PREVALENCE AND PREDICTORS OF ACUTE KIDNEY INJURY AMONG NEONATES WITH BIRTH ASPHYXIA ADMITTED AT DODOMA REGIONAL REFERRAL HOSPITAL

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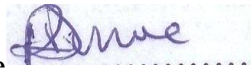
BY

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DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER IN PAEDIATRIC AND CHILD HEALTH

THE UNIVERSITY OF DODOMA

DECEMBER, 2021

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I, **Rogatus Rogatus Duwe,** declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

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CERTIFICATION

The undersigned certifies that she has read and hereby recommends for acceptance of the dissertation entitled: **prevalence and predictors of acute kidney injury in term babies with birth asphyxia admitted at Dodoma regional referral hospital neonatal ward** in partial fulfilment of the requirements for the degree of Master of Medicine in Paediatric and Child Health of the University of Dodoma, School of Medicine and Dentistry. Tanzania**.**

Dr. Fransisca Kimaro, MD, MMED PCH

Signature………………………………… Date   16 DECEMBER 2021

SUPERVISOR

ACKNOWLEDGEMENTS

DEDICATION

To my mother and father, for their continual inspiration and guidance.

To my children, for being my daily motivation and strengths.

ABSTRACT

Background: Acute kidney injury (AKI) is recognized complication in neonates with birth asphyxia**.** In all neonates with birth asphyxia the emphasis should be laid on early identification of AKI, so that it can provides the way of timely and appropriate management by avoiding consequences of irreversible renal failure. However, the true burden of AKI in terms of its magnitude and associated predictors among term babies with birth asphyxia in Tanzania is unknown due to limited Data.

Objectives: This study was done to determine the prevalence and predictors of acute kidney injury in term babies with birth asphyxia admitted at Dodoma regional referral hospital neonatal ward.

Methods: This was a cross-section study which enrolled term babies admitted at DRRH neonatal ward with diagnosis of birth asphyxia in a period of 6 months from August, 2020 to January, 2021. Variables such as demographics and blood samples were taken. AKI was defined using Kidney Disease Improving Global Outcome (KDIGO) criteria. Data were analysed using SPSS version 26.

Results: A total of 187 neonates with birth asphyxia were recruited, male neonates were 96/187(51.3%) and female neonates were 91/187. 20/187(10.7%) of neonates had AKI. After controlling other factors, the independent predictors of AKI included shock (aOR 4.6, 95% CI [1.2-21.8], p=0.025), clinical neonatal sepsis (aOR 17.7, 95% CI [4.2-69.7], p<0.001), prolonged labor (aOR 28, 95% CI [2.9-348.97], p<0.004) and maternal gentamicin use (aOR 4.8, 95% CI [1.9-26.7], p<0.003) were statistically significant associated with AKI.

Conclusion: AKI was very common in term neonates with birth asphyxia. Predictors of AKI in term neonates with birth asphyxia included, clinical sepsis, shock, prolonged labour and maternal gentamicin use.

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LIST OF ABBREVIATIONS

ANC	Antenatal clinic
APGAR	Appearance, pulse, grimace, activity, Respiration
ARF	Acute renal failure
AKI	Acute kidney injury
DRRH	Dodoma referral regional hospital
HIE	Hypoxic ischemic encephalopathy
IUGR	Intrauterine growth retardation
pKDIGO	Paediatric kidney disease improving global outcomes
MAS	Meconium aspiration syndrome
NICU	Neonatal intensive care unit
PICU	Paediatric intensive care unit
PROM	Premature rupture of membrane
PIH	Pregnancy induced hypertension
SCr	Serum creatinine
SPSS	Statistical package for the social science
UTI	Urinary tract infection
UDOM	University of Dodoma
WHO	World health organization

DEFINITION OF TERMS

Acute kidney injury (AKI)

AKI was defined according to neonatal AKI definition modifications from Kidney Disease Improvement Goal Outcome (KDIGO) pediatric AKI definition, using serum creatinine (SCr) criteria (Zappitelli et al., 2017)

Stage	Serum Creatinine level (in mg/dl)
1	≥0.3 rise within 48 h or ≥1.5–1.9 × rise from baseline (previous lowest value) within 7 days
2	2.0-2.9 times baseline
3	≥3 × rise from baseline or ≥2.5

Birth asphyxia

Birth asphyxia is defined as failure to establish spontaneous breathing after delivery and/or 5-Minute Apgar Score < 7(Tanzania national neonatal guideline, 2019).

Term babies

Term babies defined as babies born from 37weeks to 42 weeks (Ramagopal, 2016).

Apgar score

Apgar score is a rapid method for assessing a neonate immediately after birth and in response to resuscitation where by this scoring system provided a standardized assessment for infants after delivery, the Apgar score comprises 5 components: (1) color (2) heart rate (3) reflexes (4) muscle tone and (5) respiration, each of these components is given a score of 0, 1, and 2. The score is recorded at 1 minute and 5 minutes respectively in all infants with expanded recording at 5 minute intervals for infants who score seven or less at 5 minutes and those requiring resuscitation as a method for monitoring response. Score of 7 to 10 are considered reassuring (Watterberg et al., 2015).

Clinical neonatal sepsis

Neonatal sepsis is defined as a clinical syndrome with systemic signs and symptoms of infection in the first four weeks of life

The presence of two or more of the following criteria can be used for clinical diagnosis: Fast breathing (> 60 breaths /min), grunting, Severe lower chest wall in drawing, cyanosis, temperature > 37.5 °C, hypothermia < 36.0 °C, Prolonged capillary refill time (CRT), Not feeding well, convulsions, Drowsiness or unconsciousness and movements only when stimulated or no movements at all (Health & Development, 2019).

CHAPTER ONE

1.1 Introduction

Due to latest estimates by the world health organization (WHO), approximately 4 million neonates die each year before reaching the age of one month. Ninety eight percent of these neonatal deaths come from developing countries and birth asphyxia and birth injuries contribute almost 29 percent of these deaths (Bhatnagar et al., 2014). Birth asphyxia refers to deprivation of blood flow or gas exchange from the new born in the period immediately before, during or after the birth process (Sugiura-Ogasawara et al., 2019). Asphyxia can cause multiorgan dysfunction together with redistribution of cardiac output in order to maintain cerebral, cardiac and adrenal perfusion while compromising the renal, gastrointestinal and skin perfusion as circulatory response (Medani et al., 2014b). According to (Medani et al., 2014b)it is, therefore, not surprising acute kidney injury is common in term newborn with birth asphyxia.

Based on acute kidney injury in term neonates with birth asphyxia, the prevalence of acute kidney injury (AKI), in neonates with birth asphyxia worldwide accounts for 38% (Jetton, Guillet, et al., 2016).

Also a study done at Muhimbili national hospital in Dar es salaam In Tanzania, showed that, the prevalence of AKI among critically ill neonates accounts for 31.5% (Mwamanenge et al., 2020).

Since the kidney is sensitive to oxygen deprivation, renal insuffiency can happen within 24 hours of hypoxic ischemic episode which can lead to irreversible cortical necrosis if prolonged (Gopal, 2014). Stable biochemical environment is important for the newborn exposed to hypoxic ischemic episode in order to facilitate appropriate fluid and the electrolyte management. Early recognition of acute kidney injury is important in babies with hypoxic ischemic encephalopathy. The diagnosis ,early recognition of acute kidney injury among neonates is challenging because many clinical, biochemical parameters are unreliable and are not well established (Hadzimuratovic et al., 2017b)

The critical advance in AKI research over the last 30 years has been developing and use for the standardized definitions for AKI to describe organ injury that can occur (Andalibi et al., 2015).

The definition of AKI has included from more than 35 different definitions to the current used modern kidney disease improving global outcomes (KDIGO). From 2004, was a series of definitions including the Risk, Injury, Failure, Loss of kidney Function and End-stage kidney disease (RIFLE) and the Acute Kidney Injury Network (AKIN) definitions (Akcan-Arikan et al., 2007;Mehta et al., 2007). Consensus expert opinion endorsed KDIGO AKI definition that to be used for research and clinical care in pediatric patients from now onwards (Jetton, Rhone, et al., 2016)

We performed this study to determine the prevalence and predictors of acute kidney injury in term neonates with birth asphyxia admitted at Dodoma regional hospital in Tanzania to mainly emphasize a continuous monitoring of renal function of asphyxiated neonates as early diagnosis of impaired neonatal kidney function in asphyxiated newborns can prevent from developing irreversible kidney injury and hence the poor outcome.

