KAIRUKI UNIVERSITY

DISSERTATION REPORT

TITLE: DIAGNOSTIC VALUE OF URINARY ALBUMIN-TO-CREATININE RATIO AMONG WOMEN WITH PRE-ECLAMPSIA AT AMANA REGIONAL REFERRAL HOSPITAL IN DAR ES SALAAM 2025

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DISSERTATION SUBMITTED TO THE FACULTY OF MEDICINE IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MATERS OF MEDICINE IN OBSTETRICS AND GYNECOLOGY OF KAIRUKI UNIVERSITY.

2025

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Kairuki University, a proposal for the dissertation titled "DIAGNOSTIC VALUE OF URINARY ALBUMIN-TO-CREATININE RATIO AMONG PREGNANT WOMEN WITH PRE-ECLAMPSIA IN DAR S SALAM "in partial fulfilment of the requirements for the degree of Master of Medicine in obstetrics and Gynaecology at Kairuki University. The work was carried out under the supervision of Dr. Monica Chiduo Lecturer, Department of Obstetrics and Gynecolog

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Date: 17/10/2025

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Date: 17/10/2025

DECLARATION AND COPYRIGHT

I, Theresia Mboya certify that this Research proposal titled "Diagnostic value of urinary Albumin-to- Creatinine Ratio among pregnant women with preeclampsia in Dar es Salaam". It has neither been presented nor will it be presented to any other University for the degree award, except were indicated by specific reference in the text. This work is my work; I have identified all material in this dissertation that is not my work through appropriate reference

Signature…… Date 17/10/25

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LIST OF `ABBREVIATIONS`

ACR	Albumin creatinine ratio
ARRH	Amana Regional Referral Hospital.
BMI	Body Mass Index
BP	Blood Pressure
DM	Diabetes mellitus
KU	Kairuki University.
IUGR	Intrauterine growth restriction
LBW	Low birth weight
L-MICS	Low- middle-income countries
PE	Preeclampsia
PIH	Pregnancy-induced hypertension
PPH	post-partum hemorrhage
SACR	Spot albumin-creatinine ratio.
SPCR	Spot protein-creatinine ratio.
SSA	Sub-Saharan Africa
WHO	World Health Organization
MMR	Maternal mortality rate
TDHS	Demographic and Health Survey
SPSS	Statistical Package for Social Science
UACR	Urine Albumin for Creatinine Ratio

Operational definitions

Hypertensive disorders in pregnancy refer to an elevation of blood pressure (BP) of 140/90 mm Hg or greater measured on two occasions at least four hours apart during pregnancy(1),(2).

Gestational Hypertension: High blood pressure is more or equal to 140/90 mm Hg blood pressure that develops after 20 weeks of gestation without proteinuria or other signs of preeclampsia(3).

-Evidence of preeclampsia/eclampsia and hypertension that resolves by 12 weeks of the postpartum period.

Preeclampsia

A multi-system disorder characterized by new onset hypertension and proteinuria or hypertension with significant end-organ dysfunction (e.g. renal insufficiency, liver dysfunction, neurological symptoms) after 20 weeks' gestation(4).

Chronic Hypertension

High blood pressure more or equal to140/90 mm Hg present before pregnancy or diagnosed before 20 weeks of gestation(1),(5).

Chronic hypertension with superimposed preeclampsia

Chronic hypertension with the new onset proteinuria or other features preeclampsia after 20 weeks of gestation(5).

Sensitivity

The proportion of people with the disease who have positive test for the disease.

Specificity

The proportion of people without the disease who have a negative test.

Positive Predictive Value

Probability of a disease in a patient with positive (abnormal) test results.

Negative Predictive Value

Probability of not have the disease when the test result is negative.

True Positive (TP): Number of correctly identified positive cases.

False Negative (FN): Number of actual positive cases incorrectly identified as negative.

ABSTRACT

Background: Pre-eclampsia remains a leading cause of maternal and neonatal morbidity, in particularly in resource-limited settings. Proteinuria is among the most predictive indicators of preeclampsia and eclampsia. The Gold standard method for evaluating proteinuria in pre-eclampsia being 24-hours urinary protein level. However, Urine dipsticks method has been used as an alternative for 24-hours protein in diagnosis of PE under clinical settings in resource limited areas. Urine dipstick is unjustifiably cumbersome and inaccurate. Urinary albumin-for-creatinine can be an alternative test and accurate but its application in local environment of Tanzania has not been reported before.

Objective: To determine diagnostic value of urine albumin-to-creatinine ratio among women with Preeclampsia from January 2025 to May 2025.

Methodology: A prospective cohort hospital-based study was conducted at Amana regional referral hospital in Dar es Salaam. Structured questionnaires were the main tool of data collection and data was analyzed using SPSS version 25.0. Sensitivity, specificity and predictive values were assessed. Neonatal, maternal, and other factors associated with maternal UACR were analyzed using multivariable binary logistic regression model. UACR ≥0.3 mg/mmoL was used as cut-off point for elevated UACR and used to signify significant proteinuria in the studied sample.

Results: We recruited and analyzed a total of 576 different expectant women. There were 288 women with pre-eclampsia (exposed) and 288

women without pre-eclampsia (unexposed). Median age of study participants was 28 (IQR): 24 – 33) years. Median gestation age at entry into the follow-up study among study participants was 24 (IQR: 22- 25) weeks. The present study findings demonstrated Urine Albumin to Creatinine Ratio (UACR) sensitivity of 90.7 % and specificity of 90.1 %. Negative predictive value of UACR was 95.8% while the positive predictive value was 75.7%. Both neonatal (Apgar score at 5^{th} minute –Adjusted Odd Ratio (AOR): 1.07, 95% 1.0 – 1.3; neonatal birth weight – AOR.: 2.0, 95% C.I.: 1.2 – 2.9 kgs) as well as maternal (gestational age at delivery – AOR.: 1.1, 95% C.I.: 1.0 – 1.62 weeks; SBP – AOR.: 1.01, 95% C.I.: 1.0 – 1.7; DBP – AOR.: 1.12, 95% C.I.: 1.0 – 1.97) were statistically significantly associated with maternal urinary albumin to creatinine ratio.

Conclusion☹

Urine albumin-to-creatinine ratio (UACR) has yielded appreciable predictive values, sensitivity and specificity indices for diagnosis of pre-eclampsia in the second trimester in this study population. Maternal systolic and diastolic BP as well as gestational age at delivery were found to be significant risks associated with UACR.

Recommendations: Urine albumin-to-creatinine ratio can be used as an alternative method in the diagnosis of pre-eclampsia in resource limited settings.

CHAPTER ONE: INTRODUCTION

1.1 Background

Pre-eclampsia is a multi-system hypertensive disorder of unknown etiology that is unique to human pregnancy(6). The pathology is characterized by the abnormal vascular response after placentation that leads to functional changes such as increased systemic vascular resistance, enhanced platelet aggregation, activation of the coagulation system, and endothelial cell dysfunctions(7). On clinical grounds, the clinical nosology of pre-eclampsia is a result of generalized vasospasms, fibrin, platelet deposition and occlusion of blood flow to vital organs(8). In severe cases, the liver is affected where sub capsular hemorrhage, necrosis and edema of the hepatocytes occurs producing epigastric pain and impaired liver functions(9). The pathology may also involve the CNS, and the brain may become edematous(8,10). Pre-eclampsia affects 5%-10% of all pregnancies with nearly universal presentation to all population groups globally(11, 12).

The study done here in Tanzania reported that there is a high proportion of women with severe maternal outcomes attributable to severe preeclampsia and eclampsia, with a reduced proportion of maternal deaths(13). This signifies a probable advance of the performance in our facility in dealing with patients with severe morbidity due to severe preeclampsia and eclampsia.However, more effort should be put to further reducing maternal mortality(6),(7).

Previous studies affirms that pregnancy-induced hypertension continues to be rampant globally and is associated with high perinatal and maternal mortality and morbidity(14),(13). It is still one of the most important and fascinating unsolved problems in obstetrics. Hypertensive disorders in pregnancy account for approximately 7 to 15% of all pregnancies and nearly 25% of antenatal ward admissions(14),(13). The condition complicates about 10% of pregnancies and is responsible for 14% of maternal deaths, 15% of perinatal deaths, and 30% of maternal near misses worldwide(14),(15).

The other study done in India reported that urine albumin- creatinine ratio (ACR) is a known method of measurement of microalbuminuria(16). Microalbuminuria may be an early marker of endothelial dysfunction which can lead to various complications during the course of pregnancy(15),(16). However, the study`s median urine ACR was 18 (IQR: 9.43-25.25) mcg/mg(16). Prevalence of microalbuminuria was 19.2%(16). It was observed that urine ACR levels were significantly higher in women with maternal complications like GDM, gestational hypertension, preeclampsia, and preterm labor(16). Also, the mean urine ACR of women who developed pre-eclampsia was higher (37.53±31.85) compared to women who developed gestational hypertension (27.40±9.71) (16). Urine ACR level was significantly higher in babies with low APGAR scores and in babies who needed NICU admission (p-value < 0.05) (16). However, it is not clear whether these findings from India could be representative to Tanzanian population.

Hypertension remains a common complication of pregnancy with pre-eclampsia particularly associated with substantial risk to both the mother and fetus.

