and absence of a registry. Even today, over 90% of patients requiring RRT in India die because of the inability to afford care, and even in those who do start RRT, 60% stop for financial reasons. Haemodialysis is the most common modality followed by transplantation, and PD (Peritoneal Dialysis) is a distant third.

1.1. Stages of CKD

The six categories of chronic kidney disease include:

- **STAGE1**: Mild kidney damage when eGFR is 90 ml/min and above
- **STAGE 2**: Mild loss of kidney function when eGFR ranges from 60 to 89 ml/min
- **STAGE 3a**: Mild to a severe loss of kidney function when eGFR ranges between 45 to 59 ml/min
- **STAGE 3b**: Moderate loss of kidney function when eGFR 30 to 44 ml/min
- **STAGE 4**: Severe loss of kidney function when eGFR ranges from 15 to 29 ml/min
- **STAGE 5 (ESRD)**: End-stage kidney disease when eGFR is less than 15 ml/min or treatment by dialysis.

An albumin-creatinine ratio (ACR) is explained below-:

- A1: Albumin-creatinine ratio less than 30 mg/gm (less than 3.4 mg/mmol)
- A2: Albumin-creatinine ratio 30 to 299 mg/gm (3.4 to 34 mg/mmol)
- A3: Albumin-creatinine ratio greater than 300 mg/gm (greater than 34 mg/mmol).

1.2. Complications

Hyperkalaemia in CKD can occur specifically in oliguria (when you pee less than usual) patients and in those where aldosterone secretion is diminished. Hyperkalaemia could be caused by dietary potassium intake, tissue deterioration, and hypoaldosteronism. Drugs such as ACE (Angiotensin-converting-enzyme) inhibitors and non-selective beta-blockers could also result in hyperkalaemia.

Metabolic acidosis is also a common complication of chronic kidney disease and it progresses with the disease. Chronic metabolic acidosis in CKD would result in osteopenia (loss of bone mineral density), increased protein catabolism, and secondary hyperparathyroidism.

CKD is a significant risk factor for CVD (cardiovascular disease) and risk increases with increased severity of chronic kidney disease. Considerable evidence suggests a significant association between epicardial adipose tissue (EAT) thickness and the incidence of CVD events in CKD patients. In CKD patients, EAT assessment (A psychological self-assessment test of whether a person has an eating disorder) could be a reliable parameter for cardiovascular risk assessment.

1.3. Standard treatment guidelines

Standard treatment guidelines play a critical role in ensuring evidence-based clinical practice and quality of care. Standard treatment guidelines also termed clinical guidelines and clinical protocols are components of health services provisioning to ensure evidence-based medicine and quality of care.

