Original paper

Clinical Profiles and Outcomes of End-Stage Kidney Disease in Adult Patients Treated with Haemodialysis at The Kenyatta National Hospital during Out-of-Pocket Payment and National Health Insurance Reimbursement for Haemodialysis Services

Kibe W[1], McLigeyo S[1], Kayima J[1], Ngigi J[2], Wambugu B[2], Kabinga S[1]

[1]University of Nairobi, East African Kidney Institute, P.O. Box 30197-00100, Nairobi, Kenya
[2]Kenyatta National Hospital, Renal Department, P.O. Box 20723-00202, Nairobi, Kenya

Address for Correspondence: Dr Wanjiru Kibe, University of Nairobi, East African Kidney Institute, P.O. Box 30197-00100, Nairobi, Kenya. Email: shiro1018@gmail.com

Abstract

Background: The demand for haemodialysis has grown briskly especially in low- and middle- income countries. Sadly, availability of kidney replacement therapy in developing countries is scarce and may be unavailable in very-low-resource regions. As a result, a compelling number of patients have finite access to Kidney Replacement Therapy (KRT) resulting in premature deaths. In July 2015, the National Hospital Insurance Fund (NHIF) launched a renal dialysis package which caters for haemodialysis two sessions per week.

Objective: To describe and compare selected clinical profiles and clinical outcomes amongst ESKD patients treated with HD in Kenyatta National Hospital (KNH) between June 2013 to June 2015 and July 2015 to May 2018 i.e., during the out-of-pocket payment period (pre-NHIF) and the national health insurance reimbursement period (post-NHIF).

Methods: This was an ambispective observational study among End Stage Kidney Disease (ESKD) patients treated with haemodialysis (HD) in KNH between June 2013 to June 2015 and July 2015 to May 2018. The medical records of the 338 randomly selected patients were retrieved from the health records and information department in KNH. Data on the patients' sociodemographic characteristics, clinical profiles and outcomes was collected and analysed.

Results: Comparing the two groups (pre- and post-NHIF), the mean age at HD initiation did not differ significantly (46.76 vs 46.96 years). Males outnumbered females in both groups, at 64% and 60% respectively. Diabetes and hypertension remained the most common documented causes of ESKD in both groups. Following the introduction of NHIF reimbursement, there was a significant rise in HD sessions (1.94 ± 0.7 vs 2.12 ± 0.4, p value 0.04), however, the HD vintage decreased (36.3 vs 30.5 months). Our mortality rate was high at 85% (pre-NHIF) and 76% (post-NHIF).

Conclusion: The mortality rate was quite high during both time periods; hence the emphasis should be on prevention, early detection, and treatment of diabetes and hypertension as well as making kidney transplantation accessible and affordable to all. Hopefully, these will have a positive impact on the mortality rate of ESKD patients.

Key words: Out-of-pocket payment, NHIF reimbursement, KNH, End Stage Kidney Disease patients, Haemodialysis

Introduction

Chronic Kidney Disease (CKD) is becoming a common disease in the general population and a major public health problem world over (1). There is a rising incidence and prevalence of CKD globally which poses an important challenge to many health systems. It is an important contributor to morbidity and mortality among the Non-Communicable Diseases (NCD). Patients with CKD have a higher mortality rate in comparison to the general population (2).

According to the Global Burden of Disease Study in 2017, the global prevalence of CKD was 9.1% across 195 countries, this translated to 697.5 million cases globally. Chronic kidney disease resulted in 1.2 million deaths in 2017 and it was ranked as the 12th leading cause of death worldwide. In a systematic review assessing the burden of CKD in Africa, the prevalence of CKD was found to range from 2% to 14% in sub-Saharan Africa (3).

