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## High prevalence of uncontrolled hypertension among patients with early chronic kidney disease attending tertiary hospitals in Dodoma, Tanzania

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#### Research Article

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## Abstract Background

The prevalence of uncontrolled hypertension has been increasing globally including Sub-Saharan Africa (SSA) accelerating the burden of chronic kidney disease (CKD), cardiovascular diseases (CVD) and noncommunicable diseases (NCDs).

## Methods

A cross-sectional study was conducted among adult patients with early-stage CKD attending the medical outpatient department (MOPD) clinics of two tertiary hospitals in Dodoma between November 2020 to March 2021. Descriptive and inferential statistics were performed using SPSS software version 26 and multivariable logistic regression analysis was used to identify variables associated with uncontrolled hypertension.

## Results

A total of 352 patients were enrolled; 64 (18.2%) were in CKD stage 2 and 288 (81.8%) in CKD stage 3, median age was 54 (47–59) years, 182 (51.7%) were males, the prevalence of hypertension was 58.5% and the prevalence of uncontrolled hypertension was 58.3%. For patients with uncontrolled hypertension, the median SBP was 146 (142–150) mmHg, the median DBP was 86(82–90) mmHg, the median BMI was 26.1 (24.0-27.5) kg/m<sup>2</sup>, the median waist circumference was 97(90–104) cm, the median eGFR of 48 (43–55) mil/min/1.73m<sup>2</sup>. Among patients with uncontrolled hypertension; 88.3% patients had CKD stage 3, 80.0% patients reported non-adherence to antihypertensives, 76.7% patients had overweight/ obesity, 72.5% patients reported current alcohol use, 60.0% patients had dyslipidemia, 43.3% patients reported current smoking, 36.7% patients had significant proteinuria and 26.7% patients had diabetes mellitus. Variables with higher odds for uncontrolled hypertension were; age  $\geq$  50 years (OR = 5.17, 95% CI 2.37–13.33, P = 0.001), alcohol use (OR = 11.21, 95% CI 3.83–32.84, P = 0.001), Overweight/obesity (OR = 6.28, 95% CI 2.54–15.53, P = 0.001), non-adherence to antihypertensives (OR = 10.19, 95% CI 4.22–24.61, P = 0.001) and CKD stage 3 (OR = 3.52, 95% CI 1.32–9.42, P = 0.012).

## Conclusion

Uncontrolled hypertension is highly prevalent among patients with early-stage CKD in our settings and it's associated with age, current alcohol use, overweight/obesity and non-adherence to antihypertensives.

### Introduction

Hypertension is a disease of major public health importance globally and it affected approximately 1.4 billion of the adult population in 2019 (1, 2). The highest burden of hypertension is in LMICs (3, 4) where uncontrolled hypertension is highly prevalent with increased risk of complications such as CKD, CVD and increased related mortality (5, 6). Most Africans with hypertension have uncontrolled hypertension associated complications such chronic kidney disease (CKD) which eventually culminates into End stage Renal Disease(ESRD) or death (7, 8). Chronic Kidney Disease (CKD) is increasing the burden of non-communicable disease (NCD) and it is estimated that the worldwide prevalence of CKD is 15.1% depending on the ethnicity, accessibility to health services and treatment of chronic conditions that increase the risk of CKD such as hypertension and Diabetes Mellitus (9, 10). Africa region reported the highest prevalence of hypertension compared to the other regions of the world at 27% in 2019 and the prevalence of CKD in Tanzania is estimated to be 13.6% where the leading cause of CKD is hypertension (11, 12).

