ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF NURING AND MIDWIFERY

DEPARTMENT OF NURSING

TREATMENT OUTCOMEOF DIABETIC KETOACIDOSIS AND ITS DETERMINANTES AMONG CHILDREN ADMITTED IN DEBRE-TABOR AND GONDER REFERRAL HOSPITALS, ETHIOPIA: RETROSPECTIVE STUDY.

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APPROVAL SHEET

I the undersigned MSC student declared that I have submitted my original work on assessing treatment outcome of DKA and its determinants among children admitted to Debre-tabor and Gondar referral hospitals.

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APPROVAL BY THE BOARD OF EXAMINATION

This thesis by Mequanint Ayehu is accepted in its present form by the board of examiners as satisfying thesis requirement for the degree of masters in pediatrics and child health nursing.

INTERNAL EXAMINER

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ABBREVIATIONS AND ACRONYMS

AOR-Adjusted Odds Ratio

AKF - Acute Kidney Failure

AKI - Acute Kidney Injury

COR-Crude Odds Ratio

DTRH - Debre-tabor Referral Hospital

DW - Dextrose in water

DKA - Diabetic Ketoacidosis

DM - Diabetes Mellitus

GRH - Gondar Referral Hospital

IDF- International Diabetes Federation

ISPAD - International Society of Pediatrics and Adolescent Diabetics

NACL - Sodium chloride

UK - United Kingdome

US - United States

USA-United States of America

TABLE OF CONTENTS

Contents

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Background: -Diabetic ketoacidosis represents a state of acute metabolic stress that occurs due to absolute or relative insulin deficiency for metabolism of glucose. It causes 0.15-0.35% death of children in developed countries and 3.4-13.4% in developing countries.

Objective: To assess the treatment outcome of diabetic ketoacidosis and its determinants among children with DKA in Debre-tabor and Gondar Referral Hospitals, North-West Ethiopia, 2021.

Methods: Institutional based retrospective cross sectional study was conducted with sample size of 244. Systematic random sampling method was applied to select the study subject. The data was collected by using checklist in the medical record. The collected data was coded and entered in Epidata version 4.6 and was transferred to SPSS 25 for further analysis. Bivariate analysis was done and all independent variables which have association with the outcome variable at p-value <0.25 were entered in to multivariable model. A p-value <0.05 was considered as a cut of value to indicate statistical significance.

Result: In this study a total of 240 DKA children with response rate of 98.4%) were included. From these, 86.7% of them recovered and 13.3% died. Respiratory tract infections (AOR=3.5; 95%CI;1.2-10), sepsis (AOR=4.9; 95%CI;1.45-16.57), cerebral edema (AOR=5.89;95%CI;1.56-22.3),renal failure (AOR=3.6;95%CI;1.06-12.45), hyponatremia (AOR=4;95%CI;1.02-16.1), hypernatremia(AOR=7.4;95%CI;1.29-42.08),vomiting(AOR=3.4;95%CI;1.06-10.8),dehydration (AOR=4; 95%CI;1.15-14.03) and not giving potassium replacement therapy (AOR=7.4; 95%CI;1.29-42.08) were significant associated factors for death of children with DKA.

Conclusion and recommendation

In general, the overall mortality of children with DKA was 13.3% in this study. The major associated factors for death of children with DKA were vomiting, dehydration, hyponatremia/ hypernatremia, Respiratory tract infections, sepsis, renal failure, cerebral edema and potassium therapy. So that early diagnosis and treatment of the above factors are necessary to prevent death of children with DKA.

Keywords: - Diabetes mellitus, Diabetic Ketoacidosis, Risk Factors and Mortality

1. INTRODUCTION

1.1. Background

Diabetes mellitus is a metabolic disorder that occurs due to an absolute and relative deficiency of insulin and body resistance to insulin. It is classified as a type1 that is typically present in children below five years and type 2 which is a rare type of diabetes mellitus (DM) among children except if the child is obese(1). The children present with early symptoms of polydipsia, polyuria, polyphagia and weight loss that occur related to hyperglycemia in both types(2).

Diabetic ketoacidosis (DKA) is considered to be a common presentation of both type 1 and type 2 diabetes mellitus in children and teenagers that emerges due to need of satisfactory insulin in the body(3). It can occur at the time of type 1 DM diagnosis or in children with type 1 DM previously diagnosed, in those who did not receive the correct dose of insulin deliberately or accidentally or who are suffering from inter-current diseases that are not adequately controlled(4).

DKA is an acute complication of diabetes mellitus that is caused by a decrease in effective circulating insulin. It is associated with elevations in counter regulatory hormones and impaired peripheral glucose utilization like glucagon, with resultant hyperglycemia and hyper-osmolality, result in osmotic diuresis, dehydration, and obligate loss of electrolytes(5). Children with diabetic ketoacidosis (DKA) have a manifestation of nausea and vomiting, weakness, flushing of face, dry mucus, confusion or being less alert, headache, muscle ache, sweet-smelling breath, belly pain and shortness of breath(6). And have certain complications like hypokalemia, hypoglycemia, cerebral edema, loss of consciousness and death as a result of lack of getting the appropriate treatment such as insulin, electrolyte and fluid at the right time(7).

Diabetic ketoacidosis can be classified as mild, moderate and severe based on the serum concentration of bicarbonate and PH venous level. Mild diabetic ketoacidosis is present when the serum concentration of bicarbonate gets below 15mmol/l and venous PH falls between 7.2 and 7.3. Moderate ketoacidosis occurs when the serum concentration of bicarbonate gets less than 10mmol/l and venous PH level falls between 7.1 and 7.2. And sever diabetic ketoacidosis manifests when the PH venous level gets below 7.1 and serum bicarbonate concentration falls less than5 mmol/l (6).

Since DKA causes loss of fluid through osmosis, it can be managed by administration of fluids like normal saline, ringer lactate and dextrose in water. In addition intravenous insulin administration is the primary and most critical initial treatment of DKA (7).

In the world every year 65,000 children are diagnosed with type 1 DM, from which 80% of them present with DKA even if its frequency differs across countries (8). International studies indicates that diabetic ketoacidosis accounts for15% - 70% in patients with newly onset type 1 DM (9). Globally, diabetic ketoacidosis causes 1 - 10% mortality of children per year in children with type1 DM(10).

In the developed countries like U.S, around 35 to 45% of children were death related to diabetes mellitus. Among those 10-15% of children become death as a result of DKA(11). Even though developing countries in Africa like Sudan use 65% of their annual expenditure for health for diabetic children like for buying medication (insulin) as a result of the incidence, the mortality rate of children related to DKA were high(12). In addition in Nigeria from 88.9% of DKA children improved and 11.1% of them died (13).

1.2. Statement of the Problem

In every year, the number of children and adolescents living with diabetes is increasing in the world. Most of them have presented with type 1 DM. Currently 1.1 million children and adolescents live with diabetes and annually 132,000 new cases of diabetic children are diagnosed around the world. In Africa, 36000 children are living with diabetes and 5900 children are diagnosed every year (14). The prevalence of DKA among children varies across the world among DM children due to different quality of health care and socioeconomic circumstance of the patient. The prevalence of DKA in Germany was 6%(15) and in Italy 38.5% (16). Whereas in Africa, frequency of DKA in north-western Nigeria 62.2% (17), in South Africa 69.8%(18) . In Ethiopia, in Addis Ababa the prevalence of DKA at diagnosis of DM is 35.8% (19), in Tigray 78.7% (20) and East-West Gojjam is 58.5%(21).

Overall mortality of children with DKA varies between developed and developing countries. The mortality in developed countries varies from 0.15% to 0.35% which is mainly due to cerebral edema and it is relatively very low when compared with the developing countries(22). And also in developing countries the mortality ranges from 3.4% to 13.4%. Children in these countries with DKA die due to cerebral edema, sepsis, shock and renal failure(23). In America like USA DKA was the leading cause of death among children (0.3%). From those cerebral edema accounts 24% of death of children with DKA(24). And also in Europe, Sweden twenty children die due to DKA from a 23 death of children related with diabetes mellitus(25).

In Asian developing countries like in Iran and India more than half of the children were diagnosed with DKA among diabetic children. The mortality ranges from 1.7%- 18.2%. Those children develop DKA as result of omission or lack of insulin, infection, sepsis and become death due to hypokalemia, hypernatremia, hypoglycemia and certain complication such as cerebral edema, renal failure, coma, pulmonary edema and septic shock(26), (27),(28).