Kidney Replacement Therapy (KRT) broadly encompasses dialytic modalities and kidney transplantation. Dialytic modalities include haemodialysis (HD) and Peritoneal Dialysis (PD). In the last two decenniums, great advances in treatment of CKD have emerged. Dialysis treatment ameliorates

most of the clinical manifestations of End Stage Kidney Disease (ESKD); this helps improve the survival of haemodialysis patients. The population of patients in need of KRT is growing rapidly particularly in Low- and Middle- Income Countries (LMIC). Currently, there are about two million people on KRT worldwide. This represents only 10% of the people who need it. The demand for HD has grown tremendously in the recent years and it has become an important issue in healthcare. Unfortunately, the availability of KRT in developing countries is scarce and may be unavailable in very-low-resource regions. As a result, a sizeable number of patients lack access to KRT and large numbers of people die due to kidney failure annually, often without any form of supportive care (4).

Health is a basic human right as enshrined in the 2010 Kenya constitution. However, health care cost limits the attainment of this constitutional right. This therefore is bound to select for those who have resources to afford the care. National Health Insurance Fund (NHIF) is the primary health insurance provider in Kenya; its mandate is to enable all Kenyans to access quality and affordable health care services. The NHIF has evolved over the years and in July 2015, NHIF launched a renal dialysis package which caters for two haemodialysis sessions per week. Before July 2015, patients used to meet all the costs by themselves. The influence of national insurance reimbursement for haemodialysis services has not been studied.

Significance of the study

Chronic Kidney Disease (CKD) has a major impact on global health given the associated significant morbidity and mortality. The outlay of HD care is high and are prone to rise. The effect of national health insurance reimbursement on HD remains largely unknown. A few sets of data suggest that decreased reimbursement may increase morbidity and mortality directly or indirectly.

It is plausible to think that national insurance reimbursement for the HD services is likely to result in improved access to this care. It is not clear whether the patients' demographics and clinical profiles have changed. The outcomes of patients on HD during the out-of-pocket payment of HD services costs and during the national health insurance reimbursement in our setting has not been studied.

Objectives

To describe and compare selected clinical profiles i.e., age at initiation of haemodialysis, sex, cause of ESKD and haemodialysis vintage of ESKD patients treated with HD in KNH between June 2013 to June 2015 and July 2015 to May 2018.

To document and compare selected clinical outcomes i.e., alive on HD, alive having transplanted, deceased while on HD, deceased after kidney transplantation, of ESKD patients treated with HD in KNH between June 2013 to June 2015 and July 2015 to May 2018.

Materials and methods

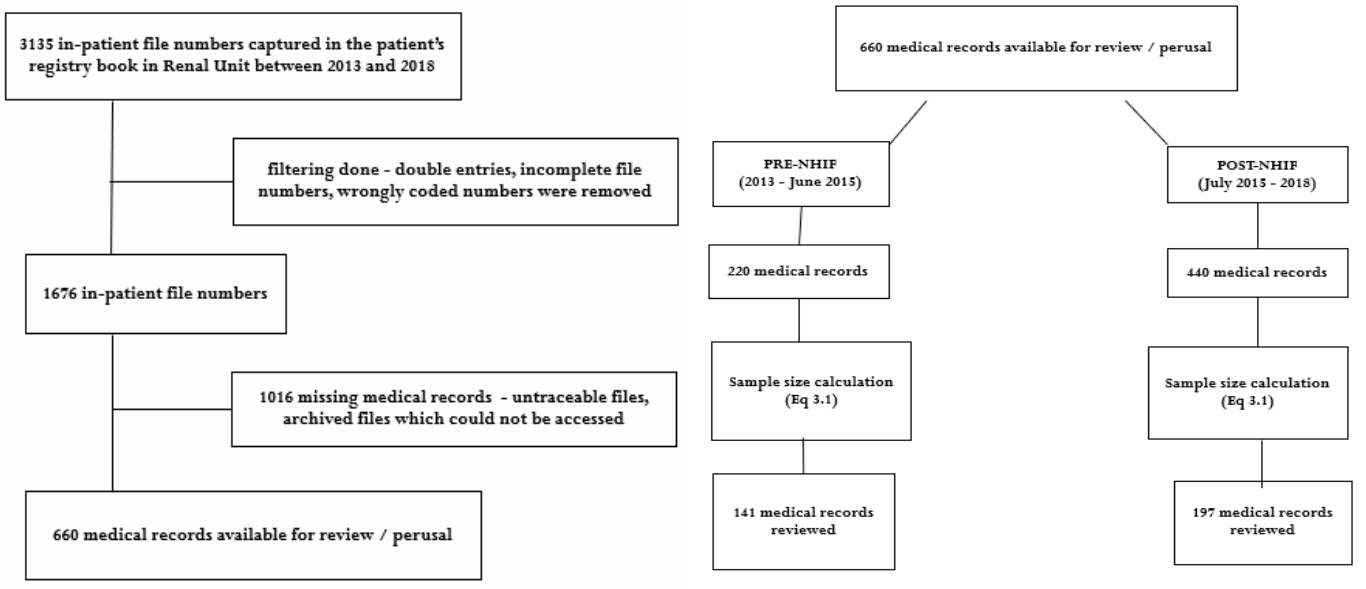
This was an ambispective observational study among ESKD patients on HD in KNH between June 2013 to June 2015 and July 2015 to May 2018. A total of 3135 patient records were captured in the patient's registry book in Renal Unit between 2013 and 2018. Filtering was done and out of the remaining 1676 files, only 660 medical records were available for review. The sample size was calculated and random sampling done, 141 medical records in the pre-NHIF group and 197 in the post-NHIF group were reviewed. The data collected was transferred to an SPSS data sheet and analysis done using SPSS. The equation below was used to calculate sample size, with a confidence interval of 95% and a margin of error of 5%.