The prevalence of hypertension in Tanzania is high, ranging between 25.7–45% in rural to urban settings respectively (13, 14). The burden of both hypertension and uncontrol hypertension is expected to increase significantly due to increasing urbanization and ongoing epidemiological transition in Tanzania and the rest of LMICs. A systematic review and meta-analysis which assessed the prevalence of uncontrolled hypertension among patients with comorbidities in SSA reported the overall prevalence of 78.6%; with a 75.9% prevalence among those with CKD while in a cross-sectional study among hypertensive adult patients in Ethiopia; the prevalence uncontrolled hypertension was 48.6% (15)(16). Previous studies conducted in Dar es Salaam, Mwanza and rural areas in Tanzania have reported high prevalence of uncontrolled hypertension especially among those with comorbidities to be 66%, 70.1% and 84.5% respectively (17)(18)(19). Studies have reported older age, male sex, poor adherence to antihypertensive medication, low diet quality, physically inactivity, and comorbidity conditions such as CKD were identified to be factors associated with uncontrolled hypertension (4, 18, 20–22) Uncontrolled hypertension become increasingly prevalent as the stage of CKD advances and studies among patients with early-stage CKD are very few. The aim of this study was to determine the prevalence of uncontrolled hypertension and its associated factors among patients with early-stage CKD attending at medical outpatient clinics in tertiary hospitals in Dodoma, Tanzania.

### **Materials And Methods**

## Study design, population and settings

This was a cross-sectional study of adult patients  $\geq$  18 years with early-stage CKD, who were attending at medical outpatient clinics (nephrology, diabetes mellitus (DM) and hypertension outpatient clinics) at BMH and DRRH in Dodoma, Dodoma is the capital city of Tanzania. Inclusion criteria included; Patients  $\geq$  18 years of age, attending the clinic for at least 3 months, eGFR of above 120 ml/min/1.73m<sup>2</sup>, eGFR of above 30 ml/min/1.73m<sup>2</sup> and a written informed consent.

## Data collection and laboratory procedures

We enrolled patients using serial sampling technique and categorized based on their eGFR as per Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula based on data from ongoing continuous medical OPD clinic records, upon recruitment they were informed on the nature of the study, procedures and laboratory testing to be done. After consenting to participate in the study, we conducted face to face interviews to collect data on age, gender, history of smoking, alcohol, comorbidities such as DM, hypertension and adherence to antihypertensives using a morisky medication adherence scale. We measured weight, height, waist circumference, blood pressure and blood glucose; systolic and diastolic blood pressure was measured 3 times, the average of the 2nd and 3rd measurements was used (23) and body mass index (BMI) was calculated using the National Health Services (NHS-UK) BMI calculator (24). Laboratory tests for standard of care were carried out at the BMH main laboratory using the Cobas 6000 analyser (Roche Diagnostics, USA). The laboratory tests performed were urinary protein creatinine ratio (uPCR), serum creatinine, BUN, HbA1C, FBG, FBP and lipid profile. Serum creatinine was measured using the isotope dilution mass spectrometry (IDMS) traceable assay (7, 25) and lipid profile were calculated using the Creating Rate (eGFR) were calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) Eq. (27–29).

## Definition of operational variables

Chronic Kidney Disease (CKD) was defined as the progressive reduction of the kidney function with an estimated glomerular filtration rate (eGFR) of less than 60 ml/min/1.73m<sup>2</sup>) that has persisted for duration of 3 months or more irrespective of the cause(s) (30). Uncontrolled BP was defined according to the Joint National committee-8 (JNC-8) as a Systolic Blood Pressure and Diastolic Blood Pressure  $\geq$  140 mmHg and >\_90 mmHg respectively among hypertensive patients (31). Adherence to antihypertensives was defined according to the Morisky Medication Adherence Scale where by Morisky score of  $\leq$  2 represent nonadherence and a Morisky score > 2 represented good adherence(4).

## Data management and analysis

Data analysis was done using IBM SPSS statistics (version 26) predictive analytics software, any errors were cross-checked and data cleaning was done. Descriptive statistics were used to summarize variable as proportions and frequency tables for categorical variables. Depending on whether variables were normally distribution, median with interquartile range were used to summarize continuous data and difference between those with normotensive, controlled and uncontrolled hypertension were compared using the Chi square test for normally distributed variables and Mann-Whitney U test for not-normally distributed variables. Logistic regression was performed to assess the relationship between uncontrolled hypertension and associated variables using the crude and adjusted odds ratio (OR) with the 95% confidence interval (CI) for significant differences between the groups. Variables with p-value less than 0.2 on univariate logistic regression models were then fitted into the multivariate logistic regression models were then fitted into the significant strength of association.