In Africa, the morbidity and mortality of children with DKA is high (10% because of overlapping of certain comorbidities and complication like malnutrition, parasite and microbial infection and cerebral edema. And also lack of accessibility of multiple daily injection or insulin pump, glucose monitoring and self- management education leads to development of diabetic ketoacidosis that leads to development of complication which causes death of children with DKA(29). In addition some patients use herbal remedies from traditional healers that complicate the disease process. As result the child presents to the health facility by developing

complications which may complicate fluid and electrolyte replacement therapy protocol and become die(30). Even if few researches are done in Ethiopia about diabetic ketoacidosis among children , researches conducted in Tigray and Hawassa revealed that 4.3% and 2.8% of the children with DKA were died respectively(20,41).

Since DKA is a life treating pediatric condition, it needs fast recognition and gradual organized treatment to decrease the mortality of children with DKA. But if it is left without treatment it is 100% fatal (31). To decrease hospital admission and mortality with DKA, increasing access to medical advice, diabetic ketoacidosis program and good follow up care are important (5). Furthermore, high level of clinical suspicion with timely administration of appropriate intravenous fluid, rational use of sodium bicarbonate, continuous insulin infusion and good monitoring were decreases death of children with DKA(29).

In spite of many advances in the management of diabetes, the mortality associated with diabetic ketoacidosis (DKA) remains high, especially in the developing countries and most of the death occurs after taking a standard dose of treatment of DKA for 24-48 hours(32). Most of the previous studies on DKA in Ethiopia focused on the prevalence or incidence with its associated factors but not particularly on determinants of treatment outcomes. Therefore this study aims at describing treatment outcome of diabetic ketoacidosis among children below 15 years and identifying factors contributing to the treatment outcome in Debre-tabor and Gondar Referral Hospital, Ethiopia.

1.3. Significance of the Study

This study will contribute data regarding to management outcome of diabetic ketoacidosis in the study area as well as it will also contribute to increases the knowledge of the patients and health care professionals on the determinant factors of treatment outcomes of diabetic ketoacidosis. The findings from this study will help the health institution administrators and other stakeholders to give great emphasis to the problem of diabetic ketoacidosis, to identify the gaps on the management of diabetic ketoacidosis and measure the effectiveness of inpatient management or treatment of diabetic ketoacidosis and develop best interventional approaches in the future. In addition, it serves as base line data for further study.

2. LITERATURE REVIEW

2.1. Introduction

Diabetic ketoacidosis is the most severe complication of diabetes mellitus that occurs when our body produces high level of ketones. The symptoms of DKA are excessive thirst, frequent urination, nausea and vomiting stomach pain and confusion. It is commonly triggered by illness particularly pneumonia and urinary tract infection and a problem with insulin therapy. Some of the possible treatment complications are hypoglycemia, hypokalemia and cerebral edema(33).

2.2. Treatment outcome of DKA in children

As DKA is a severe acute complication of diabetes mellitus, it should be managed quickly as much as possible through the use of 10-20ml/kg of 0.9% of normal saline and 0.5-0.1unit/kg of insulin drip for the first hour and then with 0.45% of normal saline(Nacl) plus continue insulin drip and add 20mEQ/l of potassium phosphate and acetate until the resolution of DKA for the next two hour and add 0.5% of DW if the blood glucose level reaches 250 mg/dl(1).

A long time population based study in Swedish revealed that 20% of children with diabetes mellitus died with diabetic ketoacidosis (34).

Different studies conducted in Asia showed that the mortality of children diagnosed with DKA differ across its countries. For instance research conducted in South India Karnataka tertiary hospitals showed that 89.5% improved and discharge and 11.5% died and another research conducted at Delhi in tertiary level care hospital in India showed that 12.7% of children with diabetic ketoacidosis died and the remaining 87.3% recovered (31),(35).

The study conducted in Bangladesh revealed that from a total of 54 DKA children admitted to Birdem general hospital, 86.6% recovered without complication and 13.4% died (36). Another study conducted in Bangladesh, Dhaka hospital also showed that from a total of 49 DKA children 88% of them improved and the remained 12% died (37). Research conducted in Karachi, Pakistan on precipitating risk factor, clinical presentation and outcome of DKA patients showed that from the total number of children with DKA 45(59.2%)of the children recovered and 13.6 % died (38).

A retrospective study conducted in Kenya reported that among children with DKA 6.9% of children died while 93.1% of children recovered and discharged to home(39). On the other hand study conducted in Congo showed that 12.7% of children died and the remaining 87.3% recovered (40). In addition research conducted in Nigeria depicted that 11.1% children died and

the remaining 88.9% recovered from DKA (13). Another cross sectional study conducted in Ethiopia, Hawassa comprehensive specialized hospital about the occurrence and associated factors of DKA among children showed that from the total of 108 patients with DKA, 105 (97.22%) improved after treatment, whereas three (2.8%) died in hospital (41). And also retrospective observational study in Tigray showed that 95.7% of children improved and 4.3% died (20).

2.2. Determinants of treatment outcome in children with DKA

2.2.1. Socio-demographic factors

Even though different researches conducted in different parts of the world about treatment outcome of DKA among children, did not showed that age as a significant factor for mortality of DKA children. However research conducted in one of Africa country in Congo depicted that age less than five year (p=0.000006) were one of the major associated factor for mortality of children who have DKA (40).

2.2.2. Clinical profile of children with DKA

Clinical profile of children with DKA involves sign and symptoms such as polyphagia, polyuria, polydipsia, abdominal pain, vomiting, diarrhea, dehydration and loss of consciousness and other biochemical parameters that are determined by laboratory like hypo/hypernatremia, hypo/hyperkalemia, and hypo/hyperglycemia, PH, bicarbonate and creatinine level.

A case control study conducted in Chennai, south India from February 2013 to February 2015, showed that altered sensorium (loss of consciousness) with p-value 0.04 and vomiting (p=0.024) at presentation were the identified sign and symptoms that increase the risk of mortality of children with DKA even if the other symptoms like polyphagia, polydipsia, dyspnea and abdominal pain were the most presented manifestation among DKA children (28).

In Africa, Kenya, Congo as well as Nigeria altered level of consciousness (OR 5.2 (95% CI 1.1-25.1)), (p= 0.007) (OR 6.76 (1.29- 160.26) (p=0.024) and (OR 3.2(1.23-67.24) (p=0.45) was respectively a significant factor for death of children with DKA (39) (40), 42).

In a retrospective study conducted in South India, PH venous level less than 7.15 (p=0, 04) and serum bicarbonate concentration less than10 mEQ/L (0.006) were the factors which have great contribution for half mortality of children diagnosed with DKA(31). And another study conducted in this place about risk factors of poor outcome of diabetic ketoacidosis also showed

that lower pH (p-0.009) and lower bicarbonates (p-0.035) were the factors associated to mortality of children with DKA(28).

A research conducted in South India and two researches in Pakistan showed that random blood sugar (RBS) greater than 700 mg/dl (p=0,032), >300 mg/dL and >500 mg/dl) 2.1(1.0-23.4)(p= 0.04) respectively were a significant factor for the death of children with DKA (38), (43),(44).

As research done in Pakistan about clinical characteristics, precipitating factors and predictor of DKA revealed that markedly low pH, serum bicarbonate, and high serum potassium at the time of presentation were the identified determinant factors for death patients with diabetic ketoacidosis(38). And also research conducted in Karachi tertiary hospital in Pakistan showed that hyponatremia(<130Meq/l) with odds of 3.1(0.2-13.6) at p-value 0.04, serum Potassium level (< 2.5 mEq/l) (hypokalemia) (OR; 3.7, 95% CI1.4-4.8) with p=0.03 were a significant risk factors for mortality of children with DKA(38). As research conducted in south India revealed that high urea (p-0.014), creatinine (p-0.042) and higher level of sodium (p-0.025) were found to be significantly associated with mortality of children with DKA at initial presentation (28). Another descriptive retrospective study conducted in Hilly Himalayan in north India showed that certain biochemical abnormalities like hyponatremia, hypernatremia, hypokalemia, hyperkalemia leads to 3.4% death of children with DKA presented in pediatric ICU (45). In addition research conducted in Iran about outcome of patients with DKA, hypokalemia (p=0.04) were associated death of children with DKA. But hypernatremia (p=0.3) were not associated with death of children with DKA (26).