Tanzania is among the sub-Saharan African countries with a high maternal mortality rate (MMR) of 556 per 10,000 live births, contributing to the world's high MMR(17). The Tanzania Demographic and Health Survey (TDHS) of the year 2015–2016 reported that 16% of MMR was due to preeclampsia and eclampsia (17). In the Mwanza region, eclampsia and severe preeclampsia accounted for about 26.2% of all deaths(18). The diagnosis of preeclampsia demands evidence of hypertension with proteinuria from the 2nd trimester of gestation(1),(19),(20). The gold standard method for proteinuria evaluation is the 24-hour urine collection(1). However, that method is cumbersome, time consuming and intolerable by both patients and the health system and delays in decision making(1),(19).

There are several ways to evaluate proteinuria in pregnant women, but the gold standard remains the 24-hour urine albumin (24-h UA) excretion(1),(19). Spot urine albumin-creatinine ratio (UACR) has been reported to reflects rapid diagnosis of PE which is fast, reliable, and easy to use(19),(20). Another study from a care center conducted in India to assess the accuracy of spot UACR with 24-h UA for detecting proteinuria in antenatal women to diagnose PE and to evaluate the obstetric outcome in

antenatal women with PE showed high sensitivity (85.7%) and specificity (95.2%) making it a practical and efficient tool for early detection and monitoring of proteinuria in PE (21).

Moreover, another study done from Denmark declared that proteinuria refers to increased excretion of all proteins through the urine, while albuminuria refers to increased urinary excretion of albumin, which is the predominant urinary protein(22). The Urine dipstick tests are not a reliable means to screen for albuminuria in the Emergency Department (ED) setting (22,23).

A recent published report that explored about correlation coefficient (r) between 24-hour urine protein and spot PCR among 150 patients sample found it to be 0.734 which was highly significant ($p<0.001$)(24). In this study, population the ROC curve analysis revealed a sensitivity of 90.3% and specificity of 97.3% with AUC 0.958 for a cut-off value of spot PCR as 0.43 to detect significant(24). However, these findings have not been replicated in Tanzanian settings.

Those studies above have summarized more in detail the review articles that have been published and retrieved online. Thus, it is of interest to test the diagnostic yield of urine albumin-to-creatinine ratio in a sample of gravid women at Amana Regional Referral Hospital in Dar es Salaam.

1.2 Problem statement

Diagnostic challenges in the detection of hypertensive disorders of pregnancy are rampant in resource limited settings including Tanzania. The consequence of which is inappropriate diagnoses and/or failure to diagnose (and consequently manage) patients when the condition is present. One of the significant clinical markers for detection of pre-eclampsia and eclampsia is proteinuria. The gold standard of detecting proteinuria in pregnant women include assessment of 24-hours urine for protein (1),(2). However, that is not currently practiced in Tanzania.

The method has been considered unjustifiably cumbersome because it is inconvenient and insensitive with over and under collection of urine, time consuming as well as reported delays in decision making. It is therefore almost abandoned in clinical practice, not only in Dar es Salaam but globally (1,19). Majority of health facilities have been using a quick, cheaper and alternative option (urine dipstick) (25). However, urine dipstick has been reported to be neither reliable nor specific (prone to false positives) as it sometimes fails to pick proteinuria (when present) as well as picking up spurious proteinuric states, some non-pathological(1),(19). Besides, diagnostic challenges in pre-eclampsia have been cited from investigators in both urban and rural areas of Tanzania(25),(26).

There is also a gap in accuracy, efficiency of diagnostic value of tools for proteinuria as well as urine-based albumin-to-creatinine ratio in pregnant women in resource limited settings like Tanzania. Most available data are in non-gravid women and adult men, and for diagnoses distant from obstetrics(27),(28). Specifically, the gap includes the fact that current local practice for diagnosing pre-eclampsia involves utilization of urine dipsticks for protein, which are meant to be screening tools rather than being diagnostic tools(25). The cornerstone of all that being ineffective management of pre-eclampsia/eclampsia as well as unreliable data when needed.

1.3 Rationale of the study

Albumin-to-creatinine ratio has a higher predictive value for diagnosis of pre-eclampsia in the 2nd trimester compared to urine dipstick thus for this reason it can be detected as early as the first 20 weeks' gestation up to delivery. This will help minimize the complications of pre-eclampsia or will help us do a close follow-up of these patients to minimize maternal and neonatal outcome complications.

There may be potential data-based evidence to convince the Ministry of health and other policymakers on better approaches towards diagnosing proteinuria in pre-eclampsia; unlike the current urine dipstick method in the detection of proteinuria, something that has been proven to be inaccurate.

It will also assists healthcare providers identify high-risk pregnancies thus providing early interventions, closely monitoring, and prevention of

progression of PE thus reducing the maternal and neonatal outcome complications.

1.4 Research questions

1. What is the sensitivity of urine albumin-to-creatinine ratio in prediction of pre-eclampsia among pregnant women?
2. What is the specificity of urine albumin-to-creatinine ratio in the detection of pre-eclampsia among pregnant women?
3. What is the association of urine albumin-to-creatinine ratio on progression (severity) of pre-eclampsia among gravid women?
4. What is the association of urine albumin-to- creatinine ratio with maternal outcomes among women with pre-eclampsia?
5. What is the association of urine albumin-to- creatinine ratio with neonatal outcomes among women with pre-eclampsia?

1.5 Objectives.

1.5.1 Broad objective:

To determine the diagnostic value of urine albumin-to-creatinine ratio among pregnant women with Preeclampsia at Amana Regional Referral Hospital, Dar es Salaam, Tanzania from January 2025 to May 2025.

1.5.2 Specific objectives

1. To assess the sensitivity of urine albumin-to-creatinine ratio in the detection of pre-eclampsia
2. To assess the specificity of urine albumin-to-creatinine ratio in the prediction of preeclampsia
3. To assess the association of urine albumin-creatinine ratio with maternal outcomes among women with preeclampsia.
4. To assess the association of urine albumin-creatinine ratio with neonatal outcomes among women with preeclampsia

1.6 Theoretical framework/ conceptual model

Preeclampsia is a multi-system disorder catheterized by a new onset of hypertension and proteinuria or hyphenation with significant end-organ dysfunction after 20 weeks' gestation. Pre-eclampsia is a global burden, especially in low and middle-income settings like Tanzania. A two-stage model of preeclampsia proposed ``poor placentation`` with un-modelling of spinal arteries of the pathway leading to maternal epithelial dysfunction. A stage 1 (pre-clinical) occurs in the first half of pregnancy before development of maternal clinical signs (stage 2). This study will assess the diagnostic value of unary albumin-to-creatinine ratio among pregnant women with pre-eclampsia. According to several studies, the ACR can be used as an early diagnostic marker for pre-eclampsia. There are relationships between variables (dependent and independent variables), thus ``Higher ACR levels

predict higher severity of preeclampsia` `and therefore can lead to poor maternal and fetal outcomes.

Conceptual Model

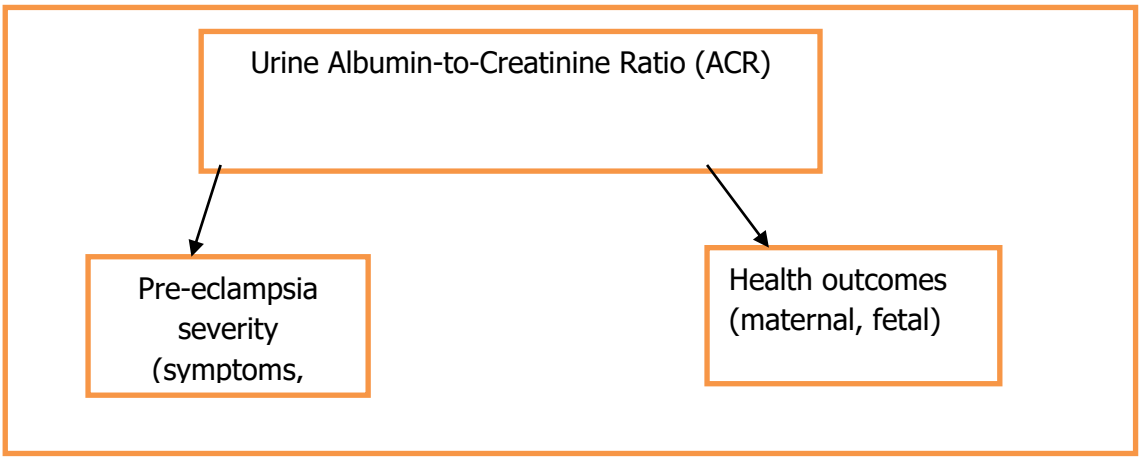

Figure 1.1 Conceptual Model

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview

Hypertensive disorders of pregnancy are one of the main causes of maternal death worldwide (6). That includes associated complications of pre-eclampsia and eclampsia(6). The exact aetiology of pre-eclampsia and eclampsia remains unclear (6). Antepartum care is devoted mostly to blood pressure screening for hypertension and specifically pre-eclampsia (5). Maternal biologic and social risk factors for pre-eclampsia include certain characteristics of the current pregnancy (e.g. conception by means of *assisted reproductive technology*), history of medical/obstetric conditions (e.g. chronic hypertension), demographic characteristics (e.g. race) and physiologic abnormalities (e.g. increased blood pressure) (12). These risk factors align with the pathogenesis of pre-eclampsia that involves uteroplacental mismatch, imbalance of angiogenic factors and syncytiotrophoblast factors that lead to maternal systemic endothelial dysregulation and inflammation, a process similar to sepsis(12).