Sample size calculation (Equation):

$$Sample\ size = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p(1-p)}{e^2 N}\right)}$$

where N = population size; e = margin of error;
z = z score; p = sample proportion.

Figure 1: Recruitment process



Study variables: Dependent variables - clinical outcome (dead or alive, on haemodialysis or transplanted)

Independent variables - age, sex, documented cause of ESKD, haemodialysis vintage

Data analysis: Descriptive statistics were used to summarize the data. For continuous variables, means (SD) or medians (IQR) were reported. For categorical variables, frequencies and proportions were reported in tables.

Ethical considerations: The study was undertaken after approval by the DoCMT, UoN and the KNH/UoN ERC, Research Approval number P325/05/2021. Authority to use the medical records was sought from the in-charge of Health Information and Records Department.

Results

A total of 338 files, 141 in the pre-NHIF group and 197 in the post-NHIF group were reviewed.

The mean age at onset of HD did not differ significantly between the two groups during the study interval, with a reported mean age of 46.76 years in the pre-NHIF group and 46.96 years in the post-NHIF group. Males constituted a larger proportion of study participants in both groups, accounting for 64% (pre-NHIF) and 60% (post-NHIF). As shown in Table 1, majority of the study participants in both groups were married.

Table 2 summarises the documented causes of ESKD. Hypertension, diabetes, chronic glomerulonephritis and obstructive uropathy were the leading causes of ESKD in both groups. Overall, the number of cases for the various causes of ESKD increased over the

Table 1: Demographics

Characteristic	Pre-NHIF (N = 141)	Post-NHIF (N = 197)	All (N = 338)	P- value
Age at HD initiation (year) Mean ± SD	46.76 ± 15.55	46.96 ± 15.54	46.88 ± 15.52	0.91
Sex				
Male n (%)	90 (63.8)	119 (60.4)	209 (61.8)	0.52
Female n (%)	51 (36.2)	78 (39.6)	129 (38.2)	
Marital status				
Married n (%)	112 (79.4)	152 (77.2)	264 (78.1)	0.82
Separated n (%)	2 (1.4)	1 (0.5)	3 (0.9)	
Single n (%)	24 (17.0)	38 (19.3)	62 (18.3)	
Widowed n (%)	3 (2.1)	6 (3.0)	9 (2.7)	

Table 2: Clinical characteristics

Characteristic	Pre-NHIF (N = 141)	Post-NHIF (N = 197)	All (N = 338)	P-value
Causes of ESKD				
DM n (%)	43 (30.5)	76 (38.6)	119 (35.2)	0.12
HTN n (%)	78 (55.3)	120 (60.9)	198 (58.6)	0.31
GN n (%)	53 (37.6)	47 (23.9)	100 (29.6)	0.08
OU n (%)	13 (9.2)	19 (9.6)	32 (9.5)	0.90
ADPKD n (%)	3 (2.1)	6 (3.0)	9 (2.7)	0.53
CAN n (%)	2 (1.4)	1 (0.5)	3 (0.9)	0.42
Preg-related n (%)	3 (2.1)	8 (4.1)	11 (3.3)	0.30
RVD n (%)	7 (5.0)	16 (8.1)	23 (6.8)	0.40

years. Diabetes and hypertension saw the greatest percentage increases, at 8% and 6%, respectively.

