Glycaemic Control (Serum HbA1c level) and its Associated Factors in Children with Type 1 Diabetes Mellitus Treated in Jimma University Specialized Hospital; Oromia, South-West Ethiopia

By

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A Thesis to be Submitted to the Department of Pediatrics and Child Health, College of Public Health and Medical Sciences, Jimma University, as a Partial Fulfillment of The Requirement for the Specialty Certificate in Pediatrics and Child Health

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Abstract

Background*:* Long term complications of type 1 diabetes mellitus are devastating for individuals and families and impose a considerable burden to health care systems. Maintaining strict glycaemic control in type 1 diabetics has been shown to greatly reduce the incidence and progression of long term complications. Various risk factors have been found to be associated with poor glycaemic control. Identification of factors associated with poor control in our setting is critical in order to institute appropriate interventions that will result in improved metabolic control and prevent chronic complications.

Objective: To assessing glycemic control using serum level of glycosylated hemoglobin (HbA1c) and its associated factors in children with Type 1 diabetes mellitus(T1DM) at Jimma University Specialized Hospital (JUSH) Ethiopia.

Methods: A cross-sectional descriptive study was carried out among children and adolescents being treated at the diabetes clinic of JUSH. A structured questionnaire was used to collect socio-demographic, diabetic related knowledge and practice of the participants and parents/guardians. The weight and the height of the patients were measured. Fasting blood sugar was also recorded .Glycemic control was assessed by measurement of serum HbA1c% by using **in2itA1c Analyzer**. Data was entered using Epidata version 3.1 and exported to SPSS 16 for analysis. Mean, standard deviation (SD), analysis, bivariate and multivariable linear regression analyses were conducted to identify independent predictors of serum HbA1c.The study was conducted from April 1 to May 30, 2006 E.C.

Results: We studied 60 children 0.25-18 years of age of which 33(55%) were males with a mean age of 11.81±3.5 yrs. The mean ± SD HbA1c was 10.4±2.6% .Thirty four (56.7%) of them had poor glycemic control (HbA1c ≥10.0 %), 16(26.7 %) of them had fair glycemic control (8-9.9%) and only 10(16.7%) of them had good glycemic control (HbA1c<7.9%). The mean % ± SD of diabetic knowledge of the adolescents and caregivers were 65.79±1.11 and 64.00 ± 1.16 respectively. Fifty one (85%) of patients had good adherence to insulin (did not miss dose in the past three months prior to data collection) while good adherence to blood glucose monitoring (BGM) at home and diet was 20 (33.3%) and 4(6.7%) respectively. Meal adherence scored out of

8points from meal content and meal frequency each having 4 points. Maximum score is 8.those who scores < 4(poor), 4-6(average), and > 6 (good). The BGM adherence was scored as good if 3 or more times tests a week; average if 1 – 2 times a week; poor if none. On bivariate analysis none educated care givers (b=2.10, 95%CI=0.23, 3.92, p value=0.028), and rural residence (b=1.40, 95%CI=0.08, 2.68, p values=0.038) have positive correlation with serum HbA1c level. Those who missed1-3 insulin doses in the preceding three months prior to data collection were also associated with increased HbA1c level(b=2.1, 95%CI=0.28,3.9,p values=0.024).Fifty (83.3%) of the study participants were wasted(BMI<18.5).

Conclusions: Most of the Children and adolescents with T1DM in Jimma university teaching hospital have poor glycemic control and poor adherence to blood glucose monitoring (BGM) and diet. Both the caregivers and adolescents have low diabetic knowledge. Regularly diabetic education should be given on regular base to improve the diabetic knowledge of the patients and the caregivers, and adherence to BGM at home, which then may improve the glycemic control. Emphasis needs to be put on dietary knowledge and adherence counseling.

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Abbreviations/Acronym

ADA - American Diabetic Association

BGM - Blood Glucose Monitoring

DCCT - Diabetes Control and Complications Trial

DKA - Diabetic Ketoacidosis

DKT-Diabetic knowledge Test

DM - Diabetes Mellitus

EDA- Ethiopia Diabetic Association

HbA1c - Glycosylated hemoglobin

IDF - International Diabetes Federation

JUSH-Jimma University Specialized Hospital

SES - Socioeconomic status

SPSS- Software Package for Statistical Sciences

T1DM - Type 1 Diabetes Mellitus

T2DM - Type 2 Diabetes Mellitus

WHO- World Health Organization

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Chapter One: Introduction

1.1: Background

Diabetes mellitus (DM) is a common, chronic, metabolic syndrome characterized by hyperglycemia as a cardinal biochemical feature. Type 1 diabetes mellitus (T1DM) is the most common endocrine-metabolic disorder of childhood and adolescence, with important consequences for physical and emotional development(1). Morbidity and mortality stem from acute metabolic derangements and from long-term complications (usually in adulthood) that affect small and large vessels resulting in retinopathy, nephropathy, neuropathy, ischemic heart disease, and arterial obstruction with gangrene of the extremities (1).