1.2 Problem Statement

Birth asphyxia, is a serious clinical problem in the world and can contributes greatly to neonatal death and morbidity, birth asphyxia is the 5th largest cause of under-5 deaths (8.5%) after pneumonia, diarrhea, neonatal infections and complications of premature birth (Yadav & Damke, 2017). Also globally, hypoxia of the newborn, estimated to account for 23% of 4 million neonatal deaths and 26% of 3.2 million stillbirths each year, an estimated 1 million children who survive birth asphyxia, live with chronic neuro-developmental morbidities, including cerebral palsy, mental retardation, and learning problems (Lee et al., 2008). Prevalence of acute kidney injury in neonates with birth asphyxia worldwide accounts 38%(Jetton, Guillet, et al., 2016). A study done at Muhimbili national hospital in Tanzania showed that, the prevalence of acute kidney injury in critically sick neonates accounts 31.5% (Mwamanenge et al., 2020). Neonate's kidneys are very susceptible to hypo perfusion and can have low glomerular filtration rate with high renal vascular

resistance together high plasma rennin activity, decreased intercortical perfusion with decreased reabsorption of sodium in the proximal tubules. All these features make neonate, more susceptible to kidney injury in the first days of life (Libório et al., 2014). There was an increasing number of morbidity and mortality of term neonates with birth asphyxia at DRRH also in our settings including Dodoma regional referral hospital, the magnitude of prevalence of acute kidney injury particularly in high-risk neonates like those with birth asphyxia is lacking. Due to lacking of data at our settings this will affect the management and outcome of these neonates by mismanagement especially in acute kidney injury secondary to birth asphyxia because most of term neonates with birth asphyxia receive management in general without considering important organs affected in early stages including kidneys.

1.3 Objectives

1.3.1 Broad Objectives

To determine the prevalence and predictors of acute kidney injury in term neonates with birth asphyxia admitted at DRRH neonatal ward

1.3.2 Specific Objectives

1) To determine the prevalence of acute kidney injury in term neonates with birth asphyxia admitted at DRRH neonatal ward
2) To determine the predictors of acute kidney injury in term babies with birth asphyxia admitted at DRRH neonatal ward

1.4 Research questions

I) What is the prevalence of acute kidney injury in term neonates with birth asphyxia admitted at DRRH neonatal ward?
II) What are the predictors of acute kidney injury in term neonates with birth asphyxia admitted at DRRH neonatal ward?

1.5 Rationale

The rationale of this study was to determine the prevalence and predictors of acute kidney injury in term neonates with birth asphyxia. Because many studies have shown that, AKI is not only associated with short term high mortality and morbidity outcomes but also high risk of long-term renal outcomes following initial episode, this includes hypertension, proteinuria and chronic kidney disease

(Vachvanichsanong et al., 2012). This implies that the care given after an initial episode of AKI is important in averting long term renal dysfunction.

Also, by knowing the prevalence and predictors of AKI in birth asphyxia, the newborn babies at DRRH new born ward will provide baseline data for recommendation of making the guideline for routine screening of AKI in newborn with birth asphyxia particularly those with risk factors for AKI so as early recognition of AKI is done to facilitate appropriate fluid and electrolyte management to maintain a stable biochemical environment in order to improve the outcome in these babies. There are no studies concerning the prevalence of acute kidney injury in birth asphyxia in Dodoma region, thus knowledge on prevalence of AKI will increase vigilance to promptly diagnose and effectively manage cases of AKI in neonates with birth asphyxia.

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CHAPTER TWO

LITERATURE REVIEW

</div>

2.1 Prevalence of acute kidney injury in term neonates with birth asphyxia

Acute kidney injury is defined as a sudden decline in kidney function resulting in abnormality in electrolytes, fluid balance and waste products (Jetton & Askenazi, 2014).

Since the kidney is sensitive to oxygen deprivation, renal insuffiency can happen within 24 hours of hypoxic ischemic episode which can lead to irreversible cortical necrosis if prolonged (Gopal, 2014)

Kidney Disease Improving Global Outcome (KDIGO) definition and staging system is the most preferred definition in the diagnosis of neonatal AKI because it has less restrictive diagnostic timeframe (Walther et al., 2014). KDIGO has three stages, and it has serum creatinine criteria and/or urine criteria.

Other classification systems available to define AKI includes pRIFLE (Pediatric Risk, Injury, Failure, Loss of kidney function and End -stage kidney disease) and AKIN (Acute Kidney Injury Network). These two classification systems AKIN and pRIFLE has greater restrictive diagnostic timeframe and this explain why KDIGO is the most preferred definition for the diagnosis of AKI in neonates (Mehta et al., 2007;Miklaszewska et al., 2014).

Globally accepted, renal failure in term neonates with birth asphyxia, is frequently non-oliguric and many neonates, can preserve a urine output of more than 1ml/kg/h despite substantial renal dysfunction, the incidence of AKI is up to 72% among neonates with perinatal asphyxia (Kupferman et al., 2018). Neonates suffering from severe asphyxia which is defined by clinical markers, as Apgar scores and the degree of HIE are likely to experience renal failure when compared with those suffering from mild asphyxia (Hilton, 2014)

A case control study conducted at Vani Vilas hospital Bangalore India from January 2009 to January 2010, the incidence of acute kidney injury (AKI) in term babies with birth asphyxia was 75.0% which showed to be higher as compared to other studies because first all asphyxiated neonates with features of HIE in the all 3 stages

were studied, second the criteria adopted for defining acute renal failure (AKI) is different from other studies (Ramagopal, 2016).

Prospective study conducted in a tertiary level neonatal intensive care unit (ICU) at pediatric clinic, Sarajevo Bosnia from June 2014 to June 2016 in 54 term asphyxiated babies reported that, the incidence of ARF was 40.7% in asphyxiated neonates which was matched with studies done by Gupta et al,(2016) and Jayashree et al,(1991) (Hadzimuratovic et al., 2017a)

There is little data on the spectrum of acute kidney injury in neonates with birth asphyxia in Africa (Matata et al., 2015)

A prospective observational hospital-based study, conducted between January and December 2013 in the neonatal unit at Gaffar lbn auf children's specialized hospital in Khartoum Sudan showed that AKI was a common consequence among neonates with birth asphyxia with prevalence of 54.1% term babies, this finding is similar to the study done in Austria, which showed that 56% of asphyxiated neonates had acute kidney injury (AKI). It is also similar to the study done in Saudi Arabia where they found that AKI in 18 out of 32 (56.25%) (Medani et al., 2014b).

Case controlled cross sectional study which conducted in Egypt among 190 neonatal patients who were hospitalized at neonatal intensive care unit (Nicu) of Tanta universality hospital, in the period from December 2015 to December 2017, showed ,44.2% of cases of HIE in term babies had AKI, this result was not in agreement with an Indian study, which was conducted for assessment of acute kidney injury (AKI) in term newborn infants in North India by Bhatnagar et al., it was found to be 61.7% of their studied neonates. However the difference can be due to difference of methodology of definition for making diagnosis of AKI in their patients, which was based on a single blood Urea and or serum creatinine level (El-Gamasy et al., 2017).

A prospective and descriptive study, conducted from February 2008 to October 2008 in four major pediatric health facilities in Kinshasa to describe the frequency of acute kidney injury and the outcome in neonates admitted to hospital for asphyxia revealed, the proportion of neonates with birth asphyxia, diagnosed with acute kidney injury was just under 43% which is showed to be similar to other worldwide

studies that have reported (43% to 57%), but higher than the 15% to 27% reported in the western countries (Matata et al., 2015).