During the study, the number of hepatitis B positive patients increased from 5 to 13. Similarly, the number of HIV-positive patients increased from 7 to 16. None of our patients were found to have hepatitis C. However, none of these increases in the number of cases were found to be statistically significant as depicted in Table 3.

Looking at the number of haemodialysis sessions per week, patients in the pre-NHIF group had a lower mean (1.94 ± 0.6 months) compared to patients in the post-NHIF (2.12 ± 0.35). This was also found to be statistically significant (p value 0.04). The average HD

Table 3: Clinical characteristics

Characteristic	Pre-NHIF (N = 141)	Post-NHIF (N = 197)	All (N = 338)	P- value
HBsAg status				
Negative n (%)	136 (96.5)	184 (93.4)	320 (94.7)	0.20
Positive n (%)	5 (3.5)	13 (6.6)	18 (5.3)	
HIV status				
Negative n (%)	134 (95.0)	181 (91.9)	315 (93.2)	0.40
Positive n (%)	7 (5.0)	16 (8.1)	23 (6.8)	
HCV status				
Negative n (%)	141 (100)	197 (100)	338 (100)	0.28

vintage in our study was 32.9 months overall, but we noted a decrease in HD vintage after introduction of NHIF (36.3 vs 30.5 months) as shown in Table 4.

The mortality rate for ESKD patients receiving haemodialysis was 79.6%. Of the 67 patients who survived, 42 were on HD, 9 had a functioning kidney graft, and 16 had recovered kidney function. As summarised in Table 4, 269 (79.6 %) patients died while

Table 4: Clinical characteristics

Characteristic	Pre-NHIF (N = 141)	Post-NHIF (N = 197)	All (N = 338)	P-value
HD sessions				
Mean ± SD	1.94 ± 0.663	2.12 ± 0.358	2.05 ± 0.515	0.04
HD vintage (month)				
Mean ± SD	36.28 ± 34.09	30.48 ± 18.99	32.90 ± 26.47	0.07

Table 5: Clinical outcomes

Characteristic	Pre-NHIF (N = 141)	Post-NHIF (N = 197)	All (N = 338)	p value
Outcomes				
Alive n (%)	20 (14.2)	47 (23.9)	67 (19.8)	0.47
Dead n (%)	121 (85.8)	150 (76.1)	271 (80.2)	
Alive on HD n (%)	9 (6.4)	33 (16.8)	42 (12.4)	0.12
Alive on KTx n (%)	6 (4.3)	3 (1.5)	9 (2.7)	0.13
Deceased on HD n (%)	120 (85.1)	149 (75.6)	269 (79.6)	0.10
Deceased after KTx n (%)	1 (0.7)	1 (0.5)	2 (0.6)	0.76
Alive not on HD or KTx n (%)	5 (3.5)	11 (5.6)	16 (4.7)	0.50

on dialysis, and only two (0.6%) died with a functioning graft. Our mortality rate was high at 80% with more deaths being reported in the pre-NHIF group (85%) but the mortality rate remained high in the post-NHIF group at 76%. Patients on haemodialysis continued to die at a higher rate than patients who had undergone kidney transplantation in both groups.

Discussion

The ever-increasing prevalence of ESKD places a huge burden on healthcare systems, as well as patients and caregivers. This presents a significant challenge in the delivery and management of ESKD services, particularly in resource-constrained settings. Unfortunately, CKD is still under-appreciated, and early diagnosis is frequently missed due to the nature of its nonspecific symptoms. The clinical profiles and clinical outcomes of 338 patients on maintenance haemodialysis at KNH were examined in this study.