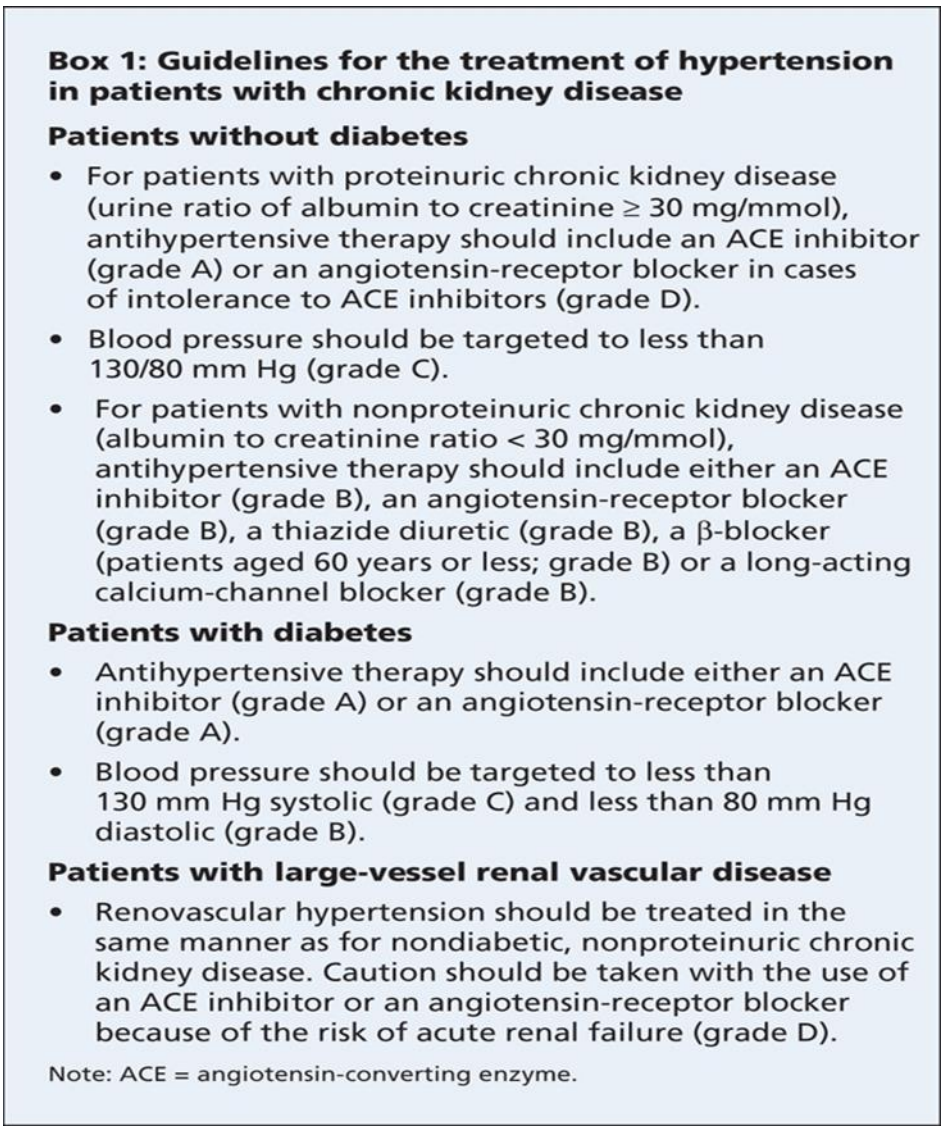
1.3.1. Standard guidelines for treatment for CKD with Hypertension

Hypertension, defined by the European Society of Cardiology and the European Society of Hypertension (ESC/ESH) as blood pressure (BP) of ≥ 140/80 mmHg that affects 30% of the general adult population and up to 90% of those suffering from CKD. Hypertension is a consequence of CKD and contributes to its progression. As eGFR falls, the prevalence, and severity of hypertension increase.

Furthermore, hypertension and chronic renal disease are both risk factors for cardiovascular disease (CVD). The risks of CVD morbidity and mortality are substantially increased when hypertension and CKD exist together. For patients suffering from stage 3 or stage 4 of CKD, as per the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines, the

risk of mortality due to CVD (cardiovascular disease) is greater than the risk of progression to end-stage renal disease (ESRD).

Patients with chronic renal disease without diabetes and who are suffering from proteinuricckd ,the urine ratio of albumin to creatinine should be ≥30mg/mmol.Those with non-proteinuric chronic kidney disease ,albumin to creatinine ratio <30 mg/ml. Blood pressure should be targeted to not exceed than 130/80mmHg.For diabetic patients antihypertensive therapy should include ACE inhibitors or an angiotensin receptor blocker as shown in figure 1.



Box 1: Guidelines for the treatment of hypertension in patients with chronic kidney disease

Patients without diabetes

- For patients with proteinuric chronic kidney disease (urine ratio of albumin to creatinine ≥ 30 mg/mmol), antihypertensive therapy should include an ACE inhibitor (grade A) or an angiotensin-receptor blocker in cases of intolerance to ACE inhibitors (grade D).
- Blood pressure should be targeted to less than 130/80 mm Hg (grade C).
- For patients with nonproteinuric chronic kidney disease (albumin to creatinine ratio < 30 mg/mmol), antihypertensive therapy should include either an ACE inhibitor (grade B), an angiotensin-receptor blocker (grade B), a thiazide diuretic (grade B), a β-blocker (patients aged 60 years or less; grade B) or a long-acting calcium-channel blocker (grade B).