The epidemiology of T1DM varies considerably based on geographic location. In the developed world, the prevalence has been found to be higher than that in Africa. However this may be due to higher diagnostic rates and surveillance in the developed world as compared to Africa. Data from different center shows there is an increasing annual rate of incidence of T1DM. The rate of increase is greatest among the youngest children. In the USA, the overall prevalence of diabetes among school-aged children is about 1.9/1,000, increasing from a prevalence of 1/1,430 children at 5 yr. of age to 1/360 children at 16 yr. It is estimated that of the 400,000 total new cases of type 1 diabetes occurring annually in all children under age 14 yr. in the world, about half are in Asia(1).

At the beginning of the 20th century, diabetes was virtually unknown in Africa, whereas in 2006 there were 10 million people with this diagnosis. This is expected to rise to almost 20 million by 2025. It is largely type 2 diabetes(T2D), but type 1 diabetes (T1D) is still the most common form of diabetes in children. The true prevalence of diabetes is unknown in Africa, because of poor infrastructure both in terms of being able to make the diagnosis and for health reporting(2).

Few African studies have been done documenting the incidence and prevalence of T1DM, most of them being hospital based studies as opposed to population studies. The true population prevalence hence remains unknown. Studies from North Africa have shown a varying incidence ranging from 4.4/100,000 in Algeria to 20/100,000 in Morocco(3).

Four studies estimating the prevalence and/or incidence of type 1 diabetes in Sub Saharan Africa region were published since1990. Observed prevalence ranged from 3.5 per 100,000 persons in Mozambique, to 12 per 100,000 persons in Zambia. Recorded incidence ranged from 1.5 per 100,000 persons per year in Tanzania to 2.1 per 100,000 persons per year in Ethiopia(4, 5).

No population-based prevalence study exists in Ethiopia but from hospital based studies it can be seen that the prevalence of diabetes admission has increased from 1.9% in 1970 to 9.5% in 1999 of all medical admissions WHO estimated the number of diabetics in Ethiopia to be about 800,000 cases by the year 2000, and the number is expected to increase to 1.8 million by 2030(6).

1.2: Statement of the problem:

Strict glycemic control has been shown to reduce the long term complications of both type 1 and type 2 DM. This was observed in DCCT (Diabetes Control and Complication Trial), the landmark trial in type 1 diabetics which showed that intensive diabetes treatment delayed the onset and slowed the progression of chronic complications of T1DM such as nephropathy, neuropathy and retinopathy by 47-76%(1, 7).

A reliable index of long-term glycemic control is provided by measurement of glycosylated hemoglobin. HbA_{1c} represents the fraction of hemoglobin to which glucose has been no enzymatically attached in the bloodstream. The formation of HbA_{1c} is a slow reaction that is dependent on the prevailing concentration of blood glucose; it continues irreversibly throughout the red blood cell's life span of approximately 120 days. Because a blood sample at any given time contains a mixture of red blood cells of varying ages, exposed for varying times to varying blood glucose concentrations, an HbA_{1c} measurement reflects the average blood glucose concentration from the preceding 2-3 mo.

When measured by standardized methods to remove labile forms, the fraction of HbA_{1c} is not influenced by an isolated episode of hyperglycemia. Consequently, as an index of long-term glycemic control, a measurement of HbA_{1c} is superior to measurements of glycosuria or even multiple blood glucose determinations. It is recommended that HbA_{1c} measurements be obtained

3-4 times per yr to obtain a profile of long-term glycemic control. The more consistently lower the HbA_{1c} level, and hence the better the metabolic control, the more likely it is that microvascular complications such as retinopathy and nephropathy will be less severe, delayed in appearance, or even avoided altogether(1)

In non-diabetic individuals, the HbA_{1c} fraction is usually less than 6%; in diabetics, values of 6-7.9% represent good metabolic control, values of 8.0-9.9%, fair control, and values of 10% or higher, poor control. Adjustments in target HbA_{1c} should be made for younger children(1). In diabetics, current recommendations of the optimum value of HbA1c depend on the age group. The risk of hypoglycaemia has to be weighed against the benefits of strict glycaemic control especially in young children. The developing brain of infants and young children is very vulnerable to the detrimental effects of hypoglycaemia. In addition, infants and young children exhibit hypoglycaemia unawareness because of the inability to communicate symptoms and a poor adrenergic response to low blood sugar.

