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Original Research Article

Comparison of Outcomes of Selective Treatment Modalities in Chronic Kidney Disease Patients Admitted in a Tertiary Care Hospital in Vadodara: A Retrospective Study

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Abstract

Background: Due to the rising incidence of diabetes mellitus, hypertension, other non-communicable diseases, and the aging of the population, chronic kidney disease (CKD), considered a severe ailment, is now at epidemic levels.

Aims & Objectives: This study is aimed to fill the dearth in literature in a local hospital in a developing country like India, where CKD is highly prevalent and needs a quicker, efficacious and standard interventional approach. Study Objectives were centered on comparison and narrowing of the single best outcome for particular CKD stage patients for improving their quality of life.

Materials & Method: This is a retrospective study, using data from the General Medicine Department and Renal Unit Database. It included all the patients between Jan 2018 and Dec 2022 who were admitted in the General Medicine wards for treatment of CKD Stages 3a to 5. The data collection focused on parameters such as improvement and reduction rates in gross clinical variables as recorded in patient's medical records; biochemical urinalysis reports, Complete blood count (CBC) as well as renal function test (RFT); in addition to mineral and bone disorder parameters in regression over the course of treatment such as drug therapy (I.V or I.M or Oral), dialysis and/or transplant in the in-patient setting. The findings were grouped into categories and percentages, described in ratio and proportions. Mean, median, mode for the data was calculated using univariate analysis wherever feasible and necessary. Significance was considered if p < 0.05.

Results: Total 384 patients diagnosed with CKD Stages 3a to 5 were enrolled in the study. Mean age of CKD patients was 49.09 ± 12.50 years. Majority of the patients were in the 51 to 60 years age group (126, 32.8%). 78.4% were male and 21.6% were female. Furthermore, 82.6% were treated with only dialysis and these patients were categorized as Group D. Remaining 16.9% were on dialysis and anti-hypertensive medicine, 0.3% were on dialysis and anti-hypertensive medicine, 0.3% were on dialysis, antihypertensives and oral hypoglycemic agents where these patients were categorized as Group O. No statistically significant difference was found between both groups when the mode of treatments were compared (p>0.05).

Conclusion: The preferred treatment modalities showed good prognosis and were all equally effective in improving the clinical condition of the patients. There was no superior or inferior mode of treatment reported.

Keywords: Chronic Kidney Disease, CKD, Dialysis, Antihypertensives, Antibiotics, Oral Hypoglycemic Agents, Renal Function Tests, Treatment Modalities.

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Introduction

Even in emerging nations, chronic kidney diseases are now a significant contributor to morbidity and mortality worldwide. Accurate estimation of the burden of chronic kidney disease (CKD) in India is impossible. End-stage renal disease (ESRD) occurs between 150 to 200 times per million people (pmp), while the prevalence of CKD is roughly 800 pmp. [1] Chronic Kidney Disease is the final outcome of many diverse pathophysiological mechanisms that ultimately lead to abnormal renal functions & progressive reduction in glomerular filtration rate. There are two major sets of mechanisms accountable. One that is specific to the underlying etiology such as Genetically determined abnormalities, Immune Complex Deposition, Inflammation and toxin Exposure. Progressive Compensatory Mechanisms like Hyperfiltration & Hypertrophy of the remaining functional nephrons is the second culprit mechanism. Both these mechanisms unify in disrupting Glomerular architecture, Podocyte functions and filtration Barrier. Long standing Diabetes & Hypertension are the two most commonly encountered diseases that give rise to such detrimental mechanisms. [2] The Slowly evolving character of CKD and its interrelated Cardiovascular complications along with the developing End-Stage Renal Disease has put immense pressure on our health care systems. [3]

In advanced-stage chronic kidney disease, the options for management are typically centered on three main approaches: conservative management, dialysis, and kidney transplantation. [4]

Conservative Management focuses on symptom management, optimizing quality of life, and delaying progression of the disease without resorting to dialysis or transplantation. It is most suitable for the elderly & patients with multiple comorbidities for whom the burdens of more aggressive treatments may outweigh the benefits. It includes medical management through Anti-Hypertensives, Oral Hypoglycemics & Antibiotics or a Combination of these. [5] Dialysis is a treatment modality where a Dialysis machine filters waste, salt, and extra water from the blood, a function typically performed by healthy kidneys. It is a lifesaving intervention for individuals with severe kidney failure & helps maintain fluid and electrolyte balance, control blood pressure, and manage waste products. [6] Kidney Transplantation involves replacing a failed kidney with a healthy one from a living or deceased donor. It offers the best chance for a return to a near-normal life, with fewer dietary and lifestyle restrictions compared to dialysis. Often provides better long-term survival rates and improved quality of life as compared to dialysis. [7]