### Results

A total of 658 patients attended renal, hypertensive, diabetic and general MOPD clinics during the 4 months of enrollment. Of the 658 patients who attended the medical outpatient clinic during the study period, 306 patients were excluded from the study including 234 patients who didn't have CKD, 69 patients had Advanced CKD (CKD stage 4 & 5) and 3 patients didn't provide consent. A total of 206 (58.5%) enrolled patients had hypertension, of whom 120 (58.3%) patients had uncontrolled hypertension (Figure 1).

#### Baseline and demographic characteristics of study patients

A total of 352 patients with median age of 54 (47-59) years met the criteria to be included in this study; 182 (51.7%) were male, 252 (71.6%) were married, 205 (58.2%) living in urban areas and 258 (73.3) had at-least secondary level education. A total of 206 (58.5%) patients had hypertension, of whom 120 (58.3%) patients had uncontrolled hypertension. For those with uncontrolled hypertension the median age was 55(50-60) years, 48(45-56) years for those with controlled hypertension and 54(48-59) years for normotensive participant. The median systolic blood pressure (SBP) was 146(142-150) mmHg for those with uncontrolled hypertension, and 125(120-128) mmHg for those with controlled hypertension, the median diastolic blood pressure (DBP) was 86 (82-90) mmHg for those with uncontrolled hypertension and 80(76-84) mmHg for those with controlled hypertension and 24.4(23.4-26.0) kg/m<sup>2</sup> for those with controlled hypertension and 90(84.5-103.0) mmHg for those with controlled hypertension and 90(84.5-103.0) mmHg for those with uncontrolled hypertension and 90(84.5-50) mil/min/1.73m<sup>2</sup> for those with uncontrolled hypertension and 53(45-62) mil/min/1.73m<sup>2</sup> for those with controlled hypertension and 53(45-62) mil/min/1.73m<sup>2</sup> for those with controlled hypertension (Table 1).

# Table 1: Socio-demographics and Clinical data of patients with early CKD by their hypertensive status (n=352)

	Uncontrolled hypertension	Controlled hypertension	Normotensive (n=146)	
Variables	(n=120)	(n=86)		p- value
	Median (IQR) or Proportion	Median (IQR) or Proportion	Median (IQR) or Proportion	
Age (years)	55 (50-60)	48 (45-56)	54(48-59)	0.001
Sex				
Male	61(50.8%)	48(55.8%)	73(50%)	
Female	59(49.2%)	38(44.2%)	73(50%)	0.631
Marital status				
Married	87(72.5%)	57(66.3%)	111(76.0%)	
Single	33(27.5%)	29(33.7%)	35(24.0%)	0.399
Level of education				
Primary or less	38(31.7%)	19(22.1%)	50(34.2%)	
Secondary and above	82(68.3%)	67(77.9%)	96(65.8%)	0.221
Residence				
Rural	58(48.3%)	32(22.1%)	58(39.7%)	
Urban	62(51.7%)	54(77.9%)	88(60.3%)	0.232
Occupation				
Employed	49(40.8%)	30(34.9%)	41(28.1%)	
Self-employed	71(59.2%)	56(65.1%)	105(71.9%)	0.712
NHIF status				
Insured	47(39.2%)	31(36.0%)	70(47.9%)	
Not insured	73(60.8%)	55(64.0%)	76(52.1%)	0.093
SBP (mmHg)	146(142-150)	125(120-128)	122(120-128)	0.001
DBP (mmHg)	86(82-90)	80(76-84)	78(76-82)	0.001
BMI (Kg/m <sup>2</sup> )	26.1(24.0-27.5)	24.4(23.4-26.0)	25.5(24.4-30.8)	0.001
Waist circumference (cm)	97(90-104)	90(84.5-103.0)	91.5(81.0-104.0)	0.003
Hb (g/dl)	12.4(10.9-13.2)	12.6(11.4-13.2)	12. 3(11.0- 13.2)	0.289