To the opposite, another research conducted in Iran and Mexico revealed that hypernatremia and hypokalemia were not associated with death of children with DKA(46) (47). In addition, research conducted in Mexico revealed hyponatremia and hyperkalemia were not associated with death of children with DKA(47). A research done in Nigeria regarding to outcome of DKA in children and adolescent showed that high serum creatinine level and decreased urine output were the associated factors for mortality of children and adolescent (42). In addition research conducted in Kenya showed that high risk of mortality was reported among children who had high serum creatinine (OR 5.8 (95% CI 1.6-21.2)) and decreased urine output (OR 9.0 (95% CI 2.2-37.3))(39). On the other hand research done in Congo showed that dehydration (p = 0.0006), hemodynamic disorders (p= 0.0006), and diarrhea (p= 0.001) were a significant factors for the death of children with DKA (40).

Observational study was conducted in China about clinical characteristics and outcome of DKA. According to this report, children with mild DKA were improved two times faster than those children with severe diabetic ketoacidosis(48). Whereas a cross sectional study conducted in Hawassa comprehensive specialized hospital about occurrence and associated factor of DKA among children revealed that moderate and severe DKA were associated with for death children with DKA(41).

2.2.3. Comorbidities and complications before or after admission of children with DKA

Children who have DKA may have different comorbidities or may develop serious complications before and after admission to hospital. These comorbidities such as: sepsis, different types of infections, malnutrition and complications such as cerebral edema, shock, intracranial thrombosis or infarction, acute tubular necrosis with acute renal failure can affect the treatment outcome of children with DKA(49).

Research conducted at tertiary care hospital in south India showed that sepsis and peritonitis were the identified cause for mortality of children with DKA (35). A similar study conducted in India also showed that urinary tract infection, skin and soft tissue infection like cellulitis and boils were the most risk factors for mortality of children who have diabetic ketoacidosis(50). While according to study conducted in Pakistan among 88 children with DKA revealed that presence of infections like sepsis as well as respiratory tract infections at (p-0.029) were majorly related factors for the mortality of children with diabetic ketoacidosis(44). In addition, research done in Bangladesh showed that septicemia and respiratory tract infections like pneumonia accounts for 40% and 20% death of children death with DKA respectively(36) .

In Ethiopia, retrospective observational study done in Tigray showed that sepsis were a cause for 27.3% of death of children diagnosed with DKA (20).

A research was conducted in Sun Yatsen memorial hospital in china to investigate the incidence, risk factor and long term outcome of AKI in hospitalized diabetic ketoacidosis patients. Based on the finding, a DKA patient with AKI had poor long term outcome than their counterparts(51). Furthermore, a retrospective study was undertaken in India to evaluate the outcome of ARF in children with diabetic ketoacidosis. According to these, ARF causes a 40% death for the children diagnosed with DKA (52). In similar way, research conducted in this place regarding to clinical profile and outcome of DKA showed that renal failure was also the identified risk factor for

mortality of children with DKA (35). And also a prospective study conducted in Chennai in south India revealed that acute renal failure was identified as a significant associated factor with p-value(0.025), OR (10.9) and CI(1.350- 88.184) (28).

Research conducted in US Florida showed that cerebral edema cause 50% death of children with DKA which resuscitated with fluid less than estimated and 68.6% death children which resuscitated with fluid more than estimated (53)

A retrospective study conducted in south India and Pakistan showed that cerebral edema OR (4.3(1.3 - 6.1) and shock were the factors for death of children living with DKA (24), (45). And also a prospective cohort study in South India Chennai, cerebral edema with (p=0.004; OR (52.322(3.451-793.29) was an associated factor for death of children with DKA (28). Another retrospective study conducted in Africa, Sudan, Khartoum a bout frequency and severity of DKA at diagnosis among children in type 1 DM showed that 1.7% of children with DKA passed away as a result of cerebral edema(54). And also study conducted in Tigray showed that cerebral edema causes a 54.5% of death of DKA children (20)

One study in India showed that delayed diagnosis was the root cause for mortality of children with DKA(55). In other study conducted in Nottingham, UK showed that delayed presentation to hospital leads children with DKA to develop a significant long term sequel (56).

As research conducted in England, London on DKA associated stroke among children and youth revealed that stroke was leading to 29% of neurological deficient and death or persistent vegetative state among children with DKA even if it depends on the region of the cerebrum affected (57). A research done in India, Chandigarh revealed that malnutrition was a factor for poor outcome of children with DKA as it increases certain diabetic ketoacidosis complication like hypokalemia and hypoglycemia as compared with normally nourished diabetic ketoacidosis (58). As well as a study conducted in South India showed that severe malnutrition leads to a long hospital stay for 40% of the children with diabetic ketoacidosis by increasing certain biochemical abnormalities(49). And also research conducted in Congo showed that severe under nutrition (p= 0.02) was a significant risk factor for mortality of children with DKA(40).

A study conducted in Chandigarh, India and Maryland, USA showed that administering more fluid bolus and high volume of fluid as well as greater initial rate of fluid resuscitation for treatment of severe DKA (>50 mL/kg) develop certain complications like cerebral edema that leads to death of children with DKA (60,61).

2.2.5. Conceptual framework

The following conceptual framework shows association between independent variables with dependent variable which is developed after reviewing many literatures (19, 26, 40, 52). The dependent variable (treatment outcome of DKA) is affected by socio-demographic characteristics; clinical profile; complications and comorbidities of the child which are described in the figure below.

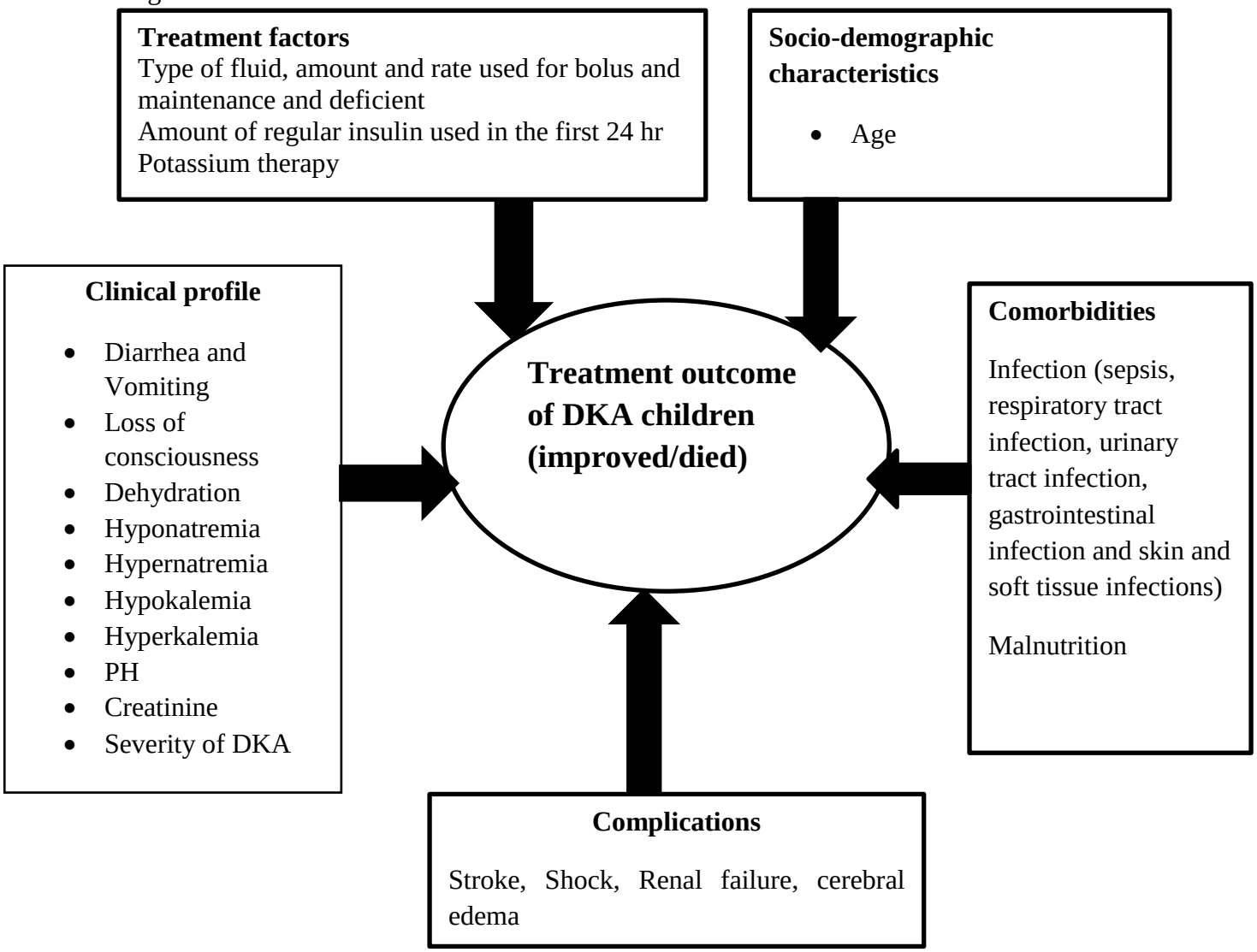

Figure 1: Conceptual framework of treatment outcome of diabetic ketoacidosis and its determinants among children in Debre-tabor and Gondar Referral Hospital, Ethiopia, 2021

3. OBJECTIVES

3.1. General objective

To assess the treatment outcome of diabetic ketoacidosis and its determinants among children in Debre-tabor and Gondar Referral hospitals, North-West, Ethiopia, 2021 G.C.