When compared to reports from developed countries where ESKD affects the elderly, 60 years and above, the participants in this study were relatively young (5). However, our findings are consistent with many reports from developing countries (6-8). According to a systematic review of studies conducted in Sub-Saharan Africa, the mean age ranged from 35.6 years (SD 13.2) to 58.2 years (SD 15.0) (9).

The mean age at HD initiation did not differ between the two groups (pre-NHIF and post-NHIF), indicating that even with NHIF reimbursement, there was no increase in the number of elderly patients on haemodialysis. Similarly, no difference in gender was found between the two groups. Males outnumbered females in both groups, this is consistent with studies from most other countries (5,10). Male gender is a known risk factor for CKD, hence male predominance among the ESKD population is a worldwide phenomenon (11).

In our study, the leading causes of ESKD were hypertension, diabetes, glomerulonephritis, and obstructive uropathy. Glomerulonephritis and HIV infection decreased with age, whereas diabetes alone or in combination with hypertension increased. This aetiologic profile is consistent with previous African studies (6, 8, 12-14). Diabetes and high blood pressure remained the most common documented causes of ESKD in both groups. Overall, the number of cases for the various documented causes of ESKD was noted to have increased in the post-NHIF group. However, none of these increases in number of cases were found to be statistically significant. It is well known that blacks are more likely to develop hypertension and glomerulonephritis, which may explain the aetiologic pattern of ESKD in our study. Sedentary lifestyles, obesity, and an ageing population may also contribute to the increase in the number of cases reported in this study. In addition, low levels of awareness, detection, treatment, and control of blood pressure and blood sugar are also possible contributing factors, like what has been found in other studies (15-17).

A third of the participants in our study had chronic glomerulonephritis, there was no statistically significant difference between the two groups. In a Nigerian retrospective study, 34.5% of the study population had CGN (18). In our study, CGN was presumed based on either a history of documented glomerular disease or the presence of a glomerular syndrome (proteinuria and/or haematuria, hypertension in the absence of identifiable secondary causes). Only about 6% of patients had a confirmatory kidney biopsy report, indicating a scarcity of facilities capable of performing kidney biopsies and histology at reasonable rates.

ESKD caused by HIV nephropathy was common among young people and women, mirroring the demographics of HIV infection in Africa (19). Only 6.8% of our study participants were infected with HIV, which is comparable to the 6.6% reported in Cameroon but slightly lower than the 10.4% reported in Tanzania (8,14). We noted a rise in the number of HIV cases in the post-NHIF group, though it was not statistically significant. This trend may be due to improved comprehensive care for patients with retroviral disease, as well as easy access to kidney-friendly regimens when indicated. It was difficult to ascertain how many of our patients had secondary hypertension due to a primary renal disease. Unfortunately, many

of our patients did not undergo a diagnostic kidney biopsy as part of their evaluation mainly due to the cost implications, availability of the service as well as late presentation.

Financial constraints are a well-known reason for developing countries' lack of access to KRT (20,21). Prior to the implementation of NHIF reimbursement in July 2015, nearly one-fourth (25%) of our study participants were on once-weekly haemodialysis. However, since the implementation of NHIF reimbursement, this figure significantly dropped to 1% (p value 0.04, 95%). Unfortunately, none of our patients were on thrice weekly dialysis. Failure to meet the international recommendation of thrice weekly dialysis despite NHIF reimbursement, may have contributed to the poor outcomes observed in this study. This reflects a lack of haemodialysis service sustainability, which has been observed in other countries as well (22,23). Haemodialysis is the most widely used form of kidney replacement therapy in the world (24). Inadequate infrastructure and high out-of-pocket costs limit ESKD patients' access to haemodialysis services. As a result, most patients go undiagnosed, untreated, and die prematurely.