Patients with diabetes

- Antihypertensive therapy should include either an ACE inhibitor (grade A) or an angiotensin-receptor blocker (grade A).
- Blood pressure should be targeted to less than 130 mm Hg systolic (grade C) and less than 80 mm Hg diastolic (grade B).

Patients with large-vessel renal vascular disease

- Renovascular hypertension should be treated in the same manner as for nondiabetic, nonproteinuric chronic kidney disease. Caution should be taken with the use of an ACE inhibitor or an angiotensin-receptor blocker because of the risk of acute renal failure (grade D).

Note: ACE = angiotensin-converting enzyme.

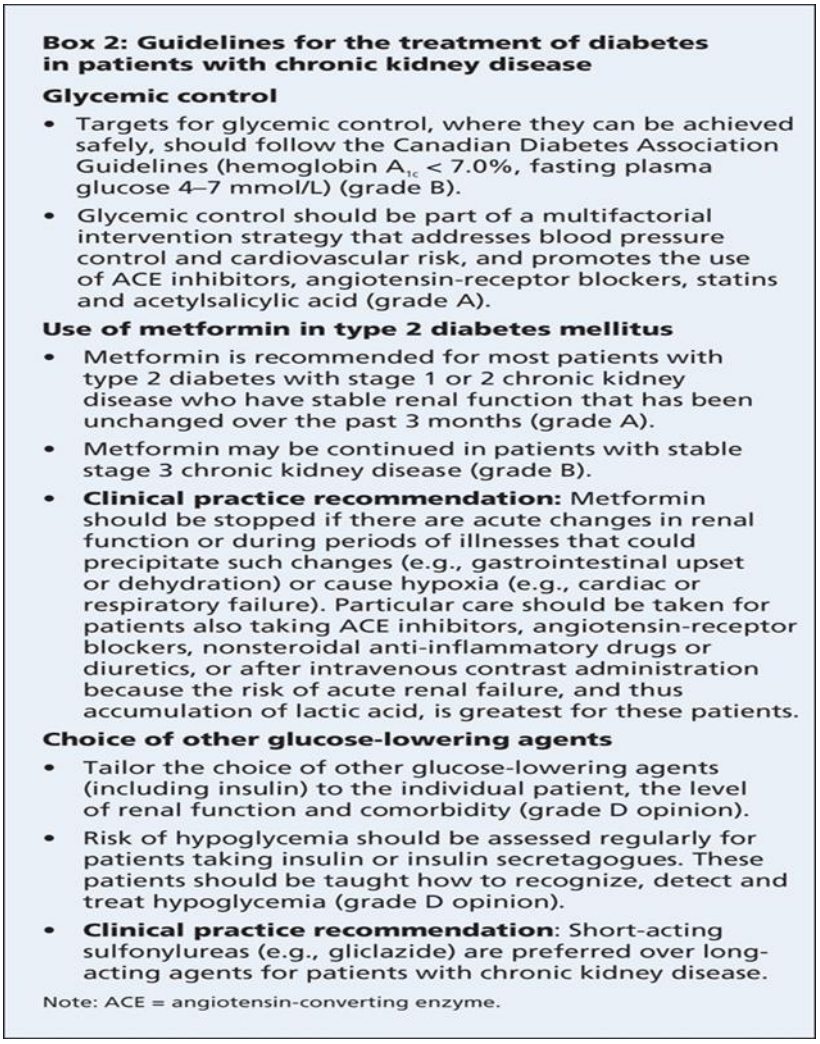
Figure 1 Standard treatment guidelines for patients suffering from chronic kidney disease with hypertension

1.3.2. Standard guidelines for treatment for CKD with Diabetes Mellitus

Patients suffering from diabetes are more likely to develop chronic renal disease and have cardiovascular disease. The Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group suggests a target HbA1c range from <6.5% to <8% in non-dialysis dependent DKD (Diabetic Kidney disease). The American Diabetes Association does not make a specific HbA1c recommendation for patients with kidney disease but recommends a target of <7% for most patients and <8% for patients with a limited life expectancy or high risk of complications as shown in table 1.Metformin is a low-priced and effective oral hypoglycaemic agent which is recommended as first-line therapy for both overweight and non-overweight patients with type 2 diabetes mellitus.