3.2 Specific objective

- ✓ To determine treatment outcome of diabetic ketoacidosis among children in Debre-tabor and Gondar Referral hospitals, North-West, Ethiopia, 2021 G.C
- ✓ To identify associated factors for treatment outcome of diabetic ketoacidosis among children in Debre-tabor and Gondar Referral hospitals, North-West, Ethiopia, 2021 G.C

4. METHODS AND MATERIALS

4.1 Study area

The study was conducted in Debre-tabor and Gondar Referral Hospitals of South and North Gondar Zones in Amara regional state. Debre-tabor and Gondar Referral Hospital are found in Debre-tabor Town; in South Gondar administrate Zone and in Gondar Town, in North Gondar administrative Zone respectively. These Hospitals are found in Northern direction748 km and 667 km far from Addis Ababa (capital City of Ethiopia) respectively.

Gondar Referral Hospital is found 168 km far from Bahir dar a regional city of Amhara. It has an altitude of 2000-2500 m above sea level and average temperature ranging from 13-34 degree Celsius. The hospital gives service for more than 5 million catchment populations. It provides both specialty and subspecialty service including pediatrics, surgery, gynecology and obstetrics, internal medicine, etc. The hospital has more than 500 beds. The number of nurses and doctors in this hospital is 270 and 150 respectively. The flow of patient ranges from 200-400 per day. The total numbers of patient with diabetes mellitus are 2556 in all age group. From these 987 is pediatrics.

Debre-tabor Referral Hospital is found 102 km far from Bahir dar a regional city of Amhara. It has an altitude of 2706 meter above sea level and the temperature ranges from 15-29.7 degree Celsius. The hospital gives a service for more than 2.5 million of a catchment population. There were 296 health professionals. From those 143 were nurses. It has 200 beds and five admission wards (Surgical, Medical, Gynecology and Obstetrics, Pediatrics and neonatal. The patient flow of the hospital ranges from 150-290. The total numbers of 678 pediatric diabetes mellitus patients have follow up in this hospital.

4.2. Study period

The study was conducted from February 8, 2021 to March 8, 2021.

4.3. Study design

Five year retrospective institutional based cross sectional study was conducted from January 1, 2016- December 30, 2020.

4.4. Population

4.4.1. Source population

All children below 15 years who were admitted for DKA management and treated in Debre-tabor and Gondar Referral Hospital from January 1, 2016 to December 30, 2020.

4.4.2. Study population

All selected children below 15 years admitted for DKA management and treated in Debre-tabor and Gondar Referral Hospital from January 1, 2016 to December 30, 2020 and fulfill the inclusion criteria.

4.5. Inclusion and exclusion criteria

4.5.1. Inclusion criteria

The **c**hildren under the age of 15 who were diagnosed as DKA and receive its treatment in Debre-tabor and Gondar Referral Hospitals from January 1, 2016 to December 30, 2020 were included.

4.5.2. Exclusion criteria

The study excludes children under the age of 15 with DKA who do not have complete record, lost cards, loss to follow up, leave against medical advice and transferred to other hospitals.

4.6. Sample size determination

The sample size in this retrospective study was determined by using a single population formula by considering the following statistical assumptions.

P= sample proportion (50%), Z α/2 = the corresponding Z score of 95% CI, d= Margin of error (5%), n= Sample size

n= Z (a/2)² P (1−P) /d^2=1.96^2×0.5(1-0.5)/0.05^2=384

Since the total population (522) is less than 10,000, we can use correction formula

Fn=$\frac{n}{1+\frac{n}{N}}$=$\frac{384}{1+\frac{384}{522}}$=221: Where FN=final sample size n=sample size N=Total number of DKA patient.

After addition of 10% sample for missing and incomplete data, the final sample size is 244 of under-15 children with DKA.

4.6.1. Sampling technique

The numbers of DKA children who visit Debre-tabor and Gondar referral hospital from January1, 2016 to December 30, 2020 were 222 and 300 respectively. And the

Sample size was distributed proportionally for each hospital. It is determine by using proportional allocation formula.

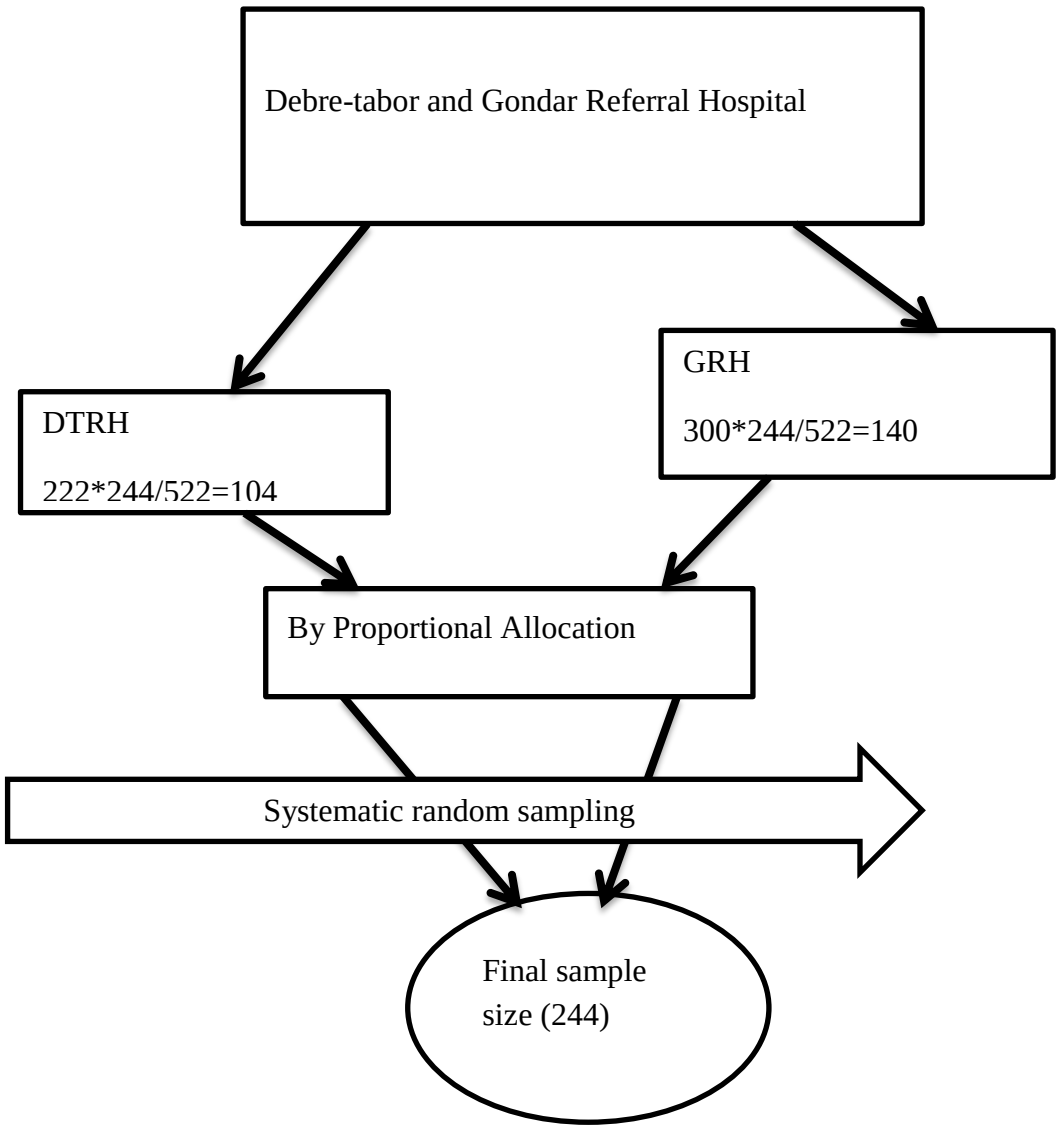

Figure 2: Schematic presentation of sampling procedure to assess treatment outcome of DKA and its determinants among children in Debre-tabor and Gondar Referral Hospitals, North West Ethiopia 2021

Systematic random sampling technique was used to select the study participants. K value was calculated by dividing the number of DKA patient in each hospital by the number of sample size which is allocated for each hospital. Therefore K value in Debre-tabor hospital=$\frac{222}{104}$=2and in Gondar Referral Hospital= $\frac{300}{140}$=2. The first chart was selected randomly.