FBG (mmol/L)	5.3(4.9-6.2)	5.1(4.9-5.7)	5.0(4.8-5.5)	0.001
HbA1c (%)	6.2(5.8-6.7)	5.6(5.0-6.0)	5.8(5.7-6.2)	0.020
Creatinine (umol/L)	130.9(123.0-138.9)	124.2(120.5-137.7)	119(116.4-132.2)	0.025
eGFR (mil/min/1.73m <sup>2</sup> )	48(43-55)	53(45-62)	55(53-61)	0.001
BUN (mmol/l)	8.0(7.2-8.9)	7.4(6.9-8.3)	6.7(6.4-7.4)	0.013
uPCR	0.025(0.025-0.130)	0.025(0.02-0.027)	0.025(0.025-0.120)	0.001
Total Cholesterol(mmol/l)	5.4(4.5-6.0)	4.8(4.1-5.9)	4.0(4.1-4.7)	0.164
Triglycerides(mmol/l)	4.6(1.5-5.4)	1.6(1.5-5.0)	1.3(1.5-4.8)	0.251
HDL-C(mmol/l)	1.2(0.8-1.4)	1.3(0.9-1.7)	1.3(0.8-1.5)	0.008
LDL-C(mmol/l)	3.8(3.1-4.4)	3.3(3.0-4.0)	3.5(3.1-4.2)	0.200

Abbreviations: BMI, Body mass index; BUN, blood urea nitrogen; CKD, chronic kidney disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; FBG, Fasting blood glucose; Hb, Hemoglobin; HbA1c, glycosylated hemoglobin; HDL, high density lipoprotein; IQR, Interquartile range; LDL, Low density lipoprotein; NHIF, national health insurance fund; SBP, systolic blood pressure; uPCR, urine protein-creatinine ratio.

#### Clinical profile of study participants

Of the 120 patients with uncontrolled hypertension, 88.3% patients had CKD stage 3, 80.0% patients reported non-adherence to antihypertensives, 76.7% patients had overweight/obesity, 72.5% patients reported current alcohol use, 60.0% patients had dyslipidemia, 43.3% patients reported current smoking, 36.7% patients presented with significant proteinuria and 26.7% patients had diabetes mellitus (Table 2)

#### Table 2: Clinical profile of patients with early CKD by their hypertensive status (n=206)

Variables	Uncontrolled hypertension	Controlled hypertension	p- value
	(n=120), Proportion (%)	(n=86), Proportion (%)	
Age (years)			
<50	26 (21.7%)	47(54.7%)	
>_50	94(78.3%)	39(45.3%)	0.001
Current alcohol use			
No	33(27.5%)	56(65.1%)	
Yes	87(72.5%)	30(34.9%)	0.001
Current smoking			
No	68(56.6%)	61(70.9%)	
Yes	52(43.3%)	24(29.1%)	0.028
Diabetes mellitus status			
No	88(73.3%)	73(84.9%)	
Yes	32(26.7%)	13(15.1%)	0.048
Adherence to antihypertensives (Morisky score)			
<_2	24(20.0%)	51(59.3%)	0.001
>2	96(80.2%)	35(40.7%)	
Overweight or obesity			
No	28(23.3%)	45(52.3%)	
Yes	92(76.7%)	41(47.7%)	0.001
Anemia status			
No	70(58.3%)	56(65.1%)	
Yes	50(41.7%)	30(34.9%)	0.326
CKD stage			
Stage 2	14(11.7%)	29(33.7%)	
Stage 3	106(88.3%)	57(66.3%)	0.001
Lipid profile			
Normal	48(40.0%)	48(55.8%)	
	Page 8/19		

Impaired	72(60.0%)	38(44.2%)	0.025
uPCR			
<0.03	76(63.3%)	75(87.2%)	
>_0.03	44(36.7%)	11(12.8%)	0.003

Abbreviations: CKD, chronic kidney disease; uPCR, urine protein-creatinine ratio.