Table 1 Factors guiding decisions on individual HbA1c targets, where G1, is the estimated glomerular filtration rate when eGFR ranges ≥90mL/min, and G5 is the estimated glomerular filtration rate when eGFR is <15 ml/min, HbA1c is glycated hemoglobin.

< 6.5%	HbA1c	< 8.0%
CKD G1	Severity of CKD	CKD G5
Absent/minor	Macrovascular complications	Present/severe
Few	Co-morbidities	Many
Long	Life expectancy	Short
Present	Hypoglycaemia awareness	Impaired
Available	Resources for hypoglycaemia management	Scare
Low	Propensity of treatment to cause hypoglycaemia	High



Box 2: Guidelines for the treatment of diabetes in patients with chronic kidney disease

Glycemic control

- Targets for glycemic control, where they can be achieved safely, should follow the Canadian Diabetes Association Guidelines (hemoglobin A_{1c} < 7.0%, fasting plasma glucose 4–7 mmol/L) (grade B).
- Glycemic control should be part of a multifactorial intervention strategy that addresses blood pressure control and cardiovascular risk, and promotes the use of ACE inhibitors, angiotensin-receptor blockers, statins and acetylsalicylic acid (grade A).

Use of metformin in type 2 diabetes mellitus

- Metformin is recommended for most patients with type 2 diabetes with stage 1 or 2 chronic kidney disease who have stable renal function that has been unchanged over the past 3 months (grade A).
- Metformin may be continued in patients with stable stage 3 chronic kidney disease (grade B).
- **Clinical practice recommendation:** Metformin should be stopped if there are acute changes in renal function or during periods of illnesses that could precipitate such changes (e.g., gastrointestinal upset or dehydration) or cause hypoxia (e.g., cardiac or respiratory failure). Particular care should be taken for patients also taking ACE inhibitors, angiotensin-receptor blockers, nonsteroidal anti-inflammatory drugs or diuretics, or after intravenous contrast administration because the risk of acute renal failure, and thus accumulation of lactic acid, is greatest for these patients.

Choice of other glucose-lowering agents

- Tailor the choice of other glucose-lowering agents (including insulin) to the individual patient, the level of renal function and comorbidity (grade D opinion).
- Risk of hypoglycemia should be assessed regularly for patients taking insulin or insulin secretagogues. These patients should be taught how to recognize, detect and treat hypoglycemia (grade D opinion).
- **Clinical practice recommendation**: Short-acting sulfonylureas (e.g., gliclazide) are preferred over long-acting agents for patients with chronic kidney disease.

Note: ACE = angiotensin-converting enzyme.

Figure 2 Standard guidelines treatment for patients suffering from chronic kidney disease with Diabetes Mellitus

Patients suffering from diabetes the target glycemic control should be i.e. HbA1c <7.0%. Metformin is recommended for the patients who are at stage 2 or stage 3 of CKD with diabetes mellitus. If there are any acute changes in renal function

then metformin should be stopped. Choice of other glucose lowering agents include insulin and sulfonylureas as shown in figure 2.