A prospective cohort conducted at Kenyatta national hospital newborn unit over a 6 month period (June 2012 to November 2012) among 56 term newborns revealed the incidence of acute kidney injury (AKI) in term babies with birth asphyxia of 33%, this result is lower compared with study done by Aggarwal et al.,(2016) found 68%.

There are limited studies concerning prevalence of AKI in term babies with birth asphyxia in Tanzania and Uganda as part of East Africa

2.2 Predictors of acute kidney injury in term babies with birth asphyxia

There are few studies concerning predictors of acute kidney injury in neonates with birth asphyxia which has been done worldwide and sub-Saharan Africa.

A cross sectional study done in India 2017 to estimate the incidence of acute kidney injury (AKI) in birth asphyxia and to find out the predictors of AKI in birth asphyxia found that, prolonged labor and the shock were associated with acute kidney injury in neonates with birth asphyxia, prolonged labor (total duration of labor >20 h) was found more frequently in AKI group, as compared to non‑ AKI group the difference being statistically significant (P < 0.05), in addition among AKI group, neonates with shock had more sever stages of AKI compared to those without shock, the difference being statistically significant (P = 0.04) (Aslam et al., 2017).

Also a prospective case control study done in India, to determine the incidence of perinatal asphyxia, to evaluate acute renal failure and predisposing risk factors for it, in term asphyxiated neonates along with correlating the severity of renal failure with hypoxic ischemic encephalopathy (HIE) staging revealed that, commonest risk factors for neonatal birth asphyxia were meconium stained amniotic fluid (40%) and positive sepsis screen (64%) while, 64% (48/75) of cases had screen positive sepsis, it was seen only in 18% (9/50) of controls, with statistical significance (P value: 0.001). 40% (30/75) of the cases had shock and 18.7% (14/75) of cases required ventilator support, so the shock and respiratory failure were significantly more common in asphyxiated neonates than those without asphyxia (Chacham et al., 2016).

Case Controlled cross sectional study done in Egypt in the period from December 2015 to December 2017, to evaluate the risk factors for AKI in neonates with HIE revealed that, the antibiotic usage to either in the mother during last week of pregnancy or to the neonate was also not reported to be statistically significantly different between the two studied groups, the shock as a predisposing factor for acute kidney injury was reported in the work to be more frequently (26.2 %) in AKI group than in non AKI group (11.32%), however, the AKI group had prolonged difficult labor (may be instrumental) more frequent than non AKI group, and the difference was statistically significant (P < 0.05) (El-Gamasy et al., 2017).
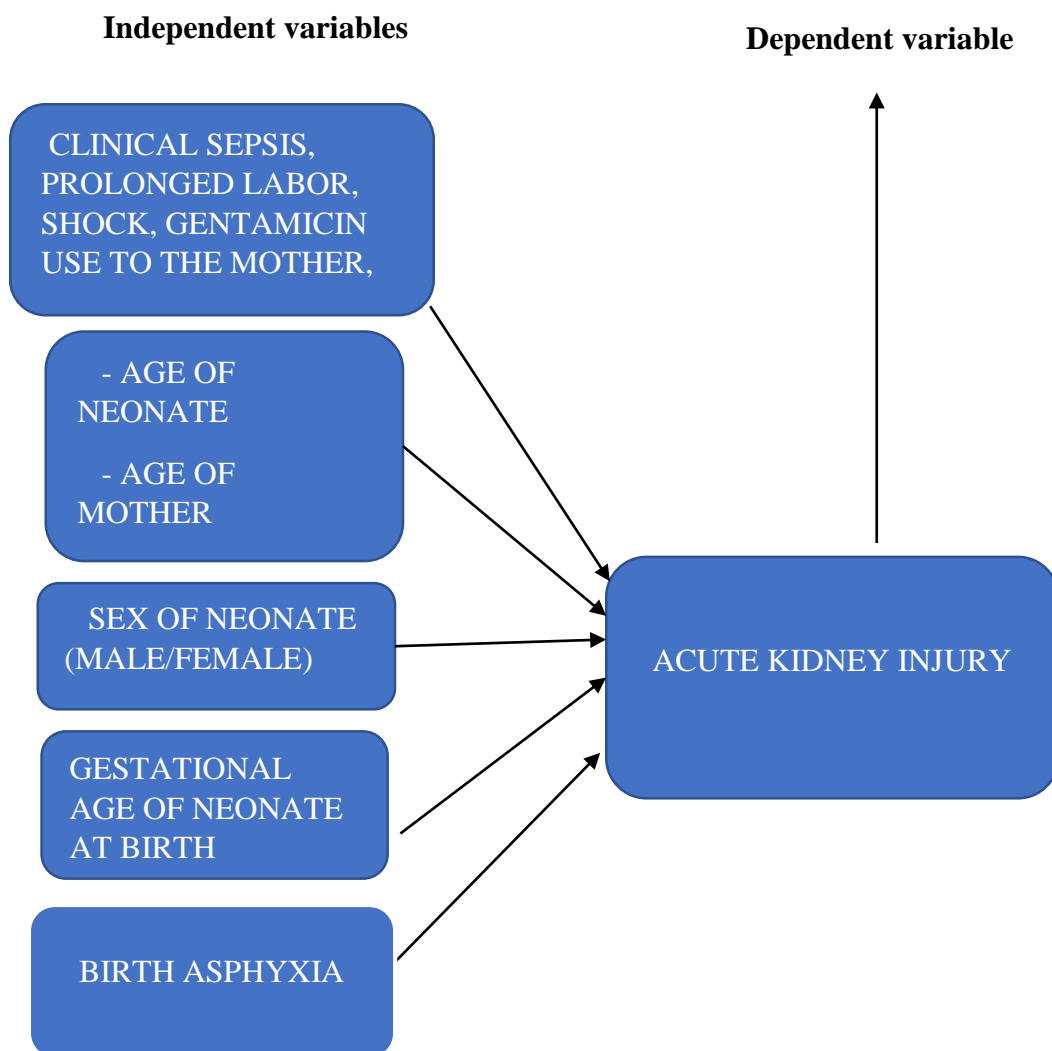
Figure 1: Conceptual framework

CHAPTER THREE
METHODOLOGY

3.1 Study Design

A cross sectional study was designed to determine the prevalence and predictors of acute kidney injury in term babies birth asphyxia who were admitted at Dodoma regional referral hospital (DRRH) neonatal ward.

3.2 Study Area

This study was conducted at Dodoma Regional Referral Hospital (DRRH) which is a Tanzania government hospital

DRRH is located in the center of the city of Dodoma as a regional Referral hospital serving patients from Dodoma region and all its districts such as Bahi, Dodoma urban, Mpwapwa, Kondoa, Chemba and Kongwa. It has twenty-one wards with a bed capacity of 434. The hospital has thirteen departments with various specialties including, emergencies, internal medicine, surgery, obstetrics and gynecology, laboratory, radiology, ophthalmology, orthopedic and traumatology, to mention a few.

The hospital has a pediatric ward which has 40 beds capacity admitting all children from the age of 0 up to 15yrs. On average about 5-10 children are admitted daily, and a total of 7-8 patients in a week could be admitted due to birth asphyxia.

3.3 Study Population

This study included term neonates admitted at DRRH newborn ward with diagnosis of birth asphyxia in a period of 6 months from August, 2020 to January, 2021.

3.3.1 Inclusion Criteria
1) Neonates with APGAR score ≤7 at 5th minute
2) Gestational age of 37weeks to 42 weeks.

3.3.2 Exclusion Criteria
All premature babies and babies delivered post-term were excluded in the study

3.4 Sample Size

The sample size was calculated using Leslie & Kish formula (1965):

$$N = \frac{Z^2 P(1-P)}{d^2}$$

Where: N = sample size

Z = Score for 95% Confidence Interval which is 1.96

P =prior prevalence of acute Kidney Injury in critically ill children, from previous study done in Kenya between June 2012 and November 2012 , with prevalence of AKI 11.7% (Alaro et al., 2014)

d = tolerable error set at 5%.

Thus $N = \frac{1.96^2 * 0.117 * (1-0.117)}{0.05^2} = 158$

158 was the minimum sample size.