#### Factors associated with uncontrolled hypertension

We divided the patients into two subgroups [(uncontrolled hypertension  $\geq$ 140/90mmHg) vs. (controlled hypertension <140/90mmHg)]. A total of 15 potential variables were identified after performing univariate logistic regression analyses. Backward elimination reduced this to 10 parameters; the factors independently associated with uncontrolled hypertension on multivariate logistic regression analysis included: age  $\geq$  50 years (OR =5.17, 95 % CI 2.37-13.33, P = 0.001), alcohol use (OR = 11.21, 95% CI 3.83-32.84, P = 0.001), Overweight and Obesity (OR=6.28, 95% CI 2.54-15.53, P = 0.001), non-adherence to antihypertensives (Morisky score >2) (OR =10.19, 95% CI 4.22-24.61, P = 0.001) and CKD stage 3 (OR=3.52, 95% CI 1.32-9.42, P = 0.012). Current history of smoking, proteinuria, and dyslipidemia were statistically significantly associated with uncontrolled hypertension on the univariate logistic regression analysis (Table 3).

#### Table 3: Factors associated with uncontrolled hypertension (n=120)

Variables	No of patients	Univariate		Multivariate	
		COR (95% CI)	P- value	AOR (95% CI)	P- value
Age					
<50	26	Ref			
≥ 50	94	4.36 (2.37- 8.01)	<0.001	5.62 (2.37- 13.33)	0.001
Residence					
Urban	58	Ref		Ref	
Rural	62	1.50(0.86- 2.64)	0.156	1.43 (0.64-3.18)	0.379
Alcohol					
No	33	Ref		Ref	
Yes	87	7.85 (3.70- 16.64)	<0.001	11.21(3.83- 32.84)	0.001
Smoking					
No	68	Ref		Ref	
Yes	52	1.94(1.07- 3.52)	0.028	1.76 (0.77-4.03)	0.179
Diabetes mellitus status					
No	88				
Yes	32	2.04(0.99- 4.18)	0.050	1.32(0.45-3.81)	0.613
Overweight or Obesity					
Normal	28	Ref		Ref	
Increased	92	3.61 (1.98- 6.56)	<0.001	6.28 (2.54- 15.53)	0.001
Adherence to antihypertensives					
≤2	24	Ref		Ref	
>2	96	5.83(3.13- 10.84)	<0.001	10.19 (4.22- 24.61)	0.001
CKD stage					
Stage 2	14	Ref		Ref	

Stage 3	106	3.85(1.89- 7.87)	<0.001	3.52(1.32-9.42)	0.012
Proteinuria					
No	76	Ref		Ref	
Yes	44	2.74(1.40- 5.35)	0.003	2.24(0.81-6.24)	0.121
Lipid profile					
Normal	48	Ref		Ref	
Impaired	72	1.90(1.08- 3.32)	0.026	1.39(0.61-3.12)	0.432

Abbreviations: 95% Cl, 95% Confidence interval; AOR, Adjusted odds ratio; CKD, chronic kidney disease; OR, odds ratio.

### Discussion

This study evaluated the prevalence of uncontrolled hypertension and its associated factors among patients with early-stage CKD attending medical outpatient clinics in tertiary hospitals in Dodoma, Tanzania. The prevalence of uncontrolled hypertension among patients with early CKD in our study was 58.3%, this is lower than findings from other studies which reported 66% in Muhimbili, 70.1% in rural Tanzania and 84.5% in Mwanza (17–19). Our study findings are also lower compared to a systematic review and meta-analysis of uncontrolled hypertension among patients with comorbidities in SSA which reported the prevalence ranging between 75.9% and 78.6% among patients with CKD (15) while the prevalence of uncontrolled hypertension among hypertensive adult patients in different parts of Ethiopia ranged from 48.0% -56.7% (16,20,32) which is lower to our study findings. These differences could be accounted by variations in the studied populations; the other studies included also patients who had advanced CKD and they were conducted at are different geographical areas compared to Dodoma with different levels of urbanization.