Clinicians in Low resource countries like India often face difficulties in making appropriate decisions regarding choice of therapies to be given to Advanced Kidney Disease patients based on their affordability, feasibility & efficacy of treatment, stage of CKD, patient's preferences, patient's age & overall health,& presence of Comorbidities. In an attempt to resolve this limitation, we did retrospective study in IPD patients admitted in Dhiraj General Hospital, Vadodara & contrasted the efficacy of different management modalities given to them in order to help our clinicians to opt for the best possible evidence based line of treatment for their patients.

Material & Methods

This is a Retrospective Cohort study carried amongst 384 IPD patients of medicine unit of Dhiraj General Hospital, Piparia, Vadodara within the time frame of June 2023–August 2023 The study was pursued after the grant of approval from the Sumandeep Vidyapeeth Institutional Ethics Committee. Sample Size was calculated to be 384 by the formula

 $n = \lambda^2 x p x (1-p)/d^2$ Patients diagnosed with CKD Stage 3a to 5 and admitted to Dhiraj General Hospital, Piparia in general medicine ward from a time period of January 2018 to December 2022 were included in our study whereas those patients were excluded who were diagnosed with CKD Stages 1 to 2 and admitted to Dhiraj General Hospital, Piparia in general medicine ward from a time period of January 2018 to December 2022. The permission for accessing record books was obtained from the Medical superintendent of the hospital prior to initiating the data collection. The confidentiality of the patients was maintained and the access to the records was given only to the concerned coinvestigators during the entire data collection period. The data was collected from the Dhiraj General Hospital Registry pertaining to the general medicine ward In-patient records about patients who suffered from CKD Stages 3a to 5 from a time frame of January 2018 to December 2022. The data collection focused on parameters such as improvement and reduction rates in gross clinical presenting symptoms & signs as recorded in patient's discharge summary; biochemical urinalysis reports, Complete blood count (CBC) as well as renal function test (RFT); in addition to mineral and bone disorder symptoms regression over the course when the patient received treatment such as drug therapy (I.V or I.M or Oral), dialysis and/or transplant in the inpatient setting. The data was processed and analyzed in order to articulate and compare each treatment modality's pros and cons so as to provide early intervention, better management and appropriate patient care which will help in actively improving the quality of life in patients affected with CKD.

Statistical Methods

The data was compiled into Microsoft Excel 2007 and results were analyzed using analytical statistics methods. The findings were grouped into categories and percentages were calculated for each of the findings. Data was also described in ratio and proportions. Mean, median, mode for the data were calculated wherever feasible and necessary. All analyses were done at 5% significance and at 95% confidence interval using SPSS version 23.0.

Results





Total 384 patients diagnosed with CKD were enrolled in the study. Mean age of CKD patients was 49.09 ± 12.50 years. Majority of the patients were in 51 to 60 years age group (126, 32.8%).



Figure 2: Gender-wise distribution of patients

Out of 384 patients, 78.4% were male and 21.6% were female.



Figure 3: Treatment wise distribution of patients

Out of 384 patients, 317 patients (82.6%) were treated with only dialysis and these patients were categorised as Group D. Remaining 65 patients (16.9%) were on dialysis and anti-hypertensive medicine, 1 patient (0.3%) was

on dialysis and antibiotic and another 1 patient (0.3%) was on dialysis and anti-hypertensive and oral hypoglycemic medicine. These patients were categorised as Group O.