The average duration of haemodialysis in our study was 32 months overall, but we noticed a significant decrease in HD vintage after introduction of NHIF (p value 0.04, 95%). This could partly be due to the fact that frail patients and patients thought to have a poor prognosis were now able to access haemodialysis services through the NHIF system. Furthermore, NHIF does not cover the entire cost of haemodialysis, so patients must pay out of pocket for investigations and medications. This in effect means that some patients are unable to cater for the other demands that come with ESKD as documented by Twahir *et al*(21). Third, NHIF only covers two haemodialysis sessions, which is insufficient for the majority of our ESKD patients, this translates to higher mortality and shorter haemodialysis vintage. According to a Tanzanian retrospective study, patients who were not enrolled in the NHIF scheme had a higher risk of poor outcomes (8). Many patients in Nigeria and Sub-Saharan Africa were unable to pay for the recommended adequate dialysis sessions due to high costs, with only 6.8 % of patients able to afford haemodialysis services beyond 3 months, according to studies from Nigeria and Sub-Saharan Africa (18,23).

The mortality observed in our study was high (80%), this was double what was reported by McLigeyo *et al* in 1985. More deaths were reported in the pre-NHIF group (85%) but the mortality rate remained high in the post-NHIF group (76%). This could be attributed to an increase in the number of critically ill patients being initiated on haemodialysis as well as late presentation resulting in unavoidable deaths. NHIF usually caters for two sessions per week meaning that most patients are on suboptimal treatment. Although we did not investigate the causes of death, most of our patients had diabetes and hypertension, which would invariably increase their cardiovascular risk, resulting in poor outcomes. This is consistent with the findings of a two-year retrospective study conducted in a tertiary hospital in southern Nigeria, where only 27% of patients were still alive at the end of the two years (18). Dialysis duration and number of sessions were strong predictors of survival among dialysis patients in Ghana and Lithuania (25,26). Even in resource-rich environments, the same has been reported (27).

Patients had to travel long distances to access haemodialysis services before county hospitals in Kenya began offering the services in 2015. This had a significant impact on adherence to haemodialysis appointments, resulting in premature dialysis discontinuation and hence poor outcomes (21). A systematic review conducted to investigate the outcomes of dialysis in ESKD in Sub-Saharan Africa discovered that the majority of ESKD patients starting dialysis in Sub-Saharan Africa discontinue treatment and die (9). The mortality rate among haemodialysis patients varies by country, ranging from 6% in Morocco and 10.4% in Tunisia and 12% in Algeria (28).

Other KRT options (peritoneal dialysis and kidney transplantation) are less common due to the high costs and lack of facilities (6). Only 3% of patients in our study went on to receive a kidney transplant. This could be because NHIF does not cater for post-transplant costs (medication, clinic visits, laboratory, and imaging costs), so most patients choose to stay on haemodialysis since it is already covered by NHIF. Given the high mortality rate reported in this study, we should endeavour to better support the kidney transplant program which is clearly associated with better outcomes.

Conclusion

This study demonstrated that the mortality rate was quite high during both time periods; hence the emphasis should be on prevention, early detection, and treatment of diabetes and hypertension as well as making kidney transplantation accessible and affordable to all. Hopefully, these will have a positive impact on the mortality rate of ESKD patients.

Recommendations

1. The causes of death in our haemodialysis patients should be investigated in order to identify any preventable measures that can be implemented to reduce mortality in our HD patients.
2. Timely kidney biopsies aid in more accurate diagnosis, especially in our young patient population.
3. Poor vascular access may have contributed to poor outcomes; therefore, we should advocate for early and planned vascular access in our patients.
4. Investigate the reasons for dialysis discontinuation and the factors that contribute to dialysis discontinuation. As well as the difficulties/ challenges faced by haemodialysis patients, this may aid in improving outcomes.
5. Implement electronic medical records, and create renal registries that include all CKD patients. Using such registries, it will be easier to plan for better care and ensure that patients are not lost to follow up only to reappear when they require urgent dialysis.

Study strength

The study center continues to house the country's largest haemodialysis unit. As a result, the population described in this study is very likely to be representative of the people with ESKD in the country.

Study limitations

1. Because this was a chart review, some data was missing or was poorly documented. Record keeping can be quite poor in the absence of electronic records. As a result, the amount and quality of data extracted may be suboptimal.
2. Many of our study participants did not have a histology report to confirm the cause of ESKD.
3. There was recall bias because some patients and their next of kin were unable to recall all the required details.
4. Because some of the potential participants were not reachable by phone, information on the patients' current clinical status was not easily accessible.

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