4.7. Variables

4.7.1. Dependent variable

Treatment outcome (improved/died)

4.7.2. Independent variable

Socio-demographic variables: Age

Clinical profiles

Vomiting, diarrhea, loss of consciousness, dehydration, hypernatremia, hypokalemia, hypo/hyper glycaemia, high creatinine level, low PH and bicarbonate, Clinical severity of DKA

Complications

Cerebral edema, renal failure, pulmonary edema, stroke and Shock

Comorbidities

Sepsis, Respiratory tract infection, Urinary tract infection, gastrointestinal infection) and Malnutrition

Treatment factors

Type of fluid used for bolus, maintenance and deficient, Amount of regular insulin administer, Potassium replacement therapy

4.7.3. Operational definition

Children: - The child whose age is less than 15 years

Treatment outcome: - in hospital mortality or improved patients from DKA.

Improved: Are those children free from urine ketone and random blood sugar < 200mg/dl and discharge well.

Died: those children discharge as death

Diabetic ketoacidosis: child random blood sugar > 200mg/dl, PH< 7.3 and urine ketone positive.

Co-morbidities: additional medical conditions presented in children with DKA.

4.8. Data collection tool

Data collection was done by using pretested checklist prepared in English. The data extraction check list was adopted from different literatures (19, 41, and 40). The checklist contains socio-demographic variables, clinical profiles, comorbidities and complications, management protocols and treatment outcome of DKA.

4.9. Data collection procedure

Records of the eligible children were retrieved from registration book. Then medical registration number (MRN) of all diabetic ketoacidosis pediatric patients was sorted. Then select randomly one chart out of two charts as (k=2). After this, systematic simple random method was applied to select the study subject. Three BSC nurses were selected for data collection and two master nurse supervisors were selected to supervise and organize the whole process during data collection for each hospital. Training was given for supervisors and data collectors. Orientation was given for the supervisor separately on how to supervise the data collectors and how to check for the completed data abstraction form. The supervisor supervised the data collectors, checked for completeness of data abstraction format; and correct any mistake or problem encountered.

10. Data Quality Control

Prior to data collection training was given for the data collectors about study objectives and how to fill the check list. Pretest was done from 5% of the total sample to ensure the agreement of the data abstraction format with the need of the study at Gondar Referral hospital. Any error found in data abstraction format (checklist) was corrected and modified. During data collection close supervision was carried out by supervisor and principal investigator. After proper collection, the supervisor checked the information for completeness and consistency regularly until data collection is completed. Then the collected data was carefully entered, cleaned, coded, and analyzed in SPSS version 25.

11. Data processing and analysis

After the necessary data was collected, it was entered, categorized, coded and summarized by using the Epidata statistical package version 4.6 and then, it was exported to SPSS version 25 for further analysis. Descriptive statics were done using percentages and frequency for categorical variables and mean and stander deviation continuous variables.

Multi-co-linearity of independent variables was check by using co-linearity diagnostic test (tolerance value <0.10 and variance inflation factor (VIF) >5 used as a cut point to test multi-co-linearity). The fitness of regression model was checked by using Hosmer Lemeshow goodness of fit. Then, bivariate and multivariate logistic regressions were used to observe the association between each predictor variables with death of DKA children. After binary logistic regression a p-value ≤0.25 was used as a cut of point to entered variables in to multivariate logistic regression. Variables which had P<0.05 were considered as statistically significant .The strength of statistical association was measured by odds ratio and 95% of confidence intervals. The result of the study was presented in table, graph and charts.

12. Ethical Considerations

Ethical clearance was obtained from the Institutional Review Board of Addis Ababa University, College of Health sciences, School of Nursing and Midwifery. Permission was obtained from selected Hospitals board. Additionally, at selected study department, the matron/ medical officer in-charge was contacted for consent and necessary information before the commencement of the study. Privacy and confidentiality of study participants was maintained by making the data coded and locked in a separate room before entered in to the computer. After entered to the computer the data was locked by password and the data were not disclosed to any person other than principal investigator. All information collected from patients' cards was kept strictly confidential.

13. Dissemination of the Study

The result of the study:

- ✓ Will be submitted and presented to Addis Ababa University, School of Nursing and Midwifery as a partial fulfillment of masters in pediatric and child health nursing.
- ✓ Will also be submitted to Debre-Tabor and Gondar referral hospitals.
- ✓ Finally, it will be published in nationally or internationally recognized journals.

5. RESULT

5.1. Socio-demographic characteristics of the study participants

Out of 244 total samples, charts of 240 children with DKA were included in this study. The rest of sample 4 (6.6%) were defaulters, referrals and had incomplete data. Among 240 DKA children, 132(55%) were males and 158(65.8%) were rural residents. The age of the DKA children ranges from 1year up to 15 years with a mean age of 9 years and majority of the children were found in the age category of 10-15 years in both referral hospitals admitted from January 1, 2016 to December 30, 2020 (**Table-1**).

Table 1: Distribution of socio-demographic characteristics of children with DKA admitted in Gondar and Debre-tabor referral hospitals in Amhara region, Ethiopia 2021.

Characteristics	**Category**	**Frequency(N=240)**	**Percentage (%)**
Age of children	<5 year	42	17.5
	5-10 year	97	40.4
	10-15 year	101	42.1
Sex of child	Male	132	55
	Female	108	45
Residence of children	Urban	82	34.2
	Rural	158	65.8

5.2 Clinical profile of children with DKA

5.2.1 Clinical feature of children

As the table 2 below shows, poly symptoms (78.8%) were reported by most children with DKA and followed by fever (57.1%). Around half of DKA children had sign of dehydration (53.3%) and 50.4% had vomiting.

Table 2: Clinical features of DKA children admitted to Gondar and Debre-tabor hospitals, Amhara region. Ethiopia 2021

Variables	Category	Frequency (N=240)	Percentage (%)
Diarrhea	Yes	89	37.1
	No	151	62.8
Vomiting	Yes	121	50.4
	No	119	49.6
Abdominal pain	Yes	83	34.6
	No	157	65.4
Loss of consciousness	Yes	33	13.8
	No	207	86.2
Dehydration	Yes	128	53.3
	No	112	46.7
Poly symptoms	Yes	189	78.8
	No	51	21.2
Fever	Yes	137	57.1
	No	103	42.9

5.2.2 Biochemical profile of children

Regarding to the biochemical profile of the children, hyponatremia accounts for 88(36.7%) and hypokalemia (serum concentration of potassium less than 3.5 mmol/l) 76(31.7%) and random blood glucose level ranges from 250-350 mg/dl 75(31.3%). More than half of the respondents (58.8%) level of PH was greater than 7.2 and majority of the children ((94.4%) had type 1 DM. And also near to third-quarter of DKA children were previously diagnosed (**Table-3**).