Hypertension tends to develop and/or get worse as the CKD progresses and patients with advanced CKD have increased odds for uncontrolled hypertension (30,33,34). In this study, 81.8% participants had CKD stage 3, CKD stage 3 had 3.5-fold increased odds for uncontrolled hypertension. Advanced CKD is a risk factor for uncontrolled hypertension have been reported from previous studies conducted elsewhere in SSA (35,36). About one third (36.7%) patients with uncontrolled hypertension presented with significant proteinuria, similar findings have been reported from other studies; 36.6% in Tanzania and 35.6% in a study done in rural parts of eastern province of Zambia but was 47.6% in a study done in Nigeria (37) (38)(39). This could be due to the fact that most (71.4%) of our study participants were already on antiproteinuric agents including angiotensin converting enzyme inhibitors (ACEIs)/angiotensin receptor blockers (ARBs) prior to enrollment into this study. There was a trend towards increased risk of

uncontrolled hypertension with increasing proteinuria but in this study, proteinuria lost its statistical significance after the multivariate binary regression analysis.

Age is an increased risk of CKD progression whereby younger age at onset and increasing age is associated with a more rapid progression of CKD to ESRD (8,40). The median age of participants with uncontrolled hypertension was 55 (50-60) years which is significantly higher than 48 (45-56) years for those with controlled hypertension. These finding has been observed in previous studies in LMICs whereby despite the fact that the age of onset of CKD in SSA is significantly higher in younger people compared to developed countries where CKD is the disease of old age (23,41). Age  $\geq$  50 years had 5 times increased risk for uncontrolled hypertension among patients with early-stage CKD; previous studies have reported that uncontrolled hypertension is associated with increasing age in CKD (8,16).

Most (64.6%) hypertensive patients reported overweight/obesity of which 76.7% had uncontrolled hypertension, this findings are higher than a study done in Dar-es Salaam, Tanzania where the prevalence of overweight/obesity was 67.2% and lower than a cross-sectional study in Mwanza, Tanzania which reported a prevalence of 92.2% (19,42). Overweight and obesity had 6fold increased odds for uncontrolled hypertension; Tanzania and other countries in the third world are undergoing epidemiological transition associated with urbanization and sedentary life style with increasing obesity, dyslipidemia, hypertension, diabetes, ischaemic heart disease and CKD (16,27,43,44). This discrepancy in prevalence in these studies can be attributed to differences in study populations and extent of urbanization between the cities. The prevalence of dyslipidemia among individuals with uncontrolled hypertension and CKD is high and is associated with significant risk of morbidity, mortality from CVD and rapid progression of CKD to ESRD and adverse renal outcomes (45,46)(47). The prevalence of dyslipidemia among patients with uncontrolled hypertension was 60.0%; previous studies reported a prevalence range of 45.5%-67.8% across the CKD stage I to CKD stage IV respectively(48,49). There was a trend towards increased risk of uncontrolled hypertension with dyslipidemia but in this study, dyslipidemia lost its statistical significance after the multivariate binary regression analysis.

Most (56.8%) of our participants reported using alcohol, of which 72.5% had uncontrolled hypertension, lower than the 66.5% reported from a community based cross-sectional study done in Dar-es Salaam. Alcohol use was 11 times more associated with uncontrolled hypertension, similar findings have been reported from previous studies (42,50). This difference in prevalence can be attributed to differences in geographical area and the population studied. A bout one third (36.9%) of patients with uncontrolled hypertension had history of current cigarette/tobacco smoking, similar to findings from a prior study among CKD patients conducted in Dodoma where the prevalence of current smoking was 34.9% (12). Smoking has been associated with uncontrolled hypertension in other studies done in SSA (50,51) unlike this study cigarette smoking was not associated with uncontrolled hypertension after multivariate analysis.