Hence it is recommended that their HbA1c be maintained at a higher level than the DCCT recommendations of < 7%. For children less than 6 years, the ADA recommends an HbA1c of between 7.5 and 8.5%. For those between 6 and 12 years, a level of < 8% is recommended while for those > 12 years, a level of < 7.5% is considered optimal. This is 0.5% higher than the recommendation for adults with T1DM because adolescence is a period of hormonal changes and achieving a lower HbA1c may be difficult (4).

There exists a wide variation in glycaemic control between Africa and the developed world. Data from Australia showed a median HbA1c of 8.2%(8);while in a study from France, the mean HbA1c was found to be 8.97%(9).In a study in Denmark, the mean HbA1c dropped from 9.05% in 1997 to 8.2% in 2006(10).

Studies from Africa have shown consistently poor glycaemic control in type 1 diabetics. In Sudan, the median HbA1c was reported to be 9.8% at puberty while a study done in Tanzania reported the mean HbA1c to be 10.65%.This poor control was attributed to lack of insulin supply, poor storage of insulin, inadequate dosing and lack of BGM(4).

The biochemical alterations in T1DM result in both acute and chronic complications. Acute complications include DKA and hypoglycaemia while chronic complications include retinopathy, neuropathy, nephropathy, growth disturbances, cardiovascular disease and diabetic foot ulceration. Most of the chronic complications are attributed to the non enzymatic glycosylation of protein residues in nerves, blood vessels and renal glomeruli.

The age of onset of chronic complications in T1DM is variable. The risk of diabetic retinopathy after 15 yrs duration of diabetes is 98% for individuals with T1DM and 78% for those with T2DM. Lens opacities are present in at least 5% of those younger than 19 yr. Diabetic nephropathy affecting 20-30% of patients with T1DM and 15-20% of T2DM patients 20 yr after onset(1).

Studies from different parts of the world have found a variety of risk factors that predict poor glycaemic control. Some of the factors include: Socioeconomic status, Family environment, Insulin dose, Age, sex, diabetic durations, Adherence to the treatment regimen, Self-monitoring of blood glucose, BMI and Knowledge of diabetes(3, 10).In Ethiopia there is no available study done to describe the risk factors associated with poor glycaemic control. Whether similar variables play a role in Jimma and in other similar resource poor settings remains to be determined.

Thus, the main aim of this study was to determine mean serum HbA1c and its associated factors in pediatrics on follow up at JUSH.

Chapter Two: Literature Review:

2.1: Overview

In view of the benefits of strict glycaemic control, numerous studies have been done to explore variables that may be associated with poor control. Most of these studies however are from Europe and North America with minimal data available from Asia and the African continent. Some of the factors include: Socioeconomic status, Family environment, Insulin dose, Age, sex, diabetic durations, Adherence to the treatment regimen, Self-monitoring of blood glucose, BMI and Knowledge of diabetes (3, 10).

2.2: Level of Glycaemic Control

A lot of published series have shown that glycemic control is still often poor in many children with Type 1 diabetes mellitus despite easier home monitoring of blood glucose, the introduction of pen devices for insulin injection, and the introduction of new insulin types and regimens during the last decade. For instance , in the study done in Bashar, Iraq the age specific target HbA1c was achieved in only 12.4%(11), only 18% of the patiens achieve target HbA1c in Kuwait(12); fewer than 15% of children and young people with diabetes in England and Wales achieve an HbA1c of <7.5(13).

Data from Australia showed a median HbA1c of 8.2% (8);while in a study from France, the mean HbA1c was found to be 8.97%(9).In a study in Denmark, the mean HbA1c dropped from 9.05% in 1997 to 8.2% in 2006(10).Studies from Africa have shown consistently poor glycaemic control in type 1 diabetics. In Sudan, the median HbA1c was reported to be 9.8% at puberty while a study done in