Table 3: Biochemical profile, type of DM and time to diagnosis of DKA children admitted to Gondar and Debre-tabor referral hospitals Amhara region, Ethiopia, 2021

Characteristics	Category	Frequency (N=(240)	Percentage (%)
Random blood glucose level in mg/dl	250-350	75	31.3
	350.1-450	74	30.8
	450.1-550	57	23.8
	>550	34	14.1
Serum concentration of sodium in mmol/l	135-145	111	46.2
	>145	41	17.1
	<135	88	36.7
Serum concentration of potassium in mmol/l	3.5-5.5	117	48.8
	>5.5	47	19.6
	<3.5	76	31.7
Level of PH	>7.2	141	58.8
	≤7.2	99	41.2
Creatinine level in mg/dl	0.5-1.1	153	63.7
	<0.5	87	36.3
Type of DM	Type 1	227	94.6
	Type 2	13	5.4
Time of diabetes diagnosis	Newly	69	28.7
	Previously	171	71.3

5.2.3 Urine ketone level and clinical severity of DKA children

Out of 240 children with DKA, about 69 (28.75%) of them had +1 and trace urine ketone level, 78(32.5%) of them had urine ketone level +2 and the rest approximately 93 (38.8%) of had urine ketone level +3 and +4 (**Fig-3**).

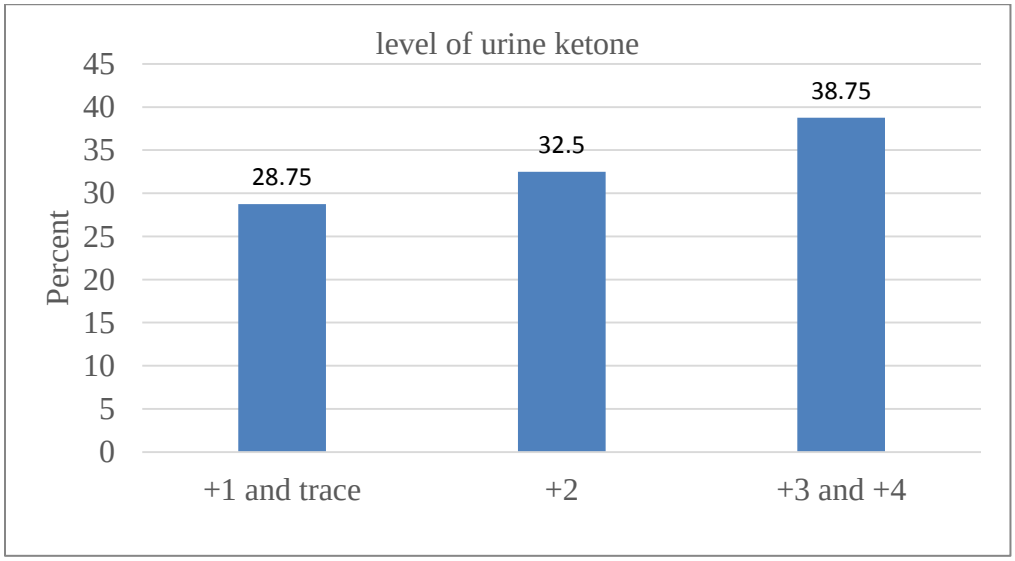

Figure 3: Urine ketone level of DKA children admitted and treated in Gondar and Debre-tabor referral hospitals in Amhara region, Ethiopia 2021

From a total of 240 DKA children, about 128(53.3%) of them had mild DKA, 65(27.1%) of them had moderate DKA and the rest 47(19.6%) had severe DKA (**Fig-4**)

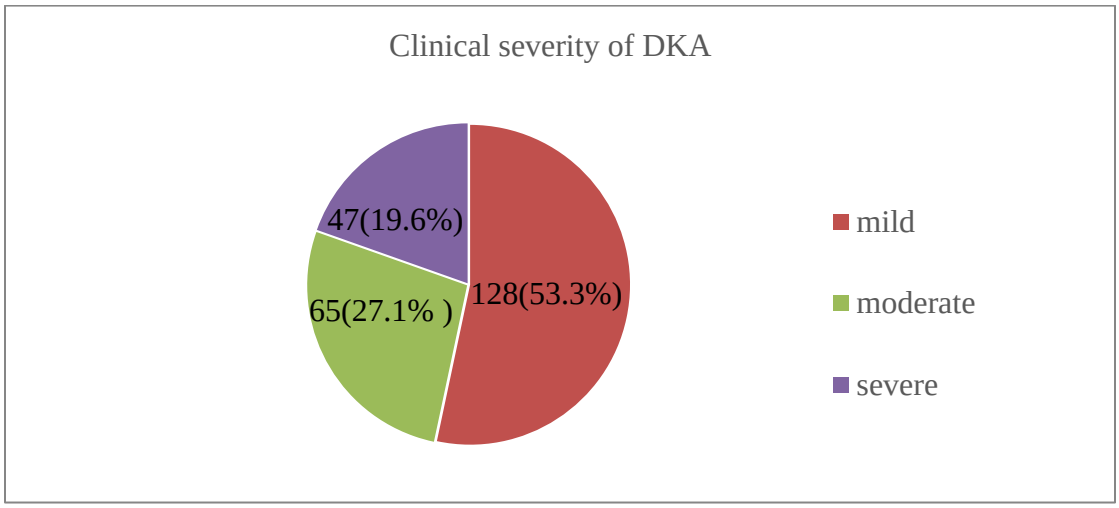

Figure 4: Clinical severity of DKA in children admitted and treated in Gondar and Debre-tabor referral hospitals in Amhara region, Ethiopia 2021

5.3. Comorbidities and complication of children with DKA

Among 240 children with DKA, about 69(28.7%) had respiratory tract infections, urinary tract infections accounts for 56(23.3%) and gastrointestinal infections 49(20.4%). In addition, malnutrition accounts for 48(20%). From a total of malnourished children, near to half (43.8%) of them had mild malnutrition, 35.4% moderate and remain 20.8% had severe malnutrition. Concerning to complications 43(19.9%) presented with shock followed by acute renal failure 36(15%) (**Table-4**)

Table 4: Comorbidities and complications among children with DKA admitted to Gondar and Debre-tabor referral hospitals Amhara region, Ethiopia 2021.

Characteristics	Category	Frequency(n=240)	Percentage (%)
Sepsis	Yes	35	14.6
	No	205	85.4
Respiratory tract infection	Yes	69	28.7
	No	171	71.3
Gastrointestinal infections	Yes	49	20.4
	No	191	79.6
Skin and soft tissue infection	Yes	26	10.8
	No	214	89.2
Urinary tract infection	Yes	56	23.3
	No	184	76.7
Malnutrition	Yes	48	20
	No	192	80
Type of malnutrition (N=48)	Mild	21	43.8
	Moderate	17	35.4
	Severe	10	20.8
Other comorbidities	Yes	25	11.6
	No	215	88.4
Complications of children with DKA			
Cerebral edema	Yes	33	13.8
	No	197	86.2
Acute renal failure	Yes	36	15
	No	204	85
Pulmonary edema	Yes	23	9.6
	No	217	90.4
Shock	Yes	43	17.9
	No	197	82.1
Other complications	Yes	27	11.3
	No	213	87.7

5.4. Management protocol of DKA children

Concerning to management protocol of DKA children, the most commonly type of fluid used for bolus and maintenance were 0.9% normal saline and 120(50%) of respondents required 3-5 litter of total fluid for maintenance and 32.9% took the maintenance fluid at rate of 70.1-90 ml/hr. From the total insulin administered in the first 24 hour, 56.3% were take less than 40IU and 125(52.1%) got potassium replacement. Regarding to outcome of treatment 86.7% was improved and 13.3% was died (**Table-5**).

Table 5: Management protocol and outcome of DKA children admitted to Gondar and Debre-tabor referral hospitals in Amhara region, Ethiopia 2021.

Characteristics	Category	Frequency (n=240)	Percentage (%)
Type of iv fluid bolus	Not received iv fluid bolus	16	6.7
	0.9% normal saline	209	87
	Ringer lactate	15	6.3
Amount of iv fluid bolus	mean±sd	0.3±0.134L	
Type of fluid used for maintenance and deficient used in the management	5% dextrose in water	96	40
	0.9% normal saline	122	50.8
	Ringer lactate	12	5
	Other fluids	10	4.2
Amount of fluid used maintenance and deficient in the management	<3 litter	98	40.8
	3-5 litter	120	50
	>5 litter	22	9.2
Rate of fluid use for maintenance and deficient in the management	50-70 ml/hr.	54	22.5
	70.1-90 ml/hr.	79	32.9
	90.1-110 ml/hr.	63	26.3
	>110 ml/hr.	44	18.3
Amount of regular insulin administered in the first 24 hour	<40 IU	135	56.3
	40-60 IU	82	34.2
	>60IU	23	9.5
Potassium replacement	Yes	125	52.1
	No	115	47.9
Hospital stay	<3 day	101	42.1
	3-5 day	40	16.7
	>5 day	99	41.2
Treatment outcome	Improved and discharge	208	86.7
	Not improved /died	32	13.3

5.5 Factors associated with treatment outcome (death) of children with DKA

Fourteen variables were identified as associated factor for death of children with DKA after bivariate logistic regression analysis was run. After adjusting in multivariate logistic regression; vomiting, hyponatremia and hypernatremia, sepsis, respiratory tract infection, acute renal failure, cerebral edema, dehydration and potassium replacement therapy were identified as significant factors affecting death of children with DKA.