Most patients (62.1%) with uncontrolled hypertension were not adhering to their antihypertensives as they had a morisky score >2, non-adherence to antihypertensives had 10-fold increased risk for uncontrolled

hypertension in our study. The prevalence of non-adherence was lower than the previous findings of 17.9% reported in Tanzania and higher findings of non-adherence of 66.7% were reported in Nigeria and 67.7% in Cameroon, non-adherence was among the important reasons for high rate of uncontrolled hypertension in SSA (4,18,19,22). This difference can be attributed to differences in operational definition of non-adherence and population studied.

### Conclusion

Uncontrolled hypertension is highly prevalent among patients with early CKD and it's associated it's associated with age, current alcohol use, overweight/obesity and non-adherence to antihypertensives and increasing CKD stage. Clinicians should strive to make sure that both pharmacotherapy and lifestyle modifications are adhered to by patients with hypertension so as to control their blood pressure which is a major risk factor for CKD.

### **Abbreviations**

BMH: Benjamin Mkapa Ultramodern Hospital; CKD: chronic kidney diseases; CKD-EPI: chronic kidney disease epidemiology collaboration; DRRH: Dodoma Regional Referral Hospital; eGFR: estimated glomerular filtration rate; ESRD: end stage renal disease; IDMS: isotope dilution mass spectroscopy; KDIGO: kidney disease improving global outcomes; LMICs: Low- and Middle-Income Countries; MOPD: Medical Outpatient Department; NCDs: non communicable diseases; NHIF: national health insurance fund; UDOM: University of Dodoma.

### Declarations

#### Ethics approval and consent to participate

Ethical approval was granted by the University of Dodoma ethical committee (Reference number: MA.84/261/02) prior to conducting this study. Patients were informed on the study and provided a written informed consent. All methods and procedures were performed in line with the principles of the Declaration of Helsinki and its later modifications.

#### Consent for publication

Not required

#### Availability of data and materials

Data cannot be shared publicly because of ethics policy at University of Dodoma, the participants signed a consent form, which states that data is exclusively available for professional research staff however study data can be obtained by anyone who meets criteria to access the data upon a reasonable request from the Director of research, publications and consultancy of the University of Dodoma who can be contacted through the email; research@udom.ac.tz

#### **Competing interests**

The authors declare that they have no competing interests.

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#### Author's contributions

DDK; participated design of the work/preparation of research proposal, collection of clinical data of patients, data analysis and manuscript writing, AM: Preparation of research proposal, collection of clinical data, data analysis and manuscript writing.

All authors have read and approved the final manuscript

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### Figures

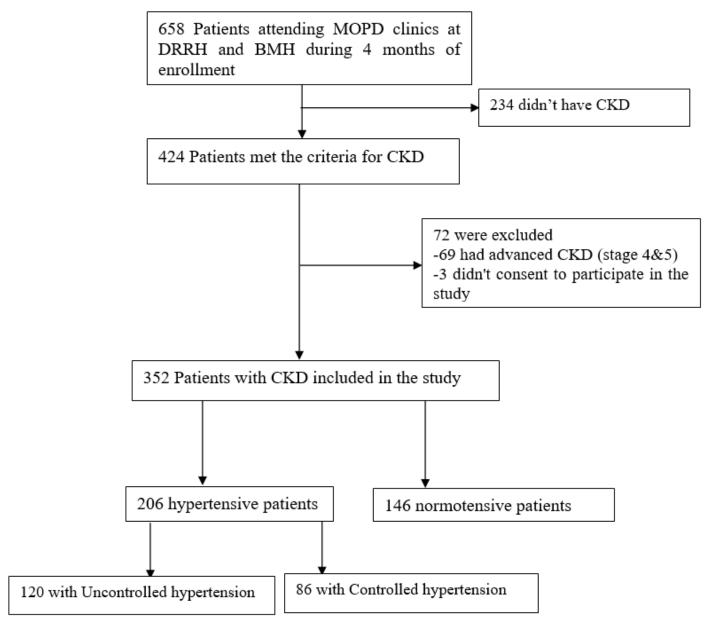


Figure 1; Enrollment flowchart for our study participants

#### Figure 1

See image above for figure legend