	Group D	Group O	Total	χ2 & p value
	(n=317)	(n=67)	(n-384)	
Elevated BUN				
 at admission 	317 (100%)	67 (100%)	384 (100%)	$\chi 2 = 0.001, p = 1.00$
 at discharge 	0 (0%)	0 (0%)	0 (0%)	$\chi 2 = 0.001, p = 1.00$
p value: at admission v/s at	< 0.001	< 0.001	< 0.001	
discharge within group				
Elevated creatinine				
 at admission 	317 (100%)	67 (100%)	384 (100%)	$\chi 2 = 0.001, p = 1.00$
 at discharge 	308 (97.2%)	64 (95.5%)	372 (96.9%)	$\chi 2 = 0.49, p = 0.48$
p value: at admission v/s at dis-	0.002	< 0.001	< 0.001	
charge within group				
Elevated Uric acid				
 at admission 	317 (100%)	67 (100%)	384 (100%)	$\chi 2 = 0.001, p = 1.00$
 at discharge 	23 (7.3%)	6 (9%)	29 (7.6%)	$\chi 2 = 0.22, p = 0.63$
p value: at admission v/s at dis-	< 0.001	< 0.001	< 0.001	
charge within group				
Elevated A/G ratio				
 at admission 	283 (89.3%)	61 (91%)	344 (89.6%)	$\chi 2 = 0.18, p = 0.66$
 at discharge 	214 (67.5%)	41 (61.2%)	255 (66.4%)	$\chi 2 = 0.98, p = 0.32$
p value: at admission v/s at dis-	< 0.001	< 0.001	< 0.001	
charge within group				
Low creatinine clearance				
 at admission 	13 (4.1%)	1 (1.5%)	14 (3.6%)	$\chi 2 = 1.07, p = 0.30$
 at discharge 	7 (2.2%)	3 (4.5%)	10 (2.6%)	$\chi 2 = 1.12, p = 0.28$
p value: at admission v/s at dis-	0.17	0.3	0.42	
charge within group				
Elevated creatinine urine				
 at admission 	301 (95%)	64 (95.5%)	365 (95.1%)	$\chi 2 = 0.03, p = 0.84$
– at discharge	0 (0%)	0 (0%)	0 (0%)	$\chi 2 = 0.001, p = 1.00$
p value: at admission v/s at dis-	< 0.001	< 0.001	< 0.001	
charge within group				

Table 1: Comparison of Improvement of Renal function test after treatment between the two grou	ps and
within group	

Renal function test such as BUN, creatinine, uric acid, A/G ratio were elevated in group D and Group O at the time of admission.

In Group D, renal function was improved significantly after treatment as BUN, creatinine, uric acid and A/G ratio returned to normal. Similarly in

Group O, renal function test such as BUN, creatinine, uric acid, A/G ratio were significantly reduced to normal.

However, there was no any statistically significant difference between the two groups regarding improvement of renal function.

Table 2: Comparison of Improvement in Blood Electrolytes levels after treatment between the two groups
and within the group

Electrolyte level	Group D (n=317)	Group O (n=67)	Total (n-384)	χ2 & p value
Hypernatremia				
 at admission 	132 (41.6%)	24 (35.8%)	156 (40.6%)	$\chi 2 = 0.01, p = 0.98$
 at discharge 	114 (36%)	24 (35.8%)	138 (35.9%)	$\chi 2 = 0.77, p = 0.38$
p value: at admission v/s at discharge within group	0.15	1.00	0.18	
Hypokalemia				
– at admission	249 (78.5%)	58 (86.6%)	307 (79.9%)	$\chi 2 = 2.21, p = 0.14$
 at discharge 	0 (0%)	0 (0%)	0 (0%)	p - 1.00

p value: at admission v/s at discharge within group	< 0.001	< 0.001	< 0.001	
Hypocalcemia				
 at admission 	317 (100%)	67 (100%)	384 (100%)	p - 1.00
 at discharge 	261 (82.3%)	55 (82.1%)	316 (82.3%)	$\chi 2 = 0.02, p = 0.96$
p value: at admission v/s at discharge within group	< 0.001	< 0.001	< 0.001	

In group D, Hypernatremia was found in 41.6% patients at admission which was reduced to 36.0% after treatment (p = 0.15). Similarly, there was no any improvement in proportion of patients having hypernatremia in group O (35.8% at admission as well as at discharge, p =1.00).

In group D, Hypernatremia was found in 41.6% patients at admission which was reduced to 36.0% after treatment (p = 0.15). Similarly, there was no any improvement in proportion of patients having hypernatremia in group O (35.8% at admission as well as at discharge, p = 1.00).