Regarding to clinical profile of DKA children, those DKA children who had symptom of vomiting three times more likely to die as compared to those children who do not had vomiting (AOR=3.4, 95% CI; 1.06-10.8). And also children who presented with dehydration more likely to die by four times as compared with children who didn't present with dehydration (AOR=4, 95% CI; 1.15-14.03).

Likewise, children whose serum sodium concentration greater than 145mmol/l were7 times more likely to die as compared to children whose serum sodium concentration were between 135-145 mmol/l (AOR=7.4, 95% CI; 1.29-42.08). In addition, children who didn't receive potassium replacement therapy more-likely to die by six times from those children who received potassium replacement (AOR=5.5, 95% CI; 1.63-18.43).

Depending on children's exposure for different disease, children who develop respiratory tract infection less likely to recover by three times as compared to DKA children who didn't develop respiratory tract infection (AOR=3.5, 95% CI; 1.2-10) and those children with sepsis 5 times more likely died than those without sepsis (AOR=4.9, 95% CI;1.45-16.57) . Concerning to complication of DKA children, those children with cerebral edema more likely to die by six times from their counterparts (AOR=5.89, 95% CI; 1.56-22.3) (**Table-6**).

Table 6: Distribution of factors associated with treatment outcome of DKA children admitted to Gondar and Debre-tabor referral hospitals in Amhara region, Ethiopia 2021.

Characteristics		**Treatment outcome**		**COR (CI95%)**	**p-value**	**AOR (CI 95%)**
		Improved	Died			
Vomiting	No	110	9	1		
	Yes	98	23	2.87(1.27-6.49)	0.039	**3.4(1.06-10.8)***
Loss of consciousness	No	184	23	1		
	Yes	24	9	3(1.24-7.23)	0.46	1.6(0.46-5.72)
Serum sodium concentration	135-145	105	6	1		
	>145	34	7	3.6(1.13-11.46)	0.025	**7.4(1.29-42.08)***
	<135	69	19	4.8(1.83-12.67)	0.047	**4(1.02-16.1)***
Sepsis	No	186	19	1		
	Yes	22	13	5.8(2.52-13.3)	0.01	**4.9(1.45-16.57)***
Respiratory tract infection	No	159	12	1		
	Yes	49	20	5.41(2.47-11.84)	0.023	**3.5(1.2-10)***
Shock	No	176	21	1		
	Yes	32	11	2.88(1.26-6.55)	0.99	1(0.29-3.43)
Cerebral edema	No	189	18			
	Yes	19	14	7.7(3.33-17.97)	0.009	**5.89(1.56-22.3)***
Acute renal Failure	No	185	19	1		
	Yes	23	13	5.5(2.4-12.59)	0.04	**3.6(1.06-12.45)***
Pulmonary edema	No	192	25			
	Yes	16	7	3.4(1.26-8..96)	0.42	0.5(0.11-2.52)
PH level	>7.2	126	15	1		
	≤7.2	82	17	1.7(0.82-3.68)	0.84	0.9(0.25-3.12)
Malnutrition	No	171	21	1		
	Yes	37	11	2.42(1.08-5.45)	0.28	2(0.57-7.12)
Blood creatinine	0.5-1.1	136	17	1		
	>1.1	72	15	1.67(0.8-3.5)	0.62	1.34(0.42-4.25)
Potassium replacement	Yes	113	12			
	No	95	20	1.98(0.92-4.26)	0.006	5.5(1.63-18.43)*
Dehydration	No	103	9	1		
	Yes	105	23	2.5(1.11-5.67)	0.029	4(1.15-14.03)*

***= associated factors for death of children with DKA (p-value<0.05)**

6. DISCUSSION

The aim of this study was to determine treatment outcome and to identify determinant factors of a DKA children. From a total of 240 children with DKA 208(86.7%) of them recovered and 32(13.3%) died. When compare with studies conducted in different countries, percentage of children improved in this study were higher than studies done in Swedish and Pakistan (80%, 59.5%) (34)(38). Difference in sample size might be the possible reason for the difference of improvement. However the number of children improved was relatively concordant with the finding in Bangladesh (86.6%) (36). Possible reason for this similarity might be presence of relatively similar socioeconomic characteristics.

However the percentage of children improved in the present study were lower than studies conducted in south India, Karnataka tertiary hospital and in Delphi tertiary hospital, Kenya, Congo, Hawassa and Tigray (31, 35, 39, 40, 41, and 20). The higher percentage of improved children in south India Karnataka (89.5%) and Delphi tertiary hospital (87.3%), Kenya (93.1%) and Congo (87.3%) might be due to different quality of care provided in each hospital, health seeking behavior and accessibility of different medications. However the difference in study conducted in Ethiopia such as Hawassa and Tigray might be due to difference in sample size and quality of health care provided by health professionals.

Regarding to predictors of treatment outcome of DKA, from all clinical profile of children vomiting, dehydration and level of serum concentration of sodium (Hyponatremia and Hypernatremia) were the only significant factors for death of children with DKA. Related to vomiting, children who had vomiting were more likely to die by three times as compared to those children who hadn't vomiting. The explanation for this association might be children who had vomiting are exposed to certain complications like biochemical disturbance and high fluid loss that complicates management process. This was in line with study conducted in south India in Chennai Tirunelveli Nadu hospital (28). However vomiting was not significant predictor of for death of children with DKA in a retrospective cross-sectional study in Pakistan, Kenya and Congo (38, 39, and 40). The possible reason for this variation might be in those hospitals complications related to vomiting were detected and treated early. And also related to dehydration, children with dehydration were more likely to die by 4 times as compared to those children without dehydration. This finding was similar with study conducted in Congo (40). The

explanation for the association might be due to dehydration causes electrolyte imbalance and vital organ damage like kidney and brain that leads to death.

Similarly, children who had hyponatremia were more-likely to die by four times as compared to those children who had normal level of serum concentration. The scientific reason for those association is unless it is prevented, detected, and treated early, hyponatremia compromise certain vital organs like brain, heart and kidney which leads to death. This finding was consistent with study conducted in south India Calicut, north India Hilly Himalayan and Karachi tertiary hospital in Pakistan (50, 45, and 38). However hyponatremia was not associated factor for death of children with DKA in study conducted Besat university hospital in Iran and Mexico (46, 47). The reason for the difference might be different in study design (prospective vs cross-sectional) as well as the health care providers working in those hospitals may detect and treat it early.

Like wises this study identified hypernatremia as one of the associated factors for death of DKA children, which is similar to study conducted in southern and northern India (28,45). The scientific explanation for this similarity could be hypernatremia leads to vital organ damage like brain shrinkage when not early detected and treated. This finding was found to be similar with result report of study done in Congo (40).

Regarding to comorbidities of DKA children, respiratory tract infection and sepsis were the predicting factor for death of DKA children. Concerning to respiratory tract infection, children with respiratory tract infection were more-likely to die by four times as compared to those children who had not respiratory tract infection. The scientific reason for the association might be infections like respiratory tract infections will result in production of counter regulatory hormones like adrenaline and cortisol that decreases the effect of insulin in glucose regulation(5). As a result of these, the severity of DKA increases with its complication. If not treating it by giving adequate medication the children with DKA will died. The present finding is founds to be similar with study done in Tigray (20).

In similar way, in the present study sepsis was one of the factors that determine death of DKA children. The reason behind it might be due to not giving adequate fluid for resuscitation as children who develop sepsis needs large volume of fluid for bolus as well as not detecting and giving early treatment for it. The present study was consistent with study conducted in south India and Pakistan (28, 43).

Regarding to complication of DKA in children, cerebral edema and acute renal failure were the associated risk factors for the death of children. Related to cerebral edema, those children presented with cerebral edema were more-likely to die by six times as compared to those children who hadn't cerebral edema. The explanation for this association might be due to cerebral edema causes herniation and compression of brain and brain stems that will lead to blocking of oxygenated blood to flow to brain and brain cell death. As a result the children will die. It is similar with study conducted in Chatradurga, Hilly himalyan, Chennai tertiary hospital in India and Pakistan (31, 45, 28, and 43).