Clinically, assessment of proteinuria is an important constituent of antenatal care for pregnant women(23). Defining pre-eclampsia is difficult because it is a syndrome characterized by a group of clinical features, that when they occur together, lead to diagnosis and treatment(29). Until now, there is no gold standard method for detection of pre-eclampsia(29). Besides, all features of pre-eclampsia are in isolation and non-specific(29). Current

numerical features such as arterial blood pressure or proteinuria are defined by thresholds, which are themselves arbitrary(29). At present, the accepted definition of pre-eclampsia is based on clinical episodes of hypertension and proteinuria developing from second half of pregnancy and which resolve within six week after delivery(29). Whereas blood pressure measurement has been standardized, there exist a gap in clinical utility of proteinuria in pre-eclampsia establishment, primarily due to diagnostic challenges associated with proteinuria in pregnancy.

A cross-sectional descriptive public health facility-based study done by Maembe et al., that aimed at assessing capability of health facilities in Dar es Salaam to manage pre-eclampsia and eclampsia gave prevalence estimates of 0.02%, 1.3% and 3% for dispensaries, health centers and hospitals respectively(25). Additionally, the study encompassed 9886, 6762 and 73406 total deliveries from selected Dar es Salaam dispensaries, health centers and hospitals respectively(25). Accordingly, total deliveries with pre-eclampsia were 2578, of which 2267 were delivered from hospitals, 89 from health centers and 222 from dispensaries(25). The exact incidence (and/or prevalence) of preeclampsia in Tanzania was not reported. Besides, of the few other available data from Tanzania; they are virtually all hospital-based cross-sectional findings. Worse still, some were conceived for factors other than determining the burden of pre-eclampsia and/or data generated from secondary analysis (30).

Another study done by Mruma determined the incidence of pre-eclampsia among pregnant women in Dar es Salaam hospitals revealed an estimated age-adjusted incidence of 1.9% with the 95% C.I. of 1.3% - 2.2%(30). However, the study was a secondary data analysis out of another study with different objectives. At present, there are no evidence of studies on prevalence of pre-eclampsia from Dar es Salaam published in retrievable peer-reviewed journals. Thus, recently, there is a gap in the burden of this otherwise potentially fatal condition in Dar es Salaam.

The study done in Nigeria on microalbuminuria and its association with adverse pregnancy outcomes occurs more commonly in developing countries and is still prevalent in our sub Saharan Africa region(31). Microalbuminuria is a marker of endothelial dysfunction leading to an increase in development of the adverse pregnancy outcomes such as pre-eclampsia, IUGR, preterm labor, and stillbirth(31). The prevalence of microalbuminuria was 58.4%(31). However, there was no statistically significant association between microalbuminuria and having these adverse outcomes ($p>0.05$)(31). However, the manner in which proteinuria was assessed was far from the gold standard of 24-urine for protein levels.

Another cross-sectional study was conducted in Zanzibar on prevalence and risk factors associated with severe preeclampsia among postpartum women, the prevalence was 26.3% but ranged depending on facility(32). The

prevalence of severe preeclampsia among admitted women at Mnazi Mmoja Hospital was 35.1%, whereas at Kivunge Hospital it was 18.5%, at Abdulla Mzee Hospital it was 9.8% and at Chake Chake Hospital was 9.5%(32). However, the proteinuria detection was via urine dipstick which leave questions on its validity.

2.2 Diagnostic value of albumin-to-creatinine ratio in the diagnosis of preeclampsia.

Khalaf and others revealed that diagnostic accuracy of urine albumin-to-creatinine ratio in the diagnosis of pre-eclampsia is scarce in retrievable peer-reviewed platforms(33). Not only that, the study added that some meta-analyses of systematic reviews have brought considerable heterogeneity to the extent of warranting extra studies(33). Another study done in Pakistan that compared urine dipstick and 24-urine for protein tests for detection of pre-eclampsia revealed pre-eclampsia was diagnosed in 202 women women(34). The sensitivity and specificity of the urine dipstick test was 84.2% and 83.3%(34) while PPV & NPV were 98.8%% and 25% respectively(34)..

This study done in Canada showed that 87 women who had completed urine collection, 74 (85%) had an initial diagnosis of pre-eclampsia and 63 (72%) had significant proteinuria confirmed by 24-hour collection. The area under the morning ROC curve was 0.92 (95% CI 0.86–0.98) and the optimal

threshold obtained for the ACR was 9 mg/mmol, with a sensitivity and specificity of 84% (95% CI 73–92) and 88% (95% CI 68–97) respectively.

This study done in USA explore that a prospective comparison of total protein-to-creatinine ratio versus 24-hour urine protein in women with suspected preeclampsia done at Metro Health medical Centre in Cleveland revealed a sensitivity of 81%, specificity of 55.8%, positive predictive value of 85.5% and negative predictive value of 47.5% for a conservative cut-off value of ≥300mg/g of protein-to-creatinine ratio(35). The study done in India asserted that there was a statistically significant positive correlation of UPOR and UPCR ($r = 0.418$ and $r = 0.512$, respectively) with 24-hour urinary protein excretion(35). Upon that they add more explanation about the sensitivity and specificity of UPOR to predict 24-hour urinary protein at cutoff point 1.32 was 82.3% and 81%, respectively(35). The sensitivity and specificity of UPCR to predict 24-hour urinary protein at cutoff point 1.09 was 87% and 86%, respectively(35).

Diagnostic challenges for pre-eclampsia have been cited both from investigators from both urban and rural areas of Tanzania(32),(13).

CHAPTER THREE: METHODOLOGY

3.1 Study design

This study was a prospective cohort hospital-based analytical study. Specifically, pregnant women with clinical features of pre-eclampsia (exposed group) were compared with those expectant mothers without pre-eclampsia (control – non-exposed) for factors (maternal, neonatal and other factors) associated with urine albumin to creatinine ratio.

3.2 Study setting

The study was conducted at Amana Regional Referral Hospital in Dar es Salaam. Amana Regional Referral Hospital (ARRH) is in Ilala urban district, Dar es Salaam. The hospital has a total bed capacity of 600 beds and serves around 3,505,598 patients per year. The study will be conducted in the obstetrics and gynecology department, which provides both outpatient and inpatient services. This department has antenatal clinics, and four wards; the antenatal ward, postnatal ward, labor ward, and gynecology ward, and has a total of 72 beds. There are about 7622 women who attend gynecological clinics per year. The department has 5 specialists: 40 midwife nurses and 9 registers. The labour ward has 6 delivery beds with sufficient privacy, 4 beds for observation after delivery, a resuscitation unit, and a nurse station. The department has a standard operating theater with 6 theater rooms. The theatre has 2 anesthesiologists, 8 anesthetists, and 10 theatre nurses.

3.3 Study population and duration

The study included pregnant women during the second trimester.

The Study duration was from January 2025 to May 2025.

3.4 Sample size

The minimum sample size was calculated by using the following formula

N =(Zα/2+Zβ)2×[p1(1−p1)+p0(1−p0)](p1−p0)2n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \times [p_1(1 - p_1) + p_0(1 - p_0)]}{(p_1 - p_0)^2}

Where:

- Zα/2 is the **Z-score** corresponding to the chosen significance level (e.g., 1.96 for 95% confidence).
- Zβ is the **Z-score** corresponding to the chosen power (e.g., 0.84 for 80% power).
- P1 is the **proportion of exposed individuals** who develop the outcome.
- P0 is the **proportion of unexposed individuals** who develop the outcome if the proportion of exposed individual is 9.5% ,

- Zα/2Z_{\alpha/2} = **1.96** (for 95% confidence)
- ZβZ_{\beta} = **0.84** (for 80% power)
- p0p_0 = **5% or 0.05** (hypothetical; you may have actual data)
- p1p_1 = **9.5% or 0.095**

Substituting values:

n=(1.96+0.84)2×[0.095(1−0.095)+0.05(1−0.05)](0.095−0.05)2n = \frac{(1.96 + 0.84)^2 \times [0.095(1 - 0.095) + 0.05(1 - 0.05)]}{(0.095 - 0.05)^2} n=7.84×(0.0861+0.0475)0.002025n = \frac{7.84 \times (0.0861 + 0.0475)}{0.002025}

n=7.84×0.13360.002025n = \frac{7.84 \times 0.1336}{0.002025}

n=1.04790.002025=517.68n = \frac{1.0479}{0.002025} = 517.68

After adding 10% of original calculated sample size loss to follow-up the calculated sample size round up to **576 participants** to ensure you still have a valid sample size after accounting for loss to follow-up.

- **288 exposed participants**
- **288 unexposed participants**.

Thus, a study done by Machano et al.,(32) from Chaka Chake, Zanzibar, argued that a minimum sample size (N) of 288 pregnant women will helpful.

3.5 Sampling Procedure

A probability sampling technique was initially used and then followed by recruiting of expectant mothers who were attending ANC and those admitted in the wards. Potential study participants who met eligibility criteria were

enrolled in the study after obtaining their consent and followed up until the intended sample size was achieved.

3.5.1 Eligibility criteria

Inclusion criteria

Women who were included in the proposed study were those able to meet the following criteria

1. Be gravid at 20 weeks of gestation with elevated blood pressure systolic equal or above 140 mm Hg and diastolic equal or above 90 mm Hg
2. Gravid women attending antenatal care and admitted at ARRH.