3.5 Sampling Method

All term neonates with diagnosis of birth asphyxia admitted during the study period were included in the study after the guardian/parents' consent.

3.6 Study Procedures

All term babies met the inclusion criteria who admitted at DRRH neonatal ward during the study period were allowed to participate in the study after their parent's/guardian's consent. Consent forms were provided and the aim of the study was explained to the parents/guardians. The Apgar score was obtained during the study period from the score done by doctors and nurses from the delivery room after being well trained on how to score the new born baby. The neonates with birth asphyxia were managed according to standard protocol. During enrolment and after 48 hours of birth under aseptic technique 1ml of blood was collected from the veins of study participants by using sterile syringe and put in the appropriate bottle and sent to laboratory for serum creatinine investigation by using method of absorbance by photometric principle by machine architect Ci 4100. Babies with serum creatinine ≥0.3mg/dl rise after 48 hours from the baseline were termed as having AKI stage 1, 2.0 to 2.9 times baseline were termed as AKI stage 2 and serum creatinine ≥3 × rise from baseline were termed as AKI stage 3 according to modified paediatric KDIGO

definition. Demographic and clinical characteristics were obtained using structured questionnaire, physical examination of neonate with birth asphyxia was done. Data were collected by using a well-structured questionnaire, by one research assistant who was trained to assist in assessing, collection of laboratory investigations and monitoring the progress of the study participants.

3.7 Study Variables

3.7.1 The independent variables

Continuous variables were age and gestational age, while categorical variables were sex, shock, clinical sepsis, time of start enteral feeding, gentamicin use to the mother, gentamicin use to the baby and prolonged labor.

3.7.2 Dependent variable (outcome)

Acute kidney injury (AKI) as a categorical variable. AKI was defined as serum creatinine ≥0.3mg/dl rise after 48 hours from baseline (previous lowest value).

3.7.3 Variable measurement

Age, sex, and gestational age was obtained as demographic data by using questionnaire. Birth asphyxia was measured by using Apgar score soon after the baby is born of which the score of less or equal to 7 was termed as having birth asphyxia by using a known tool refer appendix 5. AKI was measured by serum creatinine which defined as serum creatinine ≥0.3mg/dl rise after 48 hours from baseline (previous lowest value). Predictors of AKI in birth asphyxia were measured by physical examination like signs of shock and sepsis, others were obtained from mother file like prolonged labor, and others were obtained from neonate file like nephrotoxic antibiotic usage and time of start of enteral feed.

3.8 Data management and analysis

Data were captured by using structured questionnaire and entered into SPSS version 26 for analysis. Results were summarized by using mean on continuous measurements and results summarized in number and percentage on categorical measurements. P value less than 0.05 was considered statistically significant. Prevalence of AKI in neonates with birth asphyxia was calculated as follows, number of cases with AKI were divided by total number of neonates with birth asphyxia then the results were multiplied by one hundred. Odds ratio was used as measure of

association. Univariate and multivariate logistic regression model were used to test associations and to identify predictors of Acute Kidney Injury (AKI) in asphyxiated term neonates. For predictors which were observed to be significant in univariate analysis, multiple logistic regression models were then used to assess the independent predictors associated with occurrence of AKI in asphyxiated term neonates.

3.9 Reliability and validity

Questionnaire was pre-tested among 10 patients from DRRH neonatal ward to verify simplicity and that the questions were well understood by the participants. This helped recognise queries and adjust the questions appropriately before actual data collection began. Data from the pre-test did not contribute towards the final data set. It was exclusively used to modify the questionnaire used in the study.

3.10 Ethical consideration

Permission to conduct the study was requested from the UDOM directorate of research and publications, also from respective health facility. Only parents who granted written informed consent to participate in the study were enrolled. Unique identification number was used to maintain patient confidentiality. Regardless of their participation, all patients received the proper management for their provisional diagnosis as per WHO and hospital guide line.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Patient enrolment

During the study period, the total of 200 term neonates with diagnosis of birth asphyxia admitted at DRRH who met the inclusion criteria were included in the study. The total of thirteen (13) neonates were excluded from the study due to various reasons such as ten neonates who died before forty-eight hours of serum creatinine sample collection whereas three mothers were denied informed consent due to unwillingness to participate in the study. A total of 187 term neonates with birth asphyxia who remained were recruited in the study Figure 1 indicates the patients' enrolment flow for the current study.

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┌──────────────────────────────────────────────────────────────┐
│  200 NEONATES WITH BIRTH ASPHYXIA ADMITTED DRRH NEONATAL       │
│  WARD DURING THE STUDY PERIOD WERE ENROLLED IN THE STUDY        │
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┌────────────────────┐
│ 10 NEONATES DIED    │
│ BEFORE 48 HOURS OF  │  ←
│ SERUM CREATININE    │
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└────────────────────┘
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                                 →  │ 3MOTHERS WERE DENIED       │
                                    │ WRITTEN CONSENT            │
                                    └──────────────────────────┘

              ╭──────────────────────────────────────╮
              │  TOTAL OF 187 NEONATES WERE           │
              │  RECRUITED IN THE STUDY               │
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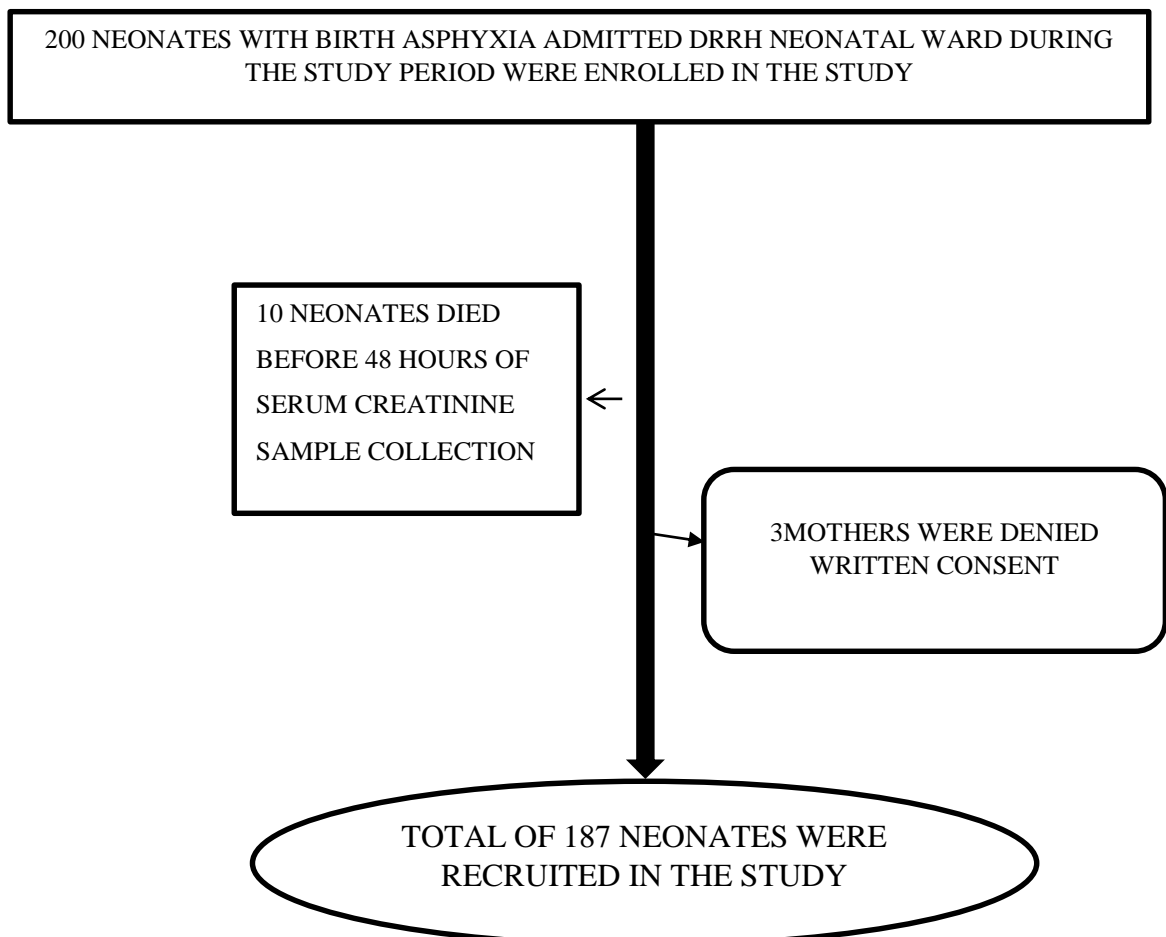
Figure 2: Patient Enrolment Flow Chart