Likewise children with acute renal failure were more-likely to die by four times as compared to those children without acute renal failure. This is similar with study conducted in India (52). The scientific explanation for the association might be having renal failure children leads to those children to develop hyperkalemia, anemia and heart disease that increase morbidity and mortality of children.

Related to management of DKA, children who didn't received potassium as a replacement were more likely to die by six times as compared to those children who received potassium as replacement. The scientific explanation for this association could be if potassium replacement therapy is not given for those children, hypokalemia that leads to problem in cardiac conduction like cardiac dysthymia will be develop. As a result the children will die. Therefore, unless the patient exhibits hyperkalemia or anuria, potassium should be added to the intravenous fluids at the beginning of the second hour of therapy (59).

7. CONCLUSION

This study tried to assess different factors such as Socio-demographic characteristics, sign and symptoms and biochemical parameters, comorbidities and complications of diabetic ketoacidosis and management protocols. Death of children was higher (13.3%). Respiratory tract infections, sepsis, cerebral edema, renal failure, vomiting, dehydration, hypo/hypernatremia and potassium replacement therapy were identified as associated factors for death of children with DKA. Therefore to reduce complications and comorbidities and death of children, emphasis should be given for improving early detection and immediate management of DKA children.

7.1. Strength of the study

The strength of this study includes:-

- ✓ Using a five year data to increase representativeness
- ✓ Including variables like management protocols that were not include in other retrospective studies.

7.2. Limitation of the study

The study was limited to merely on secondary data. So analysis of associated factors for treatment outcome of DKA was based on only information that could be obtained from charts. In addition it didn't include information's related to families' economic status, educational level and occupation. Further, children who are defaulters, lost to follow up and refer to other institution were not included. On the other hand diagnosis of DKA was based on the diagnosis obtained from the charts that might be misdiagnosed.

8. RECOMMENDATIONS

Based on the finding of study, the following recommendation could be mentioned:-

For policy makers

- ✓ Incorporate the need of training for health professionals about prevention and management of complications of diabetic ketoacidosis and develop standard protocol for all facilities to aware health care providers.

For health professionals

- ✓ The health care professionals should work in improving parents' awareness regarding to early sign and symptoms of complications like cerebral edema which is one of the most cause of death of children with DKA.
- ✓ The health care providers must give more attention to early identification of sign and symptoms and take early action to sepsis and other infections like respiratory tract infections.
- ✓ They should detect complications as early possible.
- ✓ The health professionals should follow strictly management protocol of diabetic ketoacidosis in order to avoid hypo/hypernatremia, cerebral edema and renal failure.

For respective hospitals

- ✓ Prepare a schedule for client's education
- ✓ Adjust on job training and refresher programs for the health care providers regarding to management of DKA complications according to national protocol to decrease death rate of diabetic ketoacidosis children.

For future researchers

- ✓ As this is, a hospital based retrospective secondary data analysis; future researchers should use a prospective cohort study design for better information including other factors not included under this study such as parental socio-demographic and socio-economic characteristics, educational status of child's families and chronic comorbidities of diabetes mellitus.

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10. ANNEX I

10.1. CHECKLIST

This checklist is prepared for collecting information on treatment outcome of diabetic ketoacidosis and its determinants among children admitted to Debre-tabor and Gondar referral hospital.

1. Data collector name _____

2. Date of data collection _____

Table 7: Questionaries' checklist

Part 1: Socio-demographic characteristics		
101	Age of the child	---------month /year
102	Sex of the child	A. Male B. Female
103	Residence	A. Urban B. rural
Part 2: clinical profile of the children with DKA		
201	Presence of diarrhea	A. Yes B. No
202	Presence of vomiting	A. Yes B. No
203	Presence of abdominal pain	A. Yes B. No
204	Presence of loss of consciousness	A. Yes B. No
205	Presence of dehydration	A. Yes B. No
206	Presence of poly symptoms	A. Yes B. No
207	Presence of fever	
207	Level of random blood glucose in mg/dl	----------
208	Serum concentration of sodium in mmol/l	A. 135-145MEq/L B. >145 MEq/L C. <135MEq/L
209	Serum concentration of potassium in mmol/l	A. 3.5-5.5MEqL B. >5.5MEq/L C. <3.5MEq/L
210	Level of PH	A. >7.3 B. 7.2-7.3 C. 7.2-7.1 D. <7.1
211	Blood creatinine level (mg/dl)	A. 0.5-1.1mg/dl B. >1.1mg/dl
212	Urine ketone	----------

213	Clinical severity of DKA	A. Mild B. Moderate C. Severe
214	Time of diabetes diagnosis	A. Newly diagnosis B. Previously diagnosis
215	Type of Diabetes mellitus	A. Type 1 B. Type 2
Part 3: Comorbidities before and after admission of children with DKA		
301	Presence of sepsis	A. Yes B. No
302	Presence of respiratory tract infection	A. Yes B. No
303	Presence of gastrointestinal infections	A. Yes B. No
304	Presence of skin and soft tissue infection	A. Yes B. No
305	Presence of urinary tract infections	A. Yes B. No
306	Presence of malnutrition	A. Yes B. No
307	If yes, Type of malnutrition	A. Mild B. Moderate C. Severe
308	Other comorbidities (specify)	----------
Part 4: Complications before and after admission of children with DKA		
401	Presence of cerebral edema	A. Yes B. No
402	Presence of renal failure	A. Yes B. No
403	Presence of stroke	A. Yes B. No
404	Presence of pulmonary edema	A. Yes B. No
405	Other complication (specify)	--------
Part 5: management protocol of DKA children		
501	Type of iv fluid bolus	Not received iv fluid bolus 0.9% normal saline Ringer lactate
502	Amount of iv fluid bolus in liter	_____
503	Type of fluid for maintenance used in the management	5% dextrose in water 0.9% normal saline

		Ringer lactate
		Other fluids
504	Amount of fluid maintenance used in the management in liter	----------
505	Rate of fluid maintenance used in the management in ml/hr	----------
506	Amount of regular insulin administered in the first 24 hour	----------
507	Potassium replacement	A. Yes
		B. No
508	Hospital stay	
Part 6: treatment outcome of DKA children		
601	Outcome	A. Improved
		B. Died

ANNEX II

Information Sheet

Title of the Research Project: Treatment outcome of DKA and its determinants among children admitted to Debre-tabor and Gonder Referral Hospital from (2016-2020, North West Ethiopia, 2021.

Name of Investigator: Mequanint Ayehu (BSc in Nursing)

Name of the Organization: Addis Ababa University College of Health Science, School of Nursing and Midwifery, Department of Pediatrics and Child Health.

Name of the Sponsor: Addis Ababa University.

Introduction: This information sheet is prepared for Debre-tabor and Gonder referral Hospital administration and emergency, pediatric ward and ICU coordinating office. The aim of the form is to make the above-concerned office clear about the purpose of research, data collection procedures and get permission to conduct the research.

Purpose of the Research Project: To assess treatment outcome of DKA and its determinants among children admitted to Debre-tabor and Gonder Referral Hospital from 2016-2020, North West Ethiopia, 2021.

Procedure: In order to achieve the above objective, information which is necessary for the study was taken from emergency, pediatric ward and ICU record form.

Risk and /or Discomfort: Since the study was conducted by taking appropriate information from medical chart, it will not cause any harm on the patients. The name or any other identifying information will not record on the questionnaire and all information is taken from the chart will kept strictly confidential and in a safe place. The information retrieved will be only used for the study purpose.

Benefits: The research have no direct benefit for one whose document/ record are included in this research. But the indirect benefit of the research for the participant and other clients in the program is clear. This is because if program planners are preparing predicted plan there is a benefit for clients in the program of getting appropriate care and treatment services for those survived and other newly born ones. In all, the research work has a principal direct benefit for health care planners and managers.

Confidentiality: To reassure confidentiality the data on the chart will be collected without the name of the clients and the information collected from this research project will be kept confidential and stored in a file cabinet. In addition, it will not be shown to anyone except the investigator and it has been kept in a key and locked system with computer password.

Person to contact: This research project will be reviewed and approved by the institutional review board of College of Health Science, School of Nursing and Midwifery, Addis Ababa University. If you have any question you can contact any of the following individuals (Investigator and Advisors) and you may ask at any the time you want.

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