Hypokalemia was reported in 78.5% patient at admission in Group D which was not found after treatment. Hence, there was significant improvement of hypokalemia in group D (p < 0.001). Similarly in Group O, 86.6% of patients had hypokalemia at the time of admission. All patients had improved, and no one had hypokalemia at the time of discharge (p < 0.001).

Similar observation was observed for Hypocalcemia.

Although, within the group there were statistically significant improvements in electrolytes levels following treatment but there were no any statistically significant difference observed regarding improvement of electrolyte balance between both the groups.

Blood analysis	Group D (n=317)	Group O (n=67)	p value
Hb (g/dL) at admission			
– at admission	5.81 ± 1.35	5.84 ± 1.52	0.56
– at discharge	9.66 ± 1.56	9.98 ± 1.78	0.76
– p value: at admission v/s at discharge within group	< 0.001	< 0.001	
Haematocrit (%) at admission			
 at admission 	28.27 ± 2.45	28.09 ± 1.94	0.43
– at discharge	34.67 ± 3.41	35.31 ± 2.32	0.24
– p value: at admission v/s at discharge within group	< 0.001	< 0.001	
RBC Count (millions/uL) at admission			
 at admission 	2.54 ± 0.71	2.46 ± 0.68	0.07
– at discharge	4.12 ± 1.23	4.23 ± 1.45	0.10
 p value: at admission v/s at discharge within group 	0.02	0.03	
MCV (fL) at admission			
 at admission 	49.21 ± 12.79	48.64 ± 12.81	0.57
– at discharge	68.45 ± 13.23	70.32 ± 14.32	0.12
– p value: at admission v/s at discharge within group	< 0.001	< 0.001	
MCHC (%) at admission			
– at admission	28.16 ± 2.46	28.3 ± 2.12	0.14
– at discharge	29.56 ± 2.12	30.12 ± 2.67	0.23
– p value: at admission v/s at discharge within group	0.23	0.12	
RDW (%) at admission			
– at admission	$15.\overline{58}\pm3.94$	14.96 ± 3.75	0.63
– at discharge	15.34 ± 2.34	14.76 ± 3.54	0.45
- p value: at admission v/s at discharge within group	0.56	0.67	

Table 3: Comparison of Improvement in Blood analysis between the two groups

Blood parameters like Hb, Hematocrit, RBC Count, MCV, MCHC & RDW showed significant improvement after therapy in both the groups but no Statistical Significance between the prognosis of both the groups could be ascertained.



Figure 4: Comparison of Improvement in urine analysis after treatment between two groups and within the group

Majority of the patients (99.7%) had pale colour of urine initially which turned clear after treatment in 53.9% patients. Acidic urine was reported in more than 3/4th patients (87.5%) at the time of admission. After treatment, mean urine pH came within normal range in Group D (pH: at admission- 5.51 ± 0.71 v/s at discharge - 6.78 ± 0.92 , p < 0.001). Similar significant improvement was observed in Group O after treatment (pH: at admission- 5.48 ± 0.68 v/s at discharge - 6.23 ± 0.86 , p < 0.001). There is significant improvement in glycosuria, ketonuria, and proteinuria in both groups after treatment. Similarly, traces of urobilinogen, bilirubin, leukocyte esterase and nitrate were not found in any patient after treatment in both the groups.

Discussion

Among the various available treatment modalities for patients suffering from CKD, a recent study by Toyama, Tadashi et al. indicated that sodium glucose cotransporter 2 (SGLT2) inhibitors reduce the risk of cardiovascular and renal outcomes in individuals with Type 2 Diabetes Mellitus and CKD. [8] It was found in a study by Xie, Xinfang et al. that people with CKD who receive ACE inhibitors or ARBs have a lower chance of developing renal failure and cardiovascular problems. ACE inhibitors may be the first line of treatment for individuals with CKD since they reduced the risk of all-cause mortality and were possibly superior to ARBs for kidney failure, cardiovascular death, and all-cause mortality. [9]

A remarkable number of patients with CKD stages 3a-5 have low bone mineral density (BMD), leading to a markedly increased risk of fracture (mainly hip fracture) and associated increased morbidity and mortality. However, a post-hoc analysis of large randomized clinical trials showed that these drugs (ie, alendronate, ribandronate, denosumab) had comparable efficacy in improving bone mineral density and reducing fracture risk in individuals (mainly women) with moderate reductions of GFR (mostly CKD stages 3-4). Therefore, in the absence of clear abnormalities in mineral metabolism associated with chronic disease, bone resorption reducing agents approved for general osteoporosis (and possibly anabolic agents) may be appropriate. [10]