Exclusion criteria:

1. Women with clinically established pre-existing hypertension before index pregnancy
2. Women with diabetes mellitus
3. Women with pre-existing renal diseases.
4. Pregnant women with clinical features of imminent eclampsia.
5. Women with any other known chronic disease before current pregnancy
6. Women with multiple pregnancies.

Cohort definition:

Exposed group: pregnant women with either hypertension and/or proteinuria first detected in the second trimester (minimum of 20th week) of index pregnancies.

Non-exposed group: pregnant women without hypertension in their second trimester of their index pregnancy.

3.6 Data Collection

3.6.1 Data collection tool:

The Structured questionnaires were used for data collection. The queries in questionnaire reflected study objectives and current good clinical practice guidelines. Each participant was followed up from labour ward up to and including 24-hours post-delivery. Specifically, in each participant woman, urine albumin, urine creatinine as well as some other vital physical and clinical parameters were initiated and act as EXPOSURE variables while PRE-ECLAMPSIA was the OUTCOME VARIABLE of interest in this prospective cohort study. Moreover, for each woman with PRE-ECLAMPSIA, another woman (matched for GESTATIONAL AGE) was also be followed-up and act as a control in this study.

Before actual collection, the CRF was pailoted-tested at Amana Hospital's main laboratory in order to assess the measurement of test-retest reliability as well as construct validity scores.

Data collection was done through direct in-person interviews by using structured questionnaires with the mothers who were attending antennal clinic and those admitted to antenatal wards. The eligible participants were identified and enrolled in the study after obtaining their conset.

Two qualified nurses and one clinician from the Amana Department of Obstetrics and Gynecology and one laboratory Technician from ARRH were recruited as research assistants and they underwent 2 days of training which was provided by the Principal Investigator (PI) on the data collection technique to familiarize data collectors with a tool. We shall be screening eight to ten clients per day until the required sample size was obtained.

Each participant`s blood pressure (BP) was measured after 5 minutes of rest using manual Sphygmomanometer (Riester™, Germany) and stethoscope (Littmann™, USA), cuff was wrapped around upper arm, a bottom edge about 1 inch above the elbow in two occasions at least 4 hours apart. Those with blood pressure 120/80 mmHg were considered normal, those with BP between 120/80 to 139/89 mmHg were considered prehypertension and those with BP greater than or equal to 140 /90 mm Hg were considered hypertensive.

Each participant`s weight (kg) and height (m2) was recorded on calibrated mechanical beam scales while dressing light cloth and without shoes and body mass index (BMI) was calculated.

Each participant was provided with a large sterile urine container for 24-hour urine collection (Abbott™, Abbott Laboratories, IL-USA) after admission for diagnostic purposes. She was requested and instructed to begin the collection at a specific time, empty her bladder completely, and discard the first urine sample. For the next 24 hours she collected all urine passed in a large sterile container, this means she started urinating, then collect the mid-catch portion of the urine stream, voiding the first and last parts (to minimize contamination). She ended at the same time as she started. Out of the total sample, at least 60 milliliters (ounces) of urine was put in a small sterile urine container well labeled with participant number (instead of name), date and time of collection then sent to the hospital laboratory for UACR test and protein test by using urine dipstick. Besides, trained research assistants under the supervision of PI was also collecting data from the RCH card. Specifically, data on anthropometric, systolic and diastolic blood pressure trends, other comorbid conditions (e.g. anaemia in pregnancy) as well as medication usage (e.g. ferrous sulphate, folic acid) used for presumptive chemoprophylaxis and/or treatment. This was done routinely to all women throughout the study period. Those who developed high BP or preeclampsia were managed according to hospital protocols. Identification numbers was used instead of names on data collection tools.

The questionnaires constituted initial demographic data before following up on specific prenatal and ANC periods. At least two different follow-ups for prenatal –labour times were made for each patient. Besides, data were also

validated using antenatal (RCH) cards of each participant, hospital files as well as required data on any morbidity or mortality antecedents (backgrounds) as may be deemed appropriate.

Tools and Equipment:

Urine collection: Sterile urine containers, urine dipsticks, labels, timer, and clean gloves.

Laboratory supplies: This includes an Abbott Afinion 2 analyzer (Abbott™, IL-USA), test cartridge (Abbott™, IL-USA), sterile urine containers (Abbott™, IL-USA), tubes (Abbott™, IL-USA), and centrifuges (Abbott™, IL-USA) needed for processing urine samples (Abbott™, IL-USA) in the laboratory.

Analytical Instruments: Abbott Affinion 2 analyzer, an automated urine analyzer will be used for quantitative determination of ACR levels. Before analyzing patient samples, run the Afinion ARC with control to ensure accurate results.

This is Afinion 2 machine (Abbott™, IL-USA) was manufactured 2019, it was purchased 2023, made from Abbott technology, the first calibration was 10/10/2023, second calibration was 10/10/2024 and next calibration will be 2025.

Procedure:

Urine Albumin-to-Creatinine Ratio Measurement: The urine sample was tested for albumin-to-creatinine ratio levels using Abbott Afinion 2 automated analyzer.

Urine Creatinine Measurement: Simultaneously, the urine sample was tested for creatinine levels. Creatinine served as a marker of urine concentration and helps standardize the albumin concentration to account for variations in urine dilution.

Calculating the Urine ACR: The urine ACR was calculated by dividing the urine albumin concentration (usually measured in milligrams per liter, mg/L) by the urine creatinine concentration (measured in grams per liter, g/L). The result was expressed as milligrams of albumin per gram of creatinine (mg/g).

ACR = Urine Albumin (mg/L / Urine creatinine (g/L)

Interpreting Results: The urine ACR provides a ratio that helps in diagnosing and monitoring kidney function. In the context of pre-eclampsia, elevated urine ACR levels (usually defined as >30 mg/g) indicate increased urinary albumin excretion, which may suggest kidney damage or dysfunction associated with pre-eclampsia.

Sensitivity = True Positive/ True Positive + False Negative X 100%

Specificity = True Negative / True Negative + False Positive × 100%

Positive Predictive Value (PPV) = True Positive /True Positive + False Positive ×100

Negative Predictive Value (NPV)= True Negative / True Negative + False Negative × 100

In the context diagnostic tests or medical screenings, sensitivity and specificity are measures of a test`s performance. Each has its own numerator and denominator. Neither sensitivity or specificity is superior to one another, they have different purposes in evaluating diagnostic

3.6.2 Study variables

Dependent variables

Albumin –to-creatinine ratio.

Independent variables

-**Socio-demographic factors:** Maternal age, level of education, residence, marital status, age at marriage, number of living children, occupation, maternal weight and height, body mass index, systolic/diastolic blood pressure.

-**Fetal characteristics:** fetal sex, Apgar score, birth weight in kg, any congenital malformation, fetal IUFD, macerated or stillbirth, gestational age at birth, mode of delivery, neonatal admission.

-Maternal characteristics: parity, gravidity, inter-gestation period, duration of labor, postpartum hemorrhage, cervical/vaginal/perinea ulceration or tear, ruptured uterus.

-**Laboratory tests:** urine volume, urine for protein levels, urine for albumin-to-creatinine ratio.

Other physical examinations prominent in obstetrics from 2nd trimester (for example; fundal

Height, obstetric USS – fetal viability, intrauterine gestation as well as vital signs).

The severity of PE assessment involves a combination of laboratory tests and clinical evaluations such as the blood pressure monitoring, if BP persist more or equal to 140/90 mm Hg is the key indicator ; Fetal monitoring using ultrasound and Doppler studies to assess fetal growth and well-being;

Proteinuria tests, the presence of urine is a significant marker; Blood tests, such complete blood counts, liver and renal function tests to check for abnormalities; Also placental Growth Factor (PIGF) testing can help in predicting the onset and severity of pre-eclampsia.

If no early intervention, the per-clampsia may progress or complicates to eclampsia, stroke, HELLP syndrome or placental abruption. The participants who develop pre-eclampsia or complications will be managed according to hospital protocols.

3.7 Data collection procedures

For each participant in the ward (admitted for diagnostic purposes), a mid-stream catch urine was collected for the calculation of the albumin/creatinine ratio. The Inpatients who delivered underwent urine collection as well. For the purpose of this study, a priori cut-off value of Proteinuria on 24-hour urine collection was defined as "significant" (≥300 mg), "severe" (≥5000 mg), and mild proteinuria was defined as 300 to 4999 mg.

3.8 Data analysis

Initial data was cleaned and checked for errors every day during the data collection exercise. The activity was performed by the Principal Investigator herself. It was mainly involve checking that no data was missing, and whether there were errors in collection/entry or storage. Exploratory data

analysis formed the initial stages of main data analysis. It involved analyzing data for important trends/patterns as well as summarizing data accordingly. Data from questionnaires was entered and analyzed using SPSS software version 25.0. Continuous data were summarized using median and interquartile range while categorical data were summarized using counts and proportions. With the use of the 24-hour urine results as the gold standard, cut-off value of 0.3 mg/mmol was used for prediction of *significantly severe* proteinuria.