4.2 Baseline Characteristics of neonates and mother

Atotal of 187 childrens were enrolled in the study, mean age was 1.01(SD 0.73) days, male neonates were 96/187(51.3%) and female neonates were 91/187(48.7%). Most of participants were born by SVD (65.2%), 59/187 (31.6%) had shock, 34/187 (18.2%) had sepsis,172/187(88.2%) had gentamicin usage, 22/187(11.8%) mothers had gentamicin usage during last week of pregnancy and also 98/185 (52.4%) mothers had prolonged labour during delivery, Mean GA was 39.1 (SD 1.32) and Median age of mothers was 26 (IQR 8). Primegravidae mother were 115/187(61.5%) .See table1and 2

Table 1: Baseline characteristics of neonates admitted at Dodoma regional referral hospital neonatal ward from August 2020 to January 2021 (N=187)

Variable	Frequency (n) (%)
Age group (Days)	
One day	186(99.5)
Two days or more	1(0.5)
Sex	
Male	96(51.3)
Female	91(48.7)
Neonate gestational age at birth (weeks)	
37-39 weeks	117(62.6)
40-42 weeks	70(37.4)
Mode of delivery	
SVD	122(65.2)
C/S	65(34.8)
Shock	
Yes	59(31.6)
No	128(68.4)
Clinical sepsis	
Yes	34(18.2)
No	153(81.8)
Gentamicin use in neonate	
Yes	172(92)
No	15(8)

*Mean age of neonate was 1.01(SD 0.73)days, Mean GA was 39.12(SD 1.32)weeks

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Table 2: Baseline characteristics of mothers admitted at Dodoma regional hospital from August 2020 to January 2021 (N=187)

Varible	Frequency n(%)
Prolonged labor	
Yes	98(52.4)
No	89(47.6)
Gentamicin use to mother during last week of Pregnancy	
Yes	22(11.8)
No	165(88,2)
Mother age group (years)	
<18	16(8.6)
18-35	171(91.4)
Parity	
Prime parity	115(61.5)
Multiparty	72(38.5)

* Median age of mothers was 26 (IQR 8)

4.3 Prevalence of acute kidney injury in term neonates with birth asphyxia admitted at DRRH

The prevalence of AKI was 20/187(10.7%), In general, among AKI patients, 10(50%) had AKI stage I, 6(30%) had stage II and stage III composed of 4(20%). Figure no.3 and figure no.4 highlights these findings.
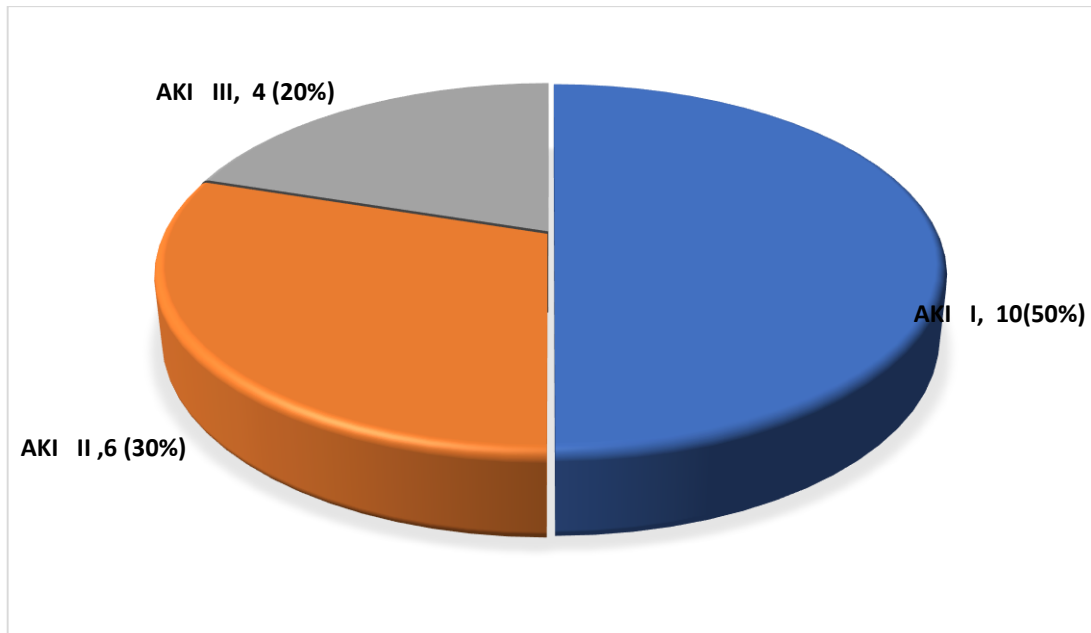
Figure 3: Pie chart showing stages of AKI in term neonates with birth asphyxia admitted at DRRH neonatal ward from August, 2020 to January,2021
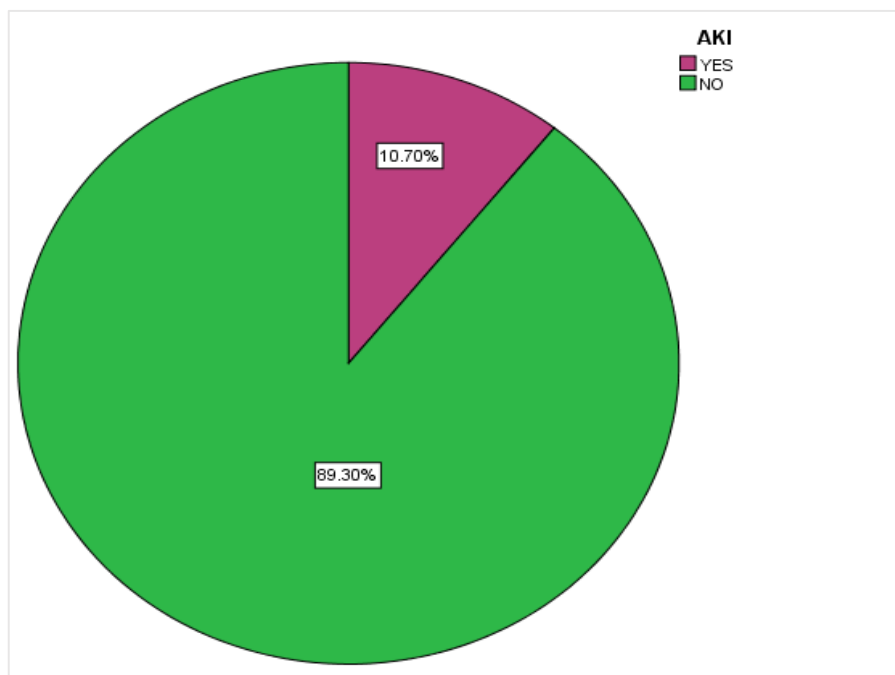
Figure 4: Pie chart showing prevalence of AKI in term neonates with birth ashyxia admitted at DRRH neonatal ward from August,2020 to January, 2021

4.4 Predictors of acute kidney injury in term babies with birth asphyxia

Among the studied predictors,shock, prolonged labour, nephrotoxic antibiotic use to the mother during the previous week of pregnancy and sepsis were statistically and significantly associated with AKI among neonates with birth asphyxia. The neonates with shock were 4 times more likely to have AKI compared to those without shock (AOR 4.6, 95% CI [1.2-21.8], p=0.025). The neonates with clinical sepsis had 17 times higher odds of having AKI compared to those without sepsis (AOR 17.7 95% CI [4.2-69.7] p<0.001). The neonates with mother who had prolonged labour were 28 times more likely to have AKI compared to their counterpart (AOR 28, 95% CI [2.9-348.97] p<0.004). Furthermore, gentamicin antibiotic use to the mother was 4 times more likely to result in AKI compared to neonates with no gentamicin antibiotic use to the mother (AOR 4.8, 95% CI [1.9-26.7] p<0.003). Table 3 and 4 indicates the predctors of acute kidney injury in term neonates with birth asphyxia.