1.4. Questionnaire- I (KDQOL SF-36)

It is a short form that comprises of total 36 questions and is used to assess the quality of life of chronic renal disease patients. KDQOL-36 items cover five domains of quality of life (physical function, mental function, burden of kidney disease, symptoms and problems of kidney disease, and effect of kidney disease on daily life).It is a standardized questionnaire form that is used to determine progression and impact of chronic kidney disease in each individual. (Kidney disease quality of Life Instrument (KDQOL) [Internet]. RAND Corporation. [cited 2023Jan30]. Available from: https://www.rand.org/health-care/surveys_tools/kdqol.html)

1.5. Questionnaire -II (Self-designed)

It is a self-designed questionnaire that is used in our current study for the analysis of prescribing patterns and standard treatment guideline followed in every individual patient suffering from chronic kidney disease. (Hussien H, Apetrii M, Covic A. Health-related quality of life in patients with chronic kidney disease. Expert Rev Pharmacoecon Outcomes Res. 2021 Feb, 21(1):43-54. doi: 10.1080/14737167.2021.1854091. Epub 2020 Dec 17. PMID: 33213186).

2. Material and Methods

2.1. Study Design

It is a prospective real-world evidence study. An observational study was conducted in a super-specialty 300 bedded hospital. A total of 100 patients were recruited. The inclusion and exclusion criteria of the study were explained to the patients and their representatives. An informed consent form was taken from the patients or their guardians who were willing to participate in the study. Patient selection was based on inclusion and exclusion criteria. In addition, representatives have informed that refusal to participate in the study or withdrawal from it would not result in any kind of harm i.e. no blood samples were required. At the time of this study, we reviewed the compliance of prescribing medications with standard treatment guidelines**.** Patient demographics, history, treatment chart, daily notes, and laboratory reports were included in the case report form.

2.2. Inclusion Criteria

Subjects must meet all the study Inclusion Criteria as outlined below:

- Patients 18-80 years of age.
- Patients of either gender.
- IPD/OPD prescription data.
- Psychiatric patients

2.3. Exclusion Criteria

- Pregnant and lactating women
- Pediatric patients.

2.4. Source of data

- Patient prescription
- Patient case files.
- Treatment chart
- Discharge notes.
- Case follow-up taken from MRD (Medical record room).

3. Results

Demographic representation of 100 studied patients revealed that the majority of patients were male (74%) while female patients were (26%). The majority of patients were from stable economic backgrounds and were unaware of the disease and its progression.

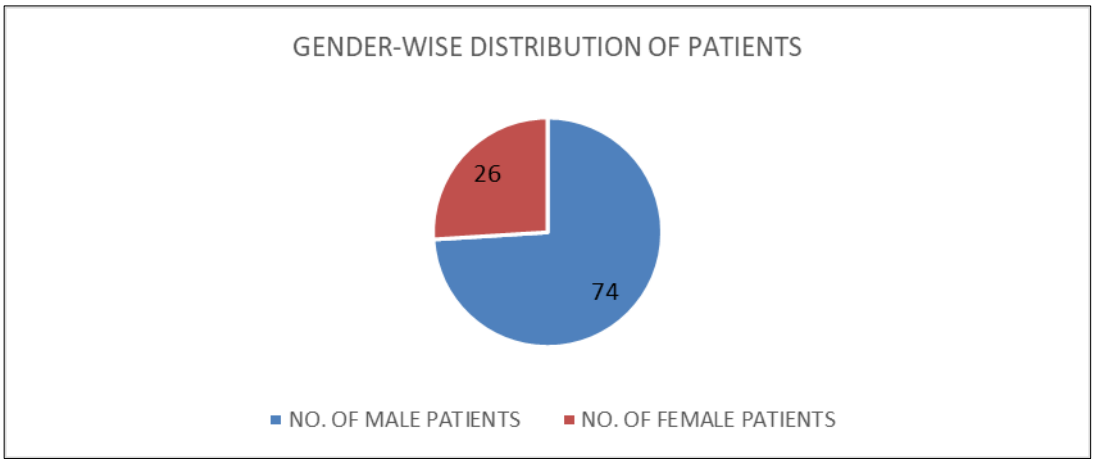


Figure 3 Demographic data

In the current study, 64 percent of patients were diagnosed with ESRD (end-stage renal disease), while just 1% of patients were diagnosed with stage 1 chronic kidney disease. There were an equal number of patients suffering from stage 3 and stage 4 with 15% suffering from both. Only 5% of patients, who remained had CKD stage 2.