Multivariable binary logistic regression analysis was performed to determine the association between the albumin/creatinine ratio and a number of independent variables. Specifically, the outcome variable was dichotomized (with a cut-off point of 0.3 mg/mmol) with 1 (≥0.3 mg/mmoL – signifying *pre-eclampsia*) and 2 (<0.3 mg/mmol - control). Before fitting the multivariable binary logistic regression model, each independent variable was assessed singly against the dependent variable (UACR) for linearity, homoscedasticity, significant multicollinearity, significant autocorrelation, and independence as well as normality assumptions. Besides, a test of interactions (effect modifications) was also performed but yielded a non-significant finding. Receiver Operator Characteristic (ROC) curves was evaluated to determine an optimal albumin/creatinine ratio value that maximizes sensitivity and specificity in the identification of significant and severe proteinuria that was based on 24-hour urine collections. An alpha-level of 5% was used as a limit of type 1 error in findings

3.9 Ethical considerations

Approval to carry out the study was obtained from the Institutional and Research Ethical Committee (IREC) of KU in Dar es Salaam Tanzania. Permission to conduct the study at the study site was requested from the Medical Officer of Health in charge at ARRH.

The participants who were willingly to participate in the study were required to sign a consent form for their willingness to participate in the study after being carefully explained the research protocol starting with the purpose of the study, the procedure, benefits, cost, confidentiality, and possible outcomes will be obtained by principal investigator or research assistants. For the participants who were less than 18 years old, the parents were consent, and they were assent.

The study involved the gravid women who underwent non-invasive procedures, and they were informed of the study process. Urine was obtained for urine dipstick and albumin-to-creatinine ratio in pregnant women at risk of developing pre-eclampsia.

Permission to collect information from the client at ARRH was obtained from the

Municipal Medical Officers of Health and Medical Officers in Charge of Health facility.

The voluntary nature of participation as well as the contact address of the principal investigator was obtained in case of any inquiry.

Each participant had the right to withdraw from the study at any time she wished without negotiating the care she had been receiving at the study site.

3.10 Dissemination

Once the research is completed, I will publish in Open Access journals and university repositories for a broader audience engagement, including healthcare professionals, students, and the public. Also, the findings from this study will be distributed to those involved in the care of women with pre-eclampsia.

CHAPTER FOUR: RESULTS OF THE STUDY.

4.1. Flow chart of Study participants.

In the current study, 576 eligible pregnant women were recruited and randomly enrolled at the selected study centers until the required sample size was reached.

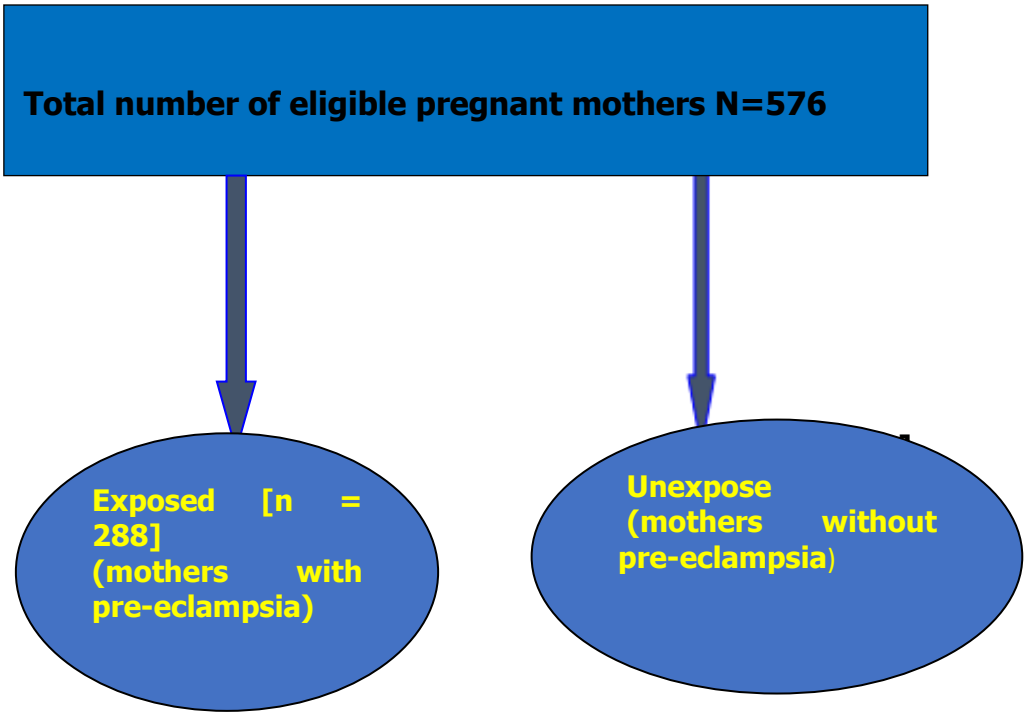

Figure 4.1: study participants' recruitment flow chart.

4.2. Baseline selected characteristics of study participants.

Table 4.1. Baseline selected characteristics of study participants.

Continuous Variable		
Variable	**Median***	**Inter-quartile range***
Maternal age (in completed years)	28	24 – 33
Gestational age at entry into the study (weeks)	24	22 – 25
Gestational age at delivery (weeks)	38	37 – 39
Maternal systolic BP (mmHg)	140	126 - 155
Maternal Diastolic BP (mm Hg)	91	81 - 99
Urine Albumin-to-Creatinine ratio	3.7	2.7 – 5.1
BMI (in kgm^{-2})	26.4	24.8 - 29.7
Neonatal birth weight (kgs)	3.4	2.9 - 3.4
Neonatal Apgar score (1^{st} minute)	8	8 - 8
Neonatal Apgar score (5^{th} minute)	10	10 – 10
Categorical Variable		
Variable	**Frequency**	**Proportion (%)**
Marital status		
- Single	64	11.1
- Married	508	88.2
- Divorced	4	0.7
Gravidity		

- Primigravida	177	30.7
- Multigravida	399	69.3
Parity		
- Nulliparous	190	33
- Primiparous	123	21.3
- Multiparous	263	45.7
Mode of delivery		
- Caesarean Section	287	49.9
- Spontaneous vertex delivery	284	49.4
- Assisted delivery	5	0.7
Highest level of education reached		
- No formal education	10	1.7
- Primary school level	360	62.5
- Secondary School level	158	27.4
- College (non-degree)	41	7.1
- University graduates/post-graduates	7	1.2

Note: N = 576. Median and corresponding inter-quartile range were used to summarize continuous data since all continuous variables displayed skewed distribution.

Baseline characteristics of study participants included summary of both continuous and categorical data. Specifically, participants' age ranged from the youngest of 18 years to the oldest of 45 years. Likewise, the youngest newborn was delivered by 23rd week of gestation and the oldest was

delivered at 42nd week. Moreover, it was also of interest to summarize statistics of blood pressure indices among pre-eclampsia groups. Table 4.2 below provides summary statistics of the distribution of pre-eclampsia among study participants.

4.3. Distribution of pre-eclampsia among study participants.

Table 4.2. Distribution of pre-eclampsia among study participants.

	Pre-eclampsia		**Severe Pre-eclampsia**	
	Present	**Absent**	**Present**	**Absent**
Elevated blood pressure	**172 (59.7%)**	**116 (40.3%)**	**57* (33.2%)**	**115 (66.8%)**
Normotensives	**0**	**288 (100%)**	**0**	**0**

*these were among those initially diagnosed with pre-eclampsia. Thus, those with severe pre-eclampsia were taken from the ones initially diagnosed with pre-eclampsia.

In the current study, 40.3% of patients with high blood pressure were found to have PE. Out of those with PE (n=172), about 57 (33%) were found to have severe PE.

4.4. Birth outcome of study participants.

Table 4.3. Distribution of birth outcomes among study participants.

Birth outcome	**Pre-eclamptic group**		**Control group**		**X^2-test (df), p-value**
Mode of delivery	**N=288**	**%**	**N=288**	**%**	**58.8 (2), 0.000**
SVD	97	33.6	187	64.9	
CS	189	65.6	100	34.7	
Assisted	2	0.7	1	0.44	
Sex of neonate					0.11 (1), 0.74
Female	135	46.9	140	48.6	
Male	153	53.1	148	51.4	
APGAR 1 min					4.03 (2), 0.132
0-3	15	5.2	6	2.1	
4-6	8	2.8	9	3.1	
>7	265	92.0	273	94.8	
APGAR 5 min					**18.7 (2), 0.001**
0-3	15	5.2	0	0.0	
4-6	0	0.0	9	3.1	
>7	273	94.8	279	96.9	
Birth weight					**13.5 (1), 0.000**
<2.5kg	74	25.7	39	13.5	
>2.5 kg	214	74.3	249	86.5	
Gestational age					**13.5 (1), 0.000**
< 37 weeks	74	25.7	39	13.5	
>37 weeks	214	74.3	249	86.5	
NICU Admission					**33.9 (1), 0.000**
NO	184	63.9	245	85.0	
YES	104	36.1	43	15.0	
Duration of labour					**6.8 (1), 0.009**
<12H	245	85.1	265	92.0	
>12H	43	14.9	23	8.0	
PPH					0 (1), 0.999
Present	1	0.03	1	0.03	
Absent	287	99.7	287	99.7	

From table 3 above, some of the selected birth associated outcomes returned statistically significant differences between women in pre-eclampsia group versus those without pre-eclampsia. Specifically, mode of delivery, gestational age, neonatal birth weights as well as NICU admission status

revealed significant differences between women in pre-eclampsia group from those without pre-eclampsia.