Table 3: Predictors of acute kidney injury in term babies with birth asphyxia admitted at DRRH neonatal ward from August 2020 to January 2021 (N=187).Univariate analysis

VARIABLE	AKI AKI	AKI NO AKI	Total	OR	Pvalue
Children Sex					
Female	10 (10.4%)	86 (89.6%)	96	0.94	1
Male	10 (11%)	81 (89%)	91		
Mode of delivery					
SVD	14 (11.3%)	110 (88.7%)	124		
C/S	6 (9.5%)	57 (90.5%)	63	0.77	0.603
Nephrotoxic antibiotic use (Neonate)	19(11%)	153(89%)	172		
YES	1(6.7%)	14(93.3%)	15	1.74	0.603
NO					
Marital Status					
Single	7 (11.5%)	46 (88.5%)	52		
Married	13 (10.2%)	115 (89.8%)	128	1.35	0.07
Nephrotoxic antibiotic use(Mother)					
YES	12(34.2%)	23 (65.7%)	37	14.6	**0.001**
NO	8(4%)	144(96%)	150		
Shock					
YES	14 (23.7%)	45(76.3%)	59		
NO	6 (4.7%)	122(95.3%)	128	6.3	**<0.001**
Sepsis					
YES	17 (45.9%)	20 (54.05%)	37		
NO	3 (2%)	147(98%)	150	17.1	**<0.001**
Prolonged labour					
YES	19 (19.4%)	79(80.6%	98		
NO	1(1.1%)	88(98.9%)	89	21.1	**<0.001**

Table 4: Predictors of acute kidney injury in term babies with birth asphyxia admitted at DRRH neonatal ward from August 2020 to January 2021(N=187). Maltivariate analysis

VARIABLES	AKI		UNADJUSTED ANALYSIS			ADJUSTED ANALYSIS		
	AKI	NO AKI	COR	95% CI	*P-VALUE*	AOR	95% CI	*P-VALUE*
Shock								
Yes	14 (23.7%)	45 (76.3%)	6.3	2.27-17.4	0.001	4.6	1.2-21.8	0.025
No	6 (4.7%)	122(95.3%)						
Sepsis								
Yes	17 (45.9%)	20 (54.05%)	17.1	5.9-49.7	<0.001	17.70	4.2-69.7	<0.001
No	3 (2%)	147(98%)						
Prolonged labour								
Yes	19 (19.4%)	79(80%)	21.1	2.7-161.7	<0.001	28.9	2.9-348.9	0.004
No	1 (1.1%)	88(98.9%)						
Gentamicin use (Mother)								
Yes	12 (34.2%)	23 (65.7%)	8.3	5-41.8	<0.001	4.8	1.9-26.7	0.003
No	8 (4%)	144(96%)						

4.5 Discussion

This study enrolled 187 term neonates with birth asphyxia admitted in neonatal ward at Dodoma referral regional hospital in Tanzania. The current study aimed to determine the Prevalence and predictors of acute kidney in term neonates with birth asphyxia. The prevalence of AKI in term neonates with birth asphyxia was found to be high because perinatal asphyxia can lead to the dysfunction of multiple organs and reperfusion mostly damages the kidneys, indicating that AKI is common in term neonates with birth asphyxia in Dodoma region and Tanzania in general. The shock, clinical sepsis, prolonged labor and gentamycin use to the mothers of neonates with birth asphyxia were strongly associated with acute kidney injury.

4.5.1 Prevalence of acute kidney injury in term asphyxiated neonates

The prevalence of AKI in this study was found to be 10.7%. This finding is almost similar to that by the study done in Kenya by Alaro et al. (2014) in that the

prevalence of AKI among term neonates with birth asphyxia was 11.7%. The similarity is caused by similar settings in which the two studies were conducted. The prevalence of AKI of the current study supports the fact that AKI is common in neonates with birth asphyxia in Tanzania and in Kenya in general due to almost the same findings found with the study done in Kenya.

The prevalence indicated by this study seems lower than the prevalence revealed by the study done by Medani et al. (2014a) in Khartoum - Sudan in that the prevalence of AKI was 54.1%. Similarly, a study done in Turkey by Bozkurt & Yucesoy (2020) indicated higher prevalence of AKI, which is 29.5%. The higher prevalence of AKI in other countries was based on a number of reasons. The first reason is based on the usage of different criteria to define AKI. For example, the study done in Khartoum - Sudan used pediatric risk, injury, failure, loss, end stage renal disease (pRIFLE) to define AKI among asphyxiated neonates as compared to this study which used the pediatric kidney disease improving global outcome (pKDIGO) and this can be explained due to the fact that, KDIGO criterion has less restrictive diagnostic time frame as compared with RIFLE criterion which has greater restrictive time frame (Mehta et al., 2007;Miklaszewska et al., 2014).

. The second reason is based on the usage of different study designs such as cohort study design, as compared to our study of which we used cross sectional study design. The third reason is based on the fact that other studies used small sample size as compared to the current study. The fourth reason is based on different geographical locations in which the studies were undertaken.

A study done by Mwamanenge et al.(2020) at Muhimbili National Hospital in Tanzania found out that the prevalence of AKI among critically ill neonates was 31.5%. This finding is high compared to the current study because our study involved only neonates with birth asphyxia.

Most of the neonates in this study had AKI stage 1. This finding is similar to that by the study done by Bozkurt & Yucesoy (2020). This can be explained by the fact that measuring serum creatinine at baseline and repetition after 48 hours help to make timely diagnosis of AKI in early stages to facilitate early management to improve the

outcome of neonates despite admonition of using creatinine (Ciccia & Devarajan, 2017). Based on standard protocol, early diagnosis and management of acute kidney injury among asphyxiated neonates with intravenous fluids made them improve well by stabilizing their biochemical environment. This was accomplished having done the diagnosis of acute kidney injury based on serum creatinine using pediatric kidney disease improving global outcome criteria (pKDIGO).

4.5.2 Predictors of acute kidney injury in term babies with birth asphyxia

The commonest predictors leading to acute kidney injury as the current study indicate include shock, clinical sepsis, gentamicin use to the mother and prolonged labor. As compared to other studies such as that done in India by Aslam et al. (2017), it was found out that the prolonged labor and shock were associated with acute kidney injury among neonates with birth asphyxia. The study by Chacham et al. (2016) found out that sepsis and shock were associated with acute kidney injury. The study by El-Gamasy et al. (2017) reported that the prolonged labor and shock were associated with acute kidney injury and no antibiotic usage to either mother or neonate correlated with AKI.

The current study revealed that sepsis was more associated with acute kidney injury among term neonates with birth asphyxia than other predictors. This finding is similar to that by a study done by Chacham et al. (2016) in that sepsis was more associated with acute kidney injury among term neonates with birth asphyxia. This finding can be explained by the derangement of immune system which can make neonates susceptible to infection. The referred infection can cause hypoperfusion to kidneys, thus leading to acute kidney injury (Subramanian & , Sushma Malik, 2019)

The study done by El-Gamasy et al. (2017) reported that prolonged labour is associated with AKI. This finding is similar with the current study and by the study done in India by Aslam et al. (2017) in that prolonged labour can lead to birth asphyxia followed by acute kidney injury due to poor management of labour during conducting deliveries and hypoxia (Abdo et al., 2019)

El-Gamasy et al. (2017) found out that there is no correlation between acute kidney injury and antibiotics usage to either mother or neonates. This finding is contrary to

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the finding by the current study in that antibiotic gentamicin usage to the mother during the previous week of pregnancy is associated with acute kidney injury to the neonate. This difference is due to the fact that gentamicin is a commonly used antbiotic in Tanzania.