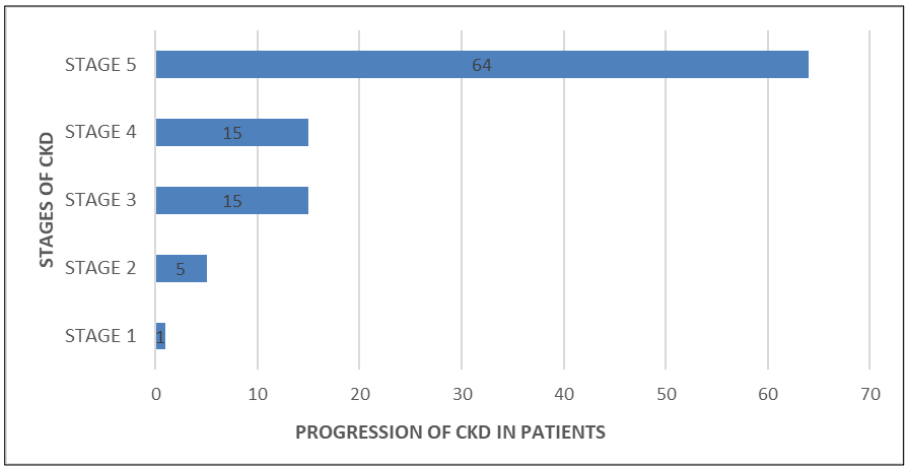


Figure 4 Stages of CKD

Diabetes and Hypertension were the most common co-morbid condition observed in the present study. Hypertension (55%) and diabetes (35%) remains the highest contributing factor for developing CKD. Urinary tract infections (5%), glomerulonephritis (2%), and hypothyroidism (1%), on the other hand, play a minor effect on disease progression.

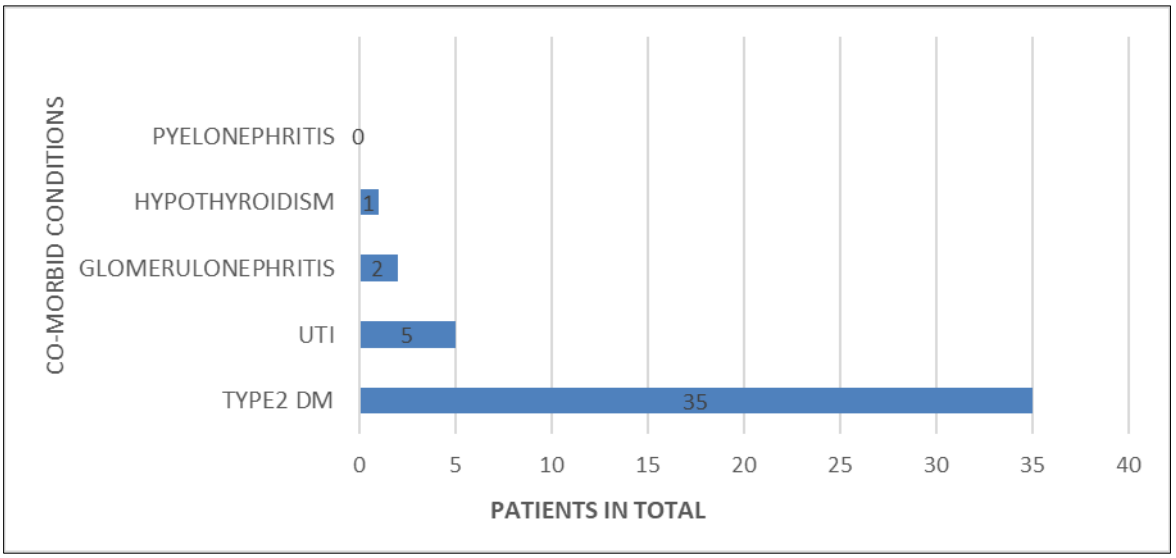


Figure 5 Co-morbid Conditions

Pantoprazole, ondansetron, darbepoetin Alfa, amlodipine, torsemide, and prazosin hydrochloride were the most commonly prescribed medicines to patients with CKD in the current study. These medications are as per the standard guideline's treatment for CKD.