Renal replacement therapy is required for individuals with end stage renal disease (ESRD), which certainly affects their health-related quality of life (HRQoL). A systematic review pertaining to comparing patients who underwent peritoneal dialysis (PD) or haemodialysis (HD) suggested that patients treated with PD had better generic HRQoL than HD. [11]

In general, through the extensive literature review we understood that by comparing the available treatment options for CKD patients with the status of its outcome through recovery or mortality will give us an insight into how these patients can be effectively managed despite the challenges of early diagnosis and the burden of managing the disease in a constructive manner.

Conclusion

The management of patients with Advance Stage Chronic Kidney Disease (CKD) who are on dialysis involves a complex interplay of medications. In our Study, we categorised patients into Group D comprising of patients treated with Dialysis only and Group O where a combination of medical regimen along with Dialysis was used. Patients on Dialysis with Medication Regimen like Antibiotics/Oral Hypoglycemics/Antihypertensives or a combination of these drugs showed equally good improvement in their clinical status as compared with Dialysis only group. Both the groups had statistically significant outcomes after the prescribed treatment. But when comparison was done between both the groups regarding which mode is a better one, there was no statistically significant results observed indicating both the groups were at par & there was no superior or inferior modality of management as far as patient's prognosis was considered.

The Study concludes that, the clinician has to take the call to choose the best possible treatment approach keeping in mind their patient's complex profile including their overall health, comorbidities, medication tolerance, stage of CKD, age & preferences. The treatment strategy can be different for different patients but if its well-tailored for them, it will have a favorable outcome no matter the choice of therapies administered.

References

- Agarwal SK, Srivastava RK. Chronic Kidney Disease in India: Challenges and Solutions. Nephron Clinical Practice. 2009 Feb 5;111(3): c197–203.
- Vallianou NG, Mitesh S, Gkogkou A, Geladari E. Chronic Kidney Disease and Cardiovascular Disease: Is there Any Relationship? Curr Cardiol Rev. 2019;15(1):55-63.
- Hill NR, Fatoba ST, Oke JL, Hirst JA, O'Callaghan CA, Lasserson DS, Hobbs FD. Global Prevalence of Chronic Kidney Disease -

A Systematic Review and Meta-Analysis. PLoS One. 2016 Jul 6;11(7):e0158765.

- Chen TK, Knicely DH, Grams ME. Chronic Kidney Disease Diagnosis and Management: A Review. JAMA. 2019 Oct 1;322(13):1294-1304.
- [Guideline] Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int Suppl. 2013. 3:1-150.
- Gondal M. Overview of, and Preparations for, Dialysis. Med Clin North Am. 2023 Jul;107(4):681-687.
- Abecassis M, Bartlett ST, Collins AJ, Davis CL, Delmonico FL, Friedewald JJ, Hays R, Howard A, Jones E, Leichtman AB, Merion RM, Metzger RA, Pradel F, Schweitzer EJ, Velez RL, Gaston RS. Kidney transplantation as primary therapy for end-stage renal disease: a National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (NKF/ KDOQ ITM) conference. Clin J Am Soc Nephrol. 2008 Mar;3(2):471-80
- Toyama, Tadashi et al. "Effect of SGLT2 inhibitors on cardiovascular, renal and safety outcomes in patients with type 2 diabetes mellitus and chronic kidney disease: A systematic review and meta-analysis." Diabetes, obesity & metabolism. 2019; 21(5): 1237-1250.
- 9. Xie, Xinfang et al. Renin-Angiotensin System Inhibitors and Kidney and Cardiovascular Outcomes in Patients With CKD: A Bayesian Network Meta-analysis of Randomized Clinical Trials. American journal of kidney diseases : the official journal of the National Kidney Foundation. 2016;67(5): 728-41.
- Bover, Jordi et al. Osteoporosis, bone mineral density and CKD-MBD: treatment considerations. Journal of nephrology vol. 30,5 (2017): 677-687.
- 11. Chuasuwan, Anan et al. Comparisons of quality of life between patients underwent peritoneal dialysis and hemodialysis: a systematic review and meta-analysis. Health and quality of life outcomes. 18 Jun. 2020; 18(1):191.