4.5. Sensitivity and specificity of urine albumin-to-creatinine ratio in prediction of pre-eclampsia among study participants attended at Amana regional referral hospital – Dar es Salaam.

Table 4.4. Sensitivity and specificity of urine albumin-to-creatinine ratio in prediction of pre-eclampsia among pregnant women.

	Pre-eclampsia			
Urine ACR	**Present**	**%**	**Absent**	**%**
Elevated	156	**90.7**	40	9.9
Normal	16	9.3	364	**90.1**

Sensitivity= TP/ (TP+FN) X 100= 156/ (156+16) X 100**=90.7%**

Specificity= TN/ (TN+FP) X100= 364/ (364+40) X100**= 90.1%**

PPV= TP/ (TP+FP) X100= 156/ (156+40) X 100**= 79.6%**

NPV= TN/ (TN+FN) X 100= 364/ (364+16) X 100**= 95.8%**

In this study the sensitivity of UACR to predict PE was 90.7 % and specificity 90.1%. Likewise, positive predictive value of urine ACR to PE was 75.7% and NPV of UACR to PE was 95.8%.

4.6. Association of urine albumin-to-creatinine ratio on progression (severity) of pre-eclampsia among study participants attended at Amana regional referral hospital.

Table 4.5: Association of urine albumin-to-creatinine ratio on progression (severity) of pre-eclampsia among pregnant women.

UACR	**Severity of PE**				
	Non-evident	Evident	**Chi-square**	**df**	**p-value**
Normal Elevated	370(71.3) 149(28.7)	10(17.5) 47(82.5)	**66.1**	**1**	**0.000**

From the above table, there appears to be evidence of an association (at significance level of 5%) between urine albumin-to-creatinine ratio and severity of pre-eclampsia among study participants.

4.7. Association of urine albumin-to- creatinine ratio with maternal and neonatal outcomes among study participants.

Table 4.6: Multivariate binary logistic regression analysis of factors associated with maternal urinary albumin-to-creatinine levels among pregnant women with pre-eclampsia at Amana regional referral hospital – Dar es Salaam.

Univariate Analysis				**Multivariate analysis**		
Variable name	**Unadjusted odds ratio**	**95% C.I.**	**P-value**	**Adjusted Odds ratio**	**95% C.I**	**P-Value**
Gestational age at baseline	1.03	1.01 – 1.04	0.000	1.00	1.00 – 1.00	0.99
BMI (kgm^{-2})	0.72	0.68 – 0.77	0.000	0.968	0.69 – 1.71	0.881
Apgar score at 1st minute	1.1	0.99 – 1.2	0.08	0.88	0.00 – 1.32	0.461
Apgar score at 5th minute	**1.11**	**1.01 – 1.21**	**0.023**	**1.07**	**1.00 – 1.33**	**0.000**
Neonatal birth weight	**2.15**	**1.6 – 2.9**	**0.000**	**2.0**	**1.2 – 2.9**	**0.000**
GA at delivery	**1.75**	**1.53 – 2.00**	**0.000**	**1.1**	**1.00 – 1.62**	**0.000**
Neonatal admission status	0.32	0.21 – 0.48	0.000	0.98	0.66 – 1.43	0.698
Systolic BP	**0.26**	**0.13 – 0.53**	**0.000**	**1.01**	**1.00 – 1.77**	**0.009**
Diastolic BP	**0.66**	**0.61 – 0.71**	**0.000**	**1.12**	**1.00 – 1.97**	**0.003**
Gravidity	1.04	0.96 – 1.13	0.365			
Parity	1.05	0.94 – 1.18	0.418			
Number of	1.09	0.97 –	0.145			0.967

living children		1.23				
Mode of delivery – Caesarean section SVD	**0.287 1**	**0.2 – 0.41**	**0.000**	**1.19 1**	**1.02 – 01.45**	**0.016**

From table 4.6 above, several factors were found to be significantly associated with urine albumin-to-creatinine ratio among study participants at 5% level. Specifically, for maternal factors – gestational age at delivery (in weeks), systolic and diastolic blood pressure (in mmHg) as well as mode of delivery were found to be statistically significantly associated with mean maternal urinary albumin-to-creatinine ratio. Likewise, for neonatal factors - Apgar score at 5^{th} minute and neonatal birth weight were statistically significant associated with mean maternal urinary-albumin-to-creatinine ratio. Conventionally, for the variables systolic and diastolic blood pressure were assessed for only those clients with clinically established pre-eclampsia. Annex 1 and 2 in the appendix displays the graphical analyses of the variables.

CHAPTER FIVE. DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS OF THE STUDY.

5.1. Introduction.

In this study, we recruited, followed-up and analysed 576 expectant women. Specifically, 288 women with pre-eclampsia were in exposed group while the other 288 women without pre-eclampsia were considered unexposed. Additionally, this study evaluated the association between the urine albumin-creatinine ratio and selected maternal and newborns outcomes.

5.2. Discussion.

In this study, we found out that the test performance characteristics yielded higher values for negative predictive value (95.8%) than the positive predictive value (75.7%). This means that in addition to its relatively higher specificity values, and therefore utility in diagnosis, the test can also be used for screening purposes. Positive and negative predictive values of test results are attractive because they are clinically intuitive, since they refer to the most important query raised by patients and regulators (e.g. clinical auditors, patients' groups)(36). The fact that our test performed better in negative predictive value also suggests that it can have dual usage as a diagnostic as well as a screening test (36). Our current findings are similar to others reported before. For instance, in a prospective study - Tourigny and colleagues reported in their research that urine albumin to creatinine ratio had a sensitivity of 84% (95% C.I.: 73% - 92%) and specificity of 88% (95% C.I.: 68% - 97%)(37). However, it is important to note that both

findings in Tourigny study were derived out of higher (tertiary) referral centers, whereas our study was done at a regional referral hospital facility in Dar es Salaam.

The present study findings demonstrated UACR sensitivity of 90.7% and specificity of 90.1%. Such higher values of test performance suggests potential utility in both diagnostic and screening process, an additional benefit even in resource limited settings(36). Additionally, elevated UACR was significantly associated with adverse birth outcomes, including a 2.0-fold increased risk of low birth weight, and a fivefold higher likelihood of preterm delivery. Neonatal complications were also more common, with a threefold increased risk of NICU admission among those with elevated UACR. Although the association with poor APGAR scores was not statistically significant, there appeared to be a trend toward unfavorable neonatal scores in this group. The current findings are similar to others reported before(30),(37),(38),(39). For instance, a retrospective cohort study of 717 pregnant women that determined prognostic value of urinary albumin-to-creatinine ratio towards maternal and neonatal outcomes during multivariate analysis of log transformed albumin-to-creatinine ratio revealed a 1-unit increase in log ACR to be associated with an increased odds of adverse neonatal outcomes of around 1.15 (95% C.I.: 1.02 – 1.29)(38). Similar findings were reported by Thulasi Devi and colleagues among pregnant women in the middle of the second trimester who were attending a tertiary hospital in India(39). They found that the UARC had an 80% sensitivity and a 99% specificity in

predicting PE(39). Furthermore, the association between elevated UACR and adverse outcome such as low birth weight, may be due to the fact that elevated UACR reflected glomerular endothelial damage, which is a central feature in the pathophysiology of pre-eclampsia(39).

Proteinuria is an indicator of systemic vascular injury, which may impair placental perfusion, leading to fetal growth restriction and preterm birth(15),(16). The increased NICU admissions further support the conclusion that elevated maternal UACR is associated with compromised fetal health and perinatal morbidity(15). Consistent results were reported in China by QIAN and colleagues where significant association of UACR and birth outcome were reported among pregnant mother attending ANC in Yantai region in China(40).

Moreover, on maternal factors associated with mean urine albumin-to-creatinine ratio we found out that on average for each week increase in gestational age, there is an upward of about 10% increased risk in the mean albumin-to-creatinine ratio among studied women given all other factors in check. These findings are consistent with other findings published before(3),(7),(38),(41). On physiological basis, it has been suggested that increased renal plasma flow, elevated glomerular filtration rate and alteration in protein excretion patterns are among few crucial changes vivid during gestational period(1),(38),(39). Specifically, there is evidence that during pregnancy – proteinuria increasingly worsens due to non-selective glomerular

filtration(1),(2),(3). Moreover, the study also found out that systolic and diastolic blood pressure were significant risk factors against urinary albumin-to-creatinine ratio among study population. The basis for this significant finding is in actual fact following logical framework of the clinical definition of pre-eclampsia, where blood pressure is one among cardinal markers of pre-eclampsia(1),(2).

Likewise, in the same multivariable binary logistic regression model, for each unit increase in neonatal birth weight, there was about 2-fold increased risk of mean urinary albumin-to-creatinine ratio all other factors in check. These findings are consistent with another study published before(38).

This study had several strengths. First, the study design was prospective cohort in nature and hence findings have potential to account for temporal association between independent variables and urinary albumin-to-creatinine ratio. Besides, the findings have yielded field-based sensitivity and specificity of easily available, non-invasive diagnostic test. Moreover, current findings have established the differential estimates of diagnostic values of urinary albumin-to-creatinine ratio compared to findings of the same when the test is used in screening as published previously. In contrast, UACR was measured at a single time point, which may not capture dynamic changes throughout pregnancy. Fluctuations in UACR due to hydration, diet, or transient stress could affect the accuracy of prediction. The study focuses on UACR in

isolation and does not compare its predictive value with other established biomarkers of pre-eclampsia, such as PlGF or sFlt-1.

Postpartum haemorrhage was assessed using subjective method. The Patient could not obtain objectively measured attributes for post-partum haemorrhage and hence a call for future studies on the same topic to consider objective assessment of blood loss during delivery process, whether in Caesarean or spontaneous vertex delivery.

5.3 Study limitations

5.3.1 Incomplete data

Participants' data that went missing or incomplete data for those who were referred from lower facilities to the study site/area. To overcome this challenge, data were collected into completion.

5.4 Potential loss to follow-up

For some women who were referred from study settings to Muhimbili National Hospital their outcomes of interest were reverted as the feedback mechanism was faulty. However, the fact that the outcomes of interest were assessed prospectively with ability to retrieve information from the referral system further assisted the cause.

5.5. Conclusions.

This study found that elevated urinary albumin-to-creatinine ratio (UACR) is significantly sensitive and specific test for detection of pre-eclampsia among pregnant women from second trimester onwards. Moreover, elevated UACR was significantly associated with adverse birth outcomes.

5.5. Recommendations.

1. The value of UACR was found to be a significant early and non-invasive marker for detection of pre-eclampsia for usage even in resource limited settings.
2. Integrating UACR testing as part of routine antenatal screening.

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APPENDICES

APPENDIX I: INFORMED CONSENT (ENGLISH VERSION)

Introduction:

I am Theresia Mboya, a third-year student undertaking a Master of Science in Obstetrics and Gynecology at Kairuki University. I am going to conduct a study titled "DIAGNOSTIC VALUE OF URINARY ALBUMIN-TO-CREATININE RATIO AMONG PREGNANT WOMEN WITH PREECLAMPSIA IN DAR ES SALAAM".

Aim of the study:

To determine the diagnostic value of urine albumin-to-creatinine ratio among women with Preeclampsia at Amana Regional Referral Hospital, Dar es Salaam, Tanzania from January 2025 to May 2025.

Participant role:

When you have agreed to take part in this study, you will be interviewed on your social demographic factors and medical complications that occurred during pregnancy. You will be given a questionnaire to which you will respond according to your understanding.

Confidentiality:

The information that you will provide will be Confidential, no one will access your information, and will not require you to write your name.

Benefits:

There is no direct benefit that you will get after participating in this study, in addition, you will get knowledge on social demographic factors and

pregnancy complications concerning preeclampsia and eclampsia, and their associated fetal-maternal outcome hence prevention of adverse perinatal outcomes. Mothers who might develop preeclampsia with severe features or eclampsia will be kept on magnesium sulfate which will be provided by hospital (ARRH). Neonates found with adverse complications will be referred for further management accordingly.

Risk:

No risk is expected to occur pertaining to the study, though if the participants display any risk they will be cared for according to the risk or injury.

Right to withdraw:

To participate in this study is on your wishes. Therefore, you have the right to withdraw at any time you wish.

Person to contact:

In case you have any questions, or you need explanations concerning this study, you can contact

IREC Chairperson
P.O.BOX 65300
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Principal investigator

Theresia Mboya
P.O Box 65,300
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Tel: 0785570431
Email: sr.mboya@gmail.com

CONSENT OF PARTICIPANT: (To be filled before data collection from a participant)

I ……have voluntarily agreed to participate in this study. I have read the information on this form. I have understood the aim of the study, therefore I voluntarily agreed to participate. I understand privacy and confidentiality will be observed and I have the freedom to withdraw at any time I wish.

Signature……. Date…….

Name of investigator……. Signature ……. Date…….

Consent for under 18 year's clients (To be filled before data collection from a participant)

I……parent/guardian of ……... I consent for my Child……... To participate in this study after understanding the purpose of the research through detailed information given as well as getting answers to my questions on this research.

Parents/guardian signature……Date…….

The child has assented, YES / NO

Names signature of researcher/research assistant……. Date…….

Witness……. Date…….

APPENDIX II: FOMU YA RIDHAA KUSHIRIKI KWENYE UTAFITI

(SWAHILI VERSION)

Utambulisho:

Mimi ni Theresia Mboya, mwanafunzi wa mwaka wa tatu anayefanya Shahada ya Uzamili ya Sayansi ya U zazi na Uzazi katika Chuo Kikuu cha Kairuki. Nitafanya utafiti unaoitwa "TAMBUZI THAMANI YA URINARY ALBUMIN-TO-CREATININE RTIO AMNG WANAWAKE WAJAWAZITO WANAO NA PRE-ECLAMPSIA JIJINI DAR ES SALAAM".

Lengo la utafiti:

Ili kubaini thamani ya uchunguzi wa uwiano wa albin-kwa-creatinine katika mkojo kati ya wanawake walio na Pre-eclampsia katika Hospitali ya Rufaa ya Mkoa ya Amana, Dar es Salaam, Tanzania kuanzia Januari 2025 hadi Mei 2025.

Jukumu la mshiriki:

Ukikubali kushiriki katika utafiti huu, utahojiwa kuhusu sababu zako za kijamii za idadi ya watu na matatizo ya kimatibabu yaliyotokea wakati wa ujauzito. Utapewa dodoso ambalo utajibu kulingana na uelewa wako.

Usiri:

Taarifa utakayotoa itakuwa ya Siri, hakuna mtu atakayefikia maelezo yako na hatahitaji kuandika jina lako.

Faida:

Hakuna manufaa ya moja kwa moja ambayo utapata baada ya kushiriki katika utafiti huu, kwa uthabiti, utapata ujuzi kuhusu vipengele vya idadi ya

watu kijamii na matatizo ya ujauzito yanayohusu priklampsia na eclampsia, na matokeo yanayohusiana nayo ya uzazi na fetusi hivyo basi kuzuia matokeo mabaya ya uzazi. Akina mama ambao wanaweza kupata eclampsia watawekwa kwenye salfati ya magnesiamu. Watoto wachanga watakaopatikana na matatizo mabaya watatumwa kwa usimamizi zaidi ipasavyo.

Hatari:

Hakuna hatari ambayo inatarajiwa kutokea kuhusiana na utafiti, ingawa kama washiriki wataonyesha hatari yoyote itatunzwa kulingana na hatari au jeraha.

Haki ya kujiondoa:

Kushiriki katika utafiti huu ni kwa matakwa yako. Kwa hivyo, una haki ya kujiondoa wakati wowote unaotaka.

Mtu wa mawasiliano:

Iwapo una swali lolote au unahitaji maelezo kuhusu utafiti huu, unaweza kuwasiliana

Mwenyekiti wa kamati ya maadili ya utafiti
S.L.P. 65,300
Chuo Kikuu Kairuki
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Barua pepe:irec@ku.ac.tz

Mtafiti Mkuu

Theresia Mboya

S.L.P. 65,300

Dar es Salaam - Tanzania

Nambari ya simu: 0785570431

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RIDHAA YA MSHIRIKI: (Ijazwe kabla ya kukusanya data kutoka kwa mshiriki)

Mimi ……nimekubali kwa hiari kushiriki katika utafiti huu. Nimesoma maelezo kwenye fomu hii nimeelewa lengo la utafiti, kwa hivyo nilikubali kwa hiari yangu kushiriki. Ninaelewa kuwa faragha na usiri vitazingatiwa na nina uhuru wa kujiondoa wakati wowote ninaotaka.

Sahihi……. Tarehe…….

Jina la mpelelezi ……Sahihi …….. Tarehe…**……**

Ridhaa ya ushiriki: mtoto chini ya umri wa miaka 18

(Ijazwe kabla ya maelezo na taarifa muhimu kutoka kwa mshiriki kabla ya utafiti)

Mimi……. mzazi/mlezi naridhia ushiriki wa mtoto wangu……. katika utafitihuu baada ya kufahamu lengo la utafiti kwa maelezo ya kina niliyopewa na kupata majibu ya maswali yangu kuhusu utafiti huu.

Sahihi ya mzazi/mlezi……. Tarehe…….

Mtoto ameridhia kushiriki kwenye utafiti, NDIYO / HAPANA.

Jinan a saini ya Mtafiti……...Tarehe…….