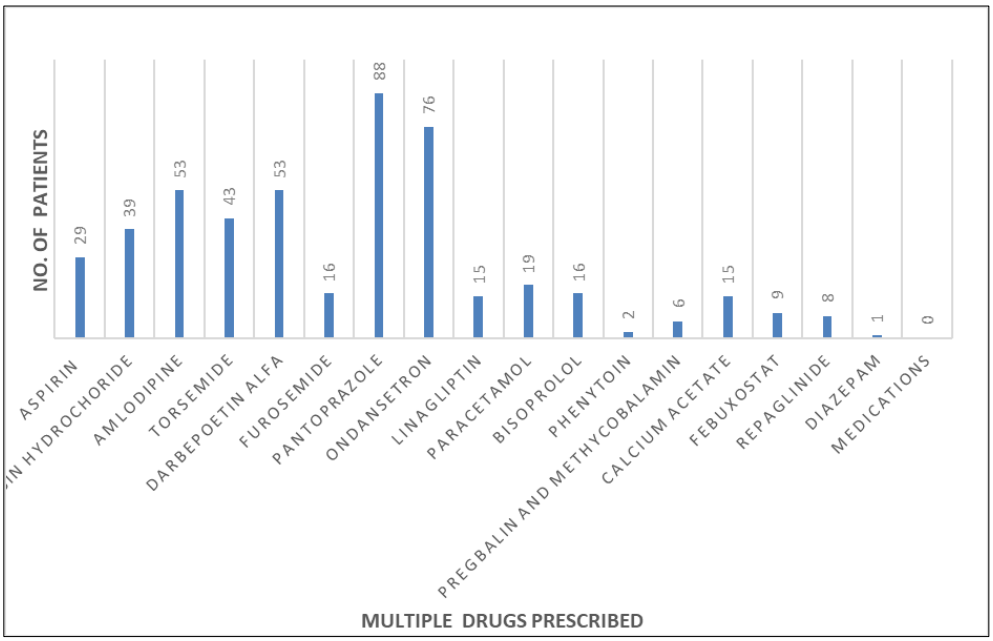


Figure 6 No. of drugs prescribed to CKD patients

In the present study, intravenous and oral route of administration was followed in the case of antibiotics. Tazact (14%),Clarimin(6%),Monocef(4%), and Mikacin(2%),were administered intravenously while amoxiclav (17%),Doxy(2%),Azee(1%) were administered orally.