In addition, the current study found out that shock is significantly associated with acute kidney injury (AKI) among neonates with birth asphyxia.This finding is similar to the finding by the study done by Aslam et al. (2017), Chacham et al.(2016) and El-Gamasy et al. (2017) in that shock was asociated with AKI among neonates with birth asphyxia. The association between shock and AKI among neonates with birth asphyxia is due to the fact that birth asphyxia is associated with multi-organ hypoxia-ischemia including kidney, thus leading to acute kidney injury (Subramanian & , Sushma Malik, 2019).

CHAPTER FIVE
CONCLUSION, LIMITATION AND RECOMMENDATIONS

5.1 Conclusion

The cross-sectional study was conducted among neonates with birth asphyxia at Dodoma regional hospital in Dodoma, Tanzania. Nearly 10.7% of neonates with birth asphyxia had AKI. The shock, Sepsis, gentamicin use to the mother and prolonged labor were observed to be independent predictors of AKI. It is therefore important for clinician to take care of neonates with birth asphyxia in order to monitor serum creatinine. The monitor of serum creatinine is ensured using pKDIGO criterion which helps in the early diagnosis and management of acute kidney injury among neonates with birth asphyxia.

5.2 Limitations

This study had the following limitations

- Only serum creatinine was used to define acute kidney injury using pKDIGO among neonates with birth asphyxia due to challenges in measuring the amount of urine output among neonates due to lack of specific catheter for new born in Tanzania. The quantification of urine output using diapers was also still a challenge due to mixture of urine and stool in most of the time.

5.3 Strengths

- The recommended consensus definition of AKI (KDIGO) was used to assess for AKI in neonates with birth asphyxia
- The study provides baseline data on AKI in neonates with birth asphyxia in our setting which can be used to build on subsequent studies and formulation of management guidelines using locally generated data.

5.4 Recommendations

- All neonates with diagnosis of birth asphyxia especially those who have risk factors for acute kidney injury need to be investigated for AKI by using paediatric KDIGO and management should be given accordingly.
- I also recommend further studies to include serum electrolytes during the assessment of AKI in term neonates with birth asphyxia

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APPENDICES

Appendix 1: Informed consent

TITLE: Prevalence and predictors of acute kidney injury in term babies with birth asphyxia admitted at DRRH neonatal ward

Introduction:

Hello, my name is Rogatus Duwe I'm an MMED Pediatrics and Child Health student working on my thesis. We are conducting a study to establish the prevalence and predictors of acute kidney injury in term babies with birth asphyxia. The findings of this study will help policy makers and clinicians to develop treatment protocol of early recognition and treatment of AKI in neonates with birth asphyxia as well as prevent poor adverse outcome. If you have any questions regarding this study, you can contact me on 0759538912.

We have approached you because your baby is having birth asphyxia, thus is a potential candidate to participate in this study.

Participation is voluntary: You are invited to participate in this study because your child is having birth asphyxia. It is your choice to participate or not to participate. You may decide to participate or to withdraw at any time. If you decide not to participate, your child will still continue to receive appropriate medical care at this hospital.

How many children will participate: This study is expected to include a total of 187 babies.

Duration of participation: the participation will be until the final in hospital outcome.

Study procedures: A physical assessment will be done on your child including: general examination, a thorough abdominal and genital examination. Also, a sample of blood about 1ml will be drawn from your child and send to the laboratory for investigation twice at first and within seven days for measurement of serum creatinine.

Risks: We do not anticipate any side effects from participating in the study. However, during the drawing of blood for measurement of SCr your child will experience brief pain from the venous puncture.

Will I be paid for participating? Participation in the study is voluntary. You will not be paid for your participation. Neither will you have to pay in order to participate.

Confidentiality: All the information obtained from this study will remain confidential. We will use a study ID number for identification of study participants, no names will be used in this study or in future publications resulting from this study. Names will appear on this consent form only, which will be kept separately by the investigator, away from other case report forms.

Do you have any questions?

Statement of consent

I …………………………………………….. have read the contents of this consent form, or this consent form has been read to me. All my questions have been answered and I have been offered a copy of this consent form. I voluntary allow my child to participate in this study

Parent/Caregiver signature …………………………Date: ………………………….

Researcher's signature: ………………………………

Consent declaration by a witness of the parent/caregiver who cannot read or write

I …………………………………………………………….. have witnessed the accurate reading of this consent form to parent/caregiver of the potential child for the study. The parent/caregiver had the opportunity to ask questions which were answered fully. I confirm that the parent/caregiver has voluntarily allowed his/her child to participate in the study

Witness signature …………… Date………Parent's/Caregiver's thumb print

Appendix 2: Informed consent Swahili version

<u>UTANGULIZI</u>

Habari, Rogatus R. Duwe, ni mwanafunzi wa udaktari bingwa wa watoto. Tunafanya utafiti juu ya uwepo na visababishi vya kushindwa kufanya kazi figo kwa Watoto waliozaliwa na shida ya kupumua**.** Matokeo ya utafiti huu yatasaidia katika kutoa mwangaza kwa wahudumu wa afya namna ya kugundua na kutibu mapema kushindwa kufanya kazi figo kwa watoto waliozaliwa na shida ya kupumua na vilevile katika kukinga madhara yake. Ukiwa na swali lolote kuhusu huu utafiti, tafadhali wasiliana kupitia namba yangu 0759538912.

Tumekushirikisha wewe kwa sababu mtoto wako ana dalili zinazoonyesha ugonjwa zaidi , hivyo kufaa kushiriki katika utafiti huu. Ukikubali ushiriki wa mtoto wako katika utafiti huu, tutakuuliza maswali yanayohusiana na ugonjwa wa mtoto wako, vile vile tutamchunguza mwanao.

<u>Ushiriki ni wa hiyari:</u> ni haki yako kuchagua, kushiriki au kutoshiriki katika utafiti huu. Na pia vile vile unaruhusiwa kuacha kuendelea kushirki wakati wowote utakapoona huhitaji tena. Kutokushiriki hakutakuzuia kupata huduma stahili katika hospitali hii

<u>Watoto wangapi watashiriki</u>:   utafiti huu unategemea kushirikisha watoto wasiopungua 187

<u>Muda wa ushiriki</u>: ushiriki utakuwa mpaka matokeo ya mwisho ya ugonjwa wa mtoto

<u>Hatua za utafiti:</u> tutakuuliza maswali yanayohusiana na ugonjwa wa mwanao. Pia mtoto wako atachunguzwa kwa ujumla. Vile vile tutahitaji kuchukua kiasi kidogo cha damu kwa ajili ya kupima ufanyaji kazi wa figo. Kipimo hiki kitachukuliwa ndani ya masaa 24, baada ya masaa 48 tokea sasa Vipimo vingine vitachukuliwa kulingana na muonekano wa ugonjwa wa mtoto wako.

<u>Madhara:</u> Hatutarajii madhara yoyote kutokana na ushiriki wako katika Utafiti huu. Lakini wakati wa kuchukua sindano, mwanao atajisikia maumivu kiasi kidogo.

Je nitalipwa kushiriki? Ushiriki katika utafiti huu Ni wa hiyari .Hutalipwa kushiriki, wala hutalipia ili ushirirki

Usiri: maelezo yote utakayoyatoa kwa ajili ya utafiti huu yatakuwa ya siri. Tutatumia namba maalumu ili kuwatambua washiriki. Majina hayata tumika katika utafiti huu wala hata kwa baadae. Majina yatatunika kwenye hii fomu ya kibali tu, na hayatatumika kwingine.

Je una swali lolote?

Ridhaa ya kukubali ushiriki

Mimi   ……………………………………………………………………. nimesoma/kusomewa. Ridhaa ya kuombwaa kibali cha ushiriki katika tafiti hii, na kukabidhiwa nakala yake. Nimeridhia kwa hiyari mtoto wangu kushiriki katika utafiti huu.

Mzazi/mlezi Sahihi…………………………………Tarehe:…………………..