Sahihi ya Shahidi……Tarehe……

APPENDIX III : QUESTIONNAIRE (ENGLISH VERSION)

A. SOCIAL-DEMOGRAPHIC PROFILE DATA QUESTIONS

1. How old are you? ……

2. Region……. District……

3. Health Facility……

4. Where do you residence?

   A. Urban

   B. Rural

5. Marital status

   A. Married

   B. Devoice

   C. Single

   D. Widow

6. Age at marriage

   A. under 18 years

   B. over 18 years

7. Gravidity

   A. Primigravida

   B. Multigravida

8. Parity

   A, Nullparous

   B. Primiparous

   C. Multiparous

D. Grandparous

9. Gestation age at study entry……

10. Estimate date of delivery (EDD)……..

11. How many children are alive? .....

12. Education level

A. Illiterate/no formal education

B. Primary level

C. Secondary level

D. College level

E. University level

13. Occupation

A. Housewife/ Peasant

B. Petty trader

C. Self-employed/business

D. Employee.

14. Maternal height…….cm,

15. Maternal weight……kg.

16. Maternal BMI…….

17. Maternal BP……mm Hg.

B. FETAL OUTCOMES

18. Sex of the new born

A. Male

B. Female

C. Ambiguous genitalia

19. APGAR score in the first minute……. fifth minute…….

20. Birth weight……

21. Visible congenital malformation

A. Yes (specify)……

B. No

22. Intrauterine fetal death

A. Yes

B. No

23. Macerated or fresh Still birth

A. Yes

B. No

24. Gestational age at delivery……

25. Mode of delivery

A. Spontaneous vertex delivery

B. Caesarean section

C. Instrumental assisted delivery

26. Need for admission after delivery

A. Yes (give reason)……..

B. No

C. MATERNAL OUTCOMES

27. Labour duration

A. Less than 12 hours

B. 12 hours or more

28. Postpartum hemorrhage

A. >500 ml in vaginal delivery

B. 500 ml or more in vaginal delivery

C. < 1000 ml by caesarean section

D. 1000 ml or more delivered by Caesarean section

29. Cervical/Vaginal/perinea laceration or tear

B. Yes (specify)….

B. N0

30. Ruptured uterus

A. Yes

B. No.

D. INVESTIGESTIONS

1. Urine dipstick for protein level

A. Negative (0)

B. 1+

C. 2+

D. 3+

E. 3+

F. 4+

2. Urine albumin……. mg/L

3. Urine creatinine…….mmol/L

4. Urine albumin-to-creatinine ratio (ACR)……mg/mmol

APPENDIX IV: DODOSO (SWAHILI VERSION)

A. Maswali ya data ya wasifu wa Social-demografia

1. Kifupi cha majina ya mhusika…….
2. Una miaka mingapi? .....
3. Mkoa……. Wilaya……. Kata
4. Kituo cha huduma ya afya ankotokea…….
5. Unaishi wapi (makazi)

   Mjini

   Kijijini
6. Hali ya ndoa

   A. Umeolewa

   B. Mtalaka

   C. Hujaolewa

   D. Mjane
7. Umri wa kuolewa

   A. Chini ya miaka 18

   B. Zaidi ya miaka 18
8. Idadi ya ujauzito……
9. Idadi ya watoto uliojifungua…….
10. Umri wa mimba wakati wakukuhojiwa…….
11. Idadi ya watoto waliohai……
12. Elimu ya mhojiwa

    A. hujasoma

B. Msingi

C. sekondari

D. Chuo

E. Chuo kikuu

13. Kazi ya mhojiwa

A. Mama wa nyumbani

B. Mkulima

C. Mjasiria mali

D. Mfanyabiashara

14. Urefu wa mama ……cm,

15. Uzito wa mama……kg

16. Mwili molekyuli index (BMI)……

17. BP……mmHg

B. MATOKEO YA MTOTO

18. Mtoto anajinsia gani?

A. Mume

B. Mke

C. Jinsia mbili

19. Kipimo cha hali ya mtoto baada ya kuzaliwa ndani ya dakika moja……. dakika tano…….

20. Uzito wa mtoto ……kg.

21. Mtoto ana ulemavu wa kuzaliwa nao?

A. Ndiyo (Ainisha)…….

B. Hapana

22. Mtoto kafia tumboni?

A. Ndiyo

B. Hapana

23. Mtoto anadalili za kufia tumboni mda mrefu au amefia tumboni wakati wa kuzaliwa?

A. Ndiyo (Ainisha) ….

B. Hapana

24. Mtoto amezaliwa na wiki ngapi? ..... (Wiki za ujauzito kuanzia tarehe ya hedhi ya mwisho).

25. Mtoto amezaliwa kwa njia gani?

A. Njia ya kawaida

B. Operesheni.

C. A Kuzaliwa kwa msaada wa vifaa,

26. Mtoto anahitaji kulazwa baada ya kuzaliwa baada ya kuzaiwa?

A. Ndiyo (Ainisha)/itaje

B. Hapana,

C. MATOKEO YA UJAUZITO KWA MAMA

27. Mda wa kuanza uchungu hadi kujifungua

A. Chini wa masaa 12

B. Masaa 12 au Zaidi

28. Kutokwa na damu nyingi baada ya kujifungua

A. <500 ml kwa njia ya kawaida

B. 500 ml au zaidi kwa njia ya kawaida

C. < 1000 ml kwa njia ya upasuaji

D. 1000 ml au Zaidi kwa njia ya upasuaji

29. Kuchanika wakati wa kujifungua

A. Ndiyo

B. Hapana

30. Kuchanika kizazi

A. Ndiyo

B. Hapana.

D. UCHUNGUZI

1. Dipstick ya mkojo kwa kiwango cha protini

A. Hasi (0)

B. 1+

C. 2+

D. 3+

E. 4+

2. Kiasi cha albumin kwenye mkojo……..mg/l

3. Kiasi cha creatinine kwenye mkojo……mmol/l

4. Uwiano wa albin-kwa-creatinine kwenye mkojo (ACR)……mg/mmol

ANNEX LIST.

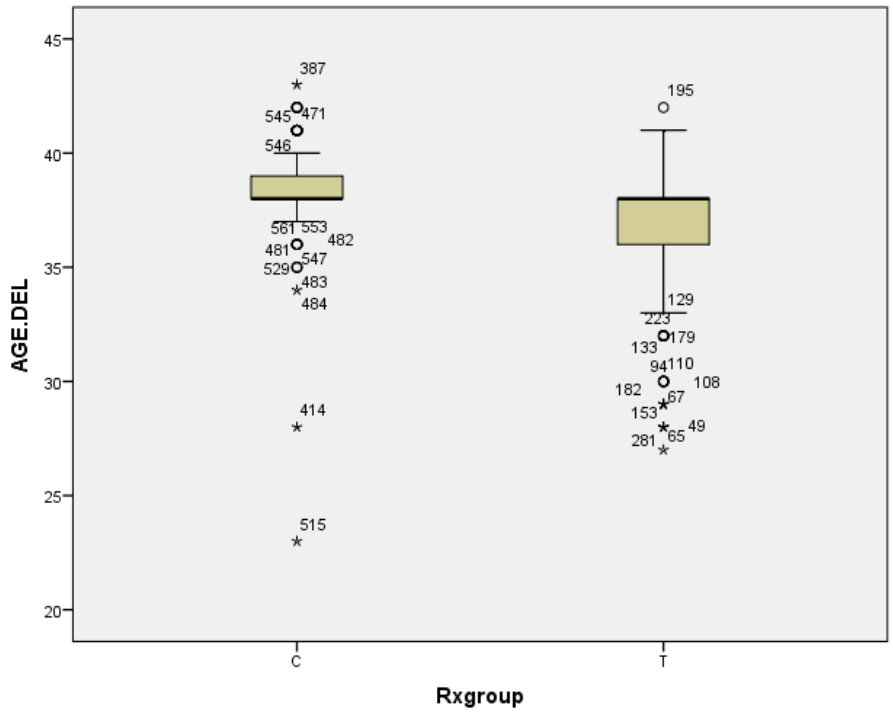

Figure 1: Box plot diagram displaying age at delivery by treatment group (T = pre-eclampsia, C = normortensives)

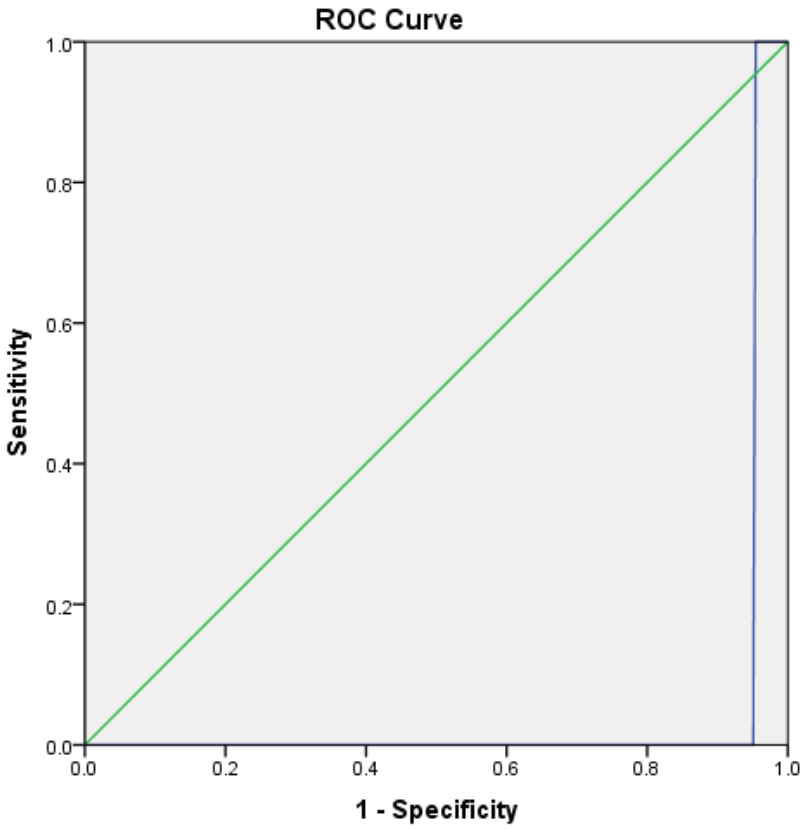

Figure 2: ROC analysis of UACR for pre-eclampsia among expectant women attended at Amana regional referral hospital in Dar es Salaam.