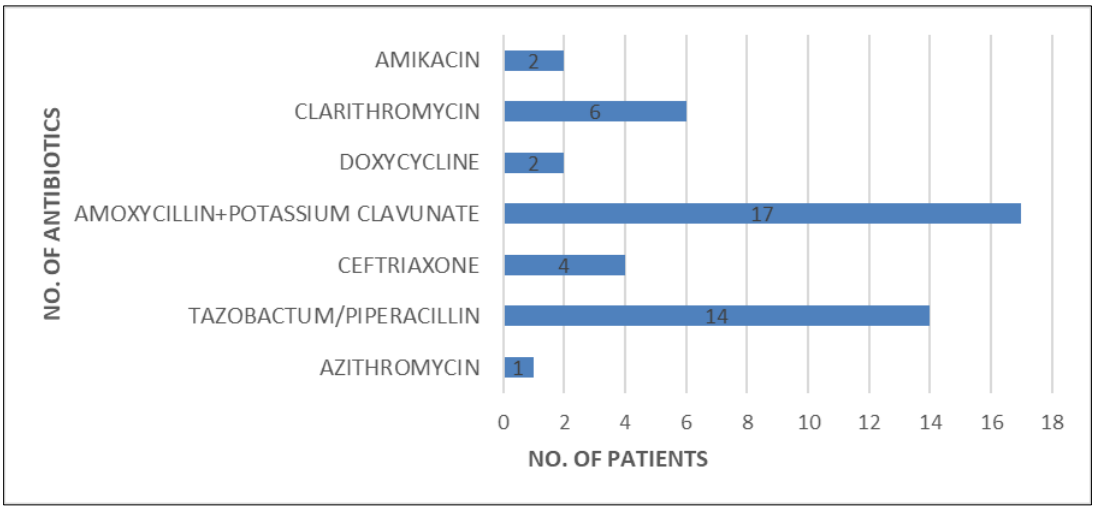


Figure 7 No. of Antibiotics prescribed

Twelve patients were administered diclofenac (NSAID), while five patients were given tramadol, an opiate (narcotic) analgesic. NSAID's have been associated with acute kidney injury in the general population and with progression of disease in those with chronic kidney disease.

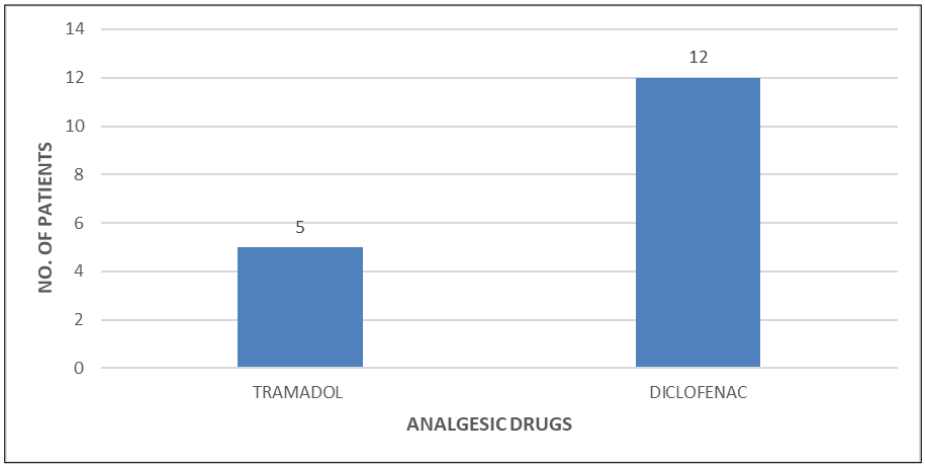


Figure 8 Analgesic drugs

4. Discussion

The research was carried out for six months at a super-specialty hospital. A total of 100 patients were recruited in this study. A health-related quality assessment form was filled out to assess the quality of life of each individual before and after treatment. It was found that before the initiation of treatment patients were unaware of the progression of the disease and the stages they are suffering from.Before treatment, the majority of patients received treatment that did not meet standard guideline treatment, leading to reduced quality of life and disease progression. The standardized questionnaire form was filled out when the patients were receiving treatment in the super-specialty hospital and their follow-up was taken, which results in that patients had significant improvement in the stages of CKD, which thereby improves the quality of life of patients.

5. Conclusion

Prospective observational research on chronic kidney disease and concomitant disease was carried out in a multispecialty hospital. The study's major aim was to focus on the compliance of drug prescribing patterns according to standard guideline treatment. Maximum compliance with standard guidelines treatment results in a better quality of life. The observational study resulted in the following outcomes.

- Demographical representation of the current study provides the count of Males (M= 74) and Females (F=26)
- The majority of diseased patients fall under the age groups of 21-41
- Diabetes and Hypertension were the most common co-morbid condition observed in the present study
- Intravenous and Oral route of administration was followed in the case of antibiotics
- Tazact (14%) was administered intravenously while amoxiclav (17%) was administered orally
- 57% of drug interactions were moderate in nature
- Since the treatment course was as per the standard treatment guidelines, which showed a significant impact on the quality of life of patients with chronic renal disease.
- This study generates the importance of clinical pharmacists in the pharmacological and non-pharmacological management of chronic renal disease. The effectiveness of patient counseling was observed in the patient's quality of life.

Compliance with ethical standards

Acknowledgments

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Disclosure of conflict of interest

All authors declare that they have no conflicts of interest.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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