Sahihi ya mtafiti: ……………………………

Ridhaa ya kukubali ushiriki kwa mzazi asiyejua kusoma wala kuandikaI

mimi……………………………………………………………….nimeshuhudia

Usomaji sahihi wa hii fomu ya ridhaa kwa mzazi/mlezi wa mtoto huyu . Mzazi/mlezi alipata nafasi ya kuuliza maswali, na yalijibiwa vizuri, na mzazi huyu ameridhia mtoto wake ashiriki katika tafiti hii

Saini ya shahidi ……………   tarehe………Mzazi/mlezi kidole gumba

Appendix 3: Questionnaire for prevalence and predictors of acute kidney injury in term babies with birth asphyxia admitted at DRRH neonatal ward

A) **Social and demographic characteristics**

Baby

1) Date…………………………………….

2) Patient no………………………….

3) Patient initials…………………….

4) Sex   1) Male   2) Female

5) Current age (in days) ………………………

6) Estimated gestation age at birth in weeks……………………………

7) Birth weight in grams…………………………………

8) Mode of delivery

1) Spontaneous vertex delivery (Svd)   2) Cesarean section (C/s)

Mother

9) Age (in completed years) ……………………

10) Parity

1) Prime parity   2) Multiparity

11) Marital status

1) Single   2) Married   3) Separated   4) Widowed

12) Occupation

1) Salaried formal employment   2) Informal employment   3) Self employment

4) Unemployed

13) Level of education

1) None 2) Primary not completed 3) Primary complete 4) Secondary not completed

5) Secondary completed   6) Tertiary and above

B) Physical examination signs and symptoms

14) Apgar score at 5th minutes…………………………

15) Thomson HIE staging at admission

1) Mild

2) Moderate

3) Severe

C) Predictors of acute kidney injury in term babies with birth asphyxia

a) Shock   1) Yes   2) No

b) Sepsis   1) Yes   2) No

c) Prolonged labor   1) Yes   2) No

d) Time of start enteral feed (in days)   1) Day one   2) Day two 3) more than day two

e) Nephrotoxic gentamicin antibiotic usage

i) In Mother during last week of pregnancy   1) Yes   2) No

ii) In the neonate   1) Yes   2) No

D) Laboratory results

 Serum creatinine

  1) Baseline……………………………………

  2) After 48 days…………………………….

Appendix 4: Questionnaire Swahili version: Dodoso kwa ajili ya kuenea kwa majeraha makali ya figo katika asfiksia ya kuzaliwa na uwiano wake kwa muda mrefu katika kipindi cha watoto katika hospitali ya rufaa ya mkoa wa Dodoma

A) **Tabia za kijamii na demografia**

Mtoto

1) tarehe...

2) Namba ya mgonjwa ....

3) vifupisho vya jina la mgonjwa..................................

4) Jinsia 1) mwanamume   2) mwanamke

5) umri wa sasa (katika siku) ....

6) Umri wa mimba wakati wa kuzaa wiki...

7) uzito wa kuzaliwa katika gramu..

8) Njia ya kuzaa

1) kujifungua kwa njia ya kawaida (svd)   2) Njia ya upasuaji (C/s)

Mama

9) umri (katika miaka iliyokamilika) ....

10) Amezaa mara ngapi

1) Mara moja 2) Mara nyingi

11) hali ya ndoa

1) Hajaolewa 2) ameolewa 3) kutengwa 4) mjane

12) kazi

1) salaried rasmi ajira 2) ajira rasmi 3) ajira ya kujiajiri

4)Hajaajiriwa

13) kiwango cha elimu

1) Hakuna 2) msingi usiokamilika 3) kukamilika kwa msingi 4) cha sekondari isiyokamilika 5) sekondari iliyokamilika 6) elimu ya juu

B) uchunguzi wa kimwili ishara na dalili

14) Apgar score dakika 5. ....

15) Thomson HIE kwa utaratibu katika uandikishaji

1)Isiyo kali

2) wastani

3) kali

C) Viashiria vya majeraha makali ya figo katika muda wa kuzaliwa kwa asfiksia

a) mshtuko 1) ndiyo 2) Hakuna

b) Sepsis 1) ndiyo 2) Hakuna

c) leba ya muda mrefu 1) ndiyo 2) Hakuna

d) muda wa kuanza kumlisha mtoto (katika siku) 1) siku moja 2) siku mbili 3) Zaidi ya siku mbili

e) Dawa za kuumiza figo zilizotolewa

i) Katika mama wakati wa wiki ya mwisho ya ujauzito 1) ndiyo 2) Hakuna

ii) Katika mtoto 1) ndiyo 2) Hakuna

D) matokeo ya maabara

 Serum creatinine

1) msingi...

2) baada ya saa 48...

Appendix 5: APGAR score chart American academy of pediatrics,2015

Apgar Score   Gestational age_____weeks

Sign	0	1	2	1 minute	5 minute	10 minute	15 minute	20 minute
Color	Blue or Pale	Acrocyanotic	Completely Pink					
Heart rate	Absent	<100 minute	>100 minute					
Reflex irritability	No Response	Grimace	Cry or Active Withdrawal					
Muscle tone	Limp	Some Flexion	Active Motion					
Respiration	Absent	Weak Cry; Hypoventilation	Good, Crying					
			Total					

Comments:	Resuscitation					
	Minutes	1	5	10	15	20
	Oxygen					
	PPV/NCPAP					
	ETT					
	Chest Compressions					
	Epinephrine					

Appendix 6: Ethical Clearance from the University of Dodoma

THE UNIVERSITY OF DODOMA
OFFICE OF THE DEPUTY VICE CHANCELLOR-ARC
DIRECTORATE OF RESEARCH, PUBLICATIONS AND CONSULTANCY

P.O. Box 259
DODOMA, TANZANIA
TEL: +255-026-2310002

FAX: +255-026-2310012
EMAIL: dvcarc@udom.ac.tz;
Website address:www.udom.ac.tz

Ref. No. MA.84/261/02

21st August, 2020

To: Duwe Rogatus Rogatus
The University of Dodoma

RE: REQUEST FOR ETHICAL CLEARANCE

This is to inform you that the proposal titled *"Prevalence of Acute Kidney Injury in Birth Asphyxia and Its Correlation with Hypoxic Ischemic Encephalopathy staging In Term Babies Admitted At Dodoma Regional Referral Hospital Neonatal Ward"* has been granted ethical clearance.

Furthermore, as the Principal Investigator of the study, the following conditions must be fulfilled:

- Progress report is submitted to the University of Dodoma.
- Permission to publish the results is obtained from the University of Dodoma.
- Copies of final publications are made available to the University of Dodoma.
- Sites: Dodoma Regional Referral Hospital

Approval is valid for a duration provided for under clause five (5) of the Ethical Clearance Form.

Best Regards,

Dr. Alex Mongi
For Chairperson- Institutional Research Review Committee (IRREC)

C: C: Deputy Vice Chancellor-Academic, Research and Consultancy

Appendix 7: Data Collection Permit From Dodoma Regional Referral Hospital

THE UNITED REPUBLIC OF TANZANIA
Ministry of Health, Community Development, Gender, Elderly and Children

Telegram: "Afya" DODOMA
Tel. No:: +255 026 23223267
(All letter should be written to Permanent Secretary)

Dodoma Regional Referral Hospital,
P. O. BOX 904,
DODOMA.

REF.NO.PB.22/130/02/............

Date: 01/08/2020

THE UNIVERSITY OF
DODOMA, P.O. BOX 259
DODOMA, TANZANIA

REF: **DATA COLLECTION PERMIT**

Please refer to the above captioned subject matter.

This is to introduce to you. Duwe Rogatus Rogatus ....who is a bonafide student at UDom....has been permitted to collect data for ~~her~~ his research titled.. Prevalence of Acute Kidney Injury in birth asphyxia and its Correlation with hypoxic Ischemic Encephalopathy staging in term babies admitted at Dodoma regional referral hospital neonatal ward

Dodoma Region Referral Hospital grants him permission to carry out his research as a requested from.. August, 2020 ....to.. January 2021

Yours,

Dr. Halima Kassim
For: **MEDICAL OFFICER INCHARGE**
DODOMA REGIONAL REFERRAL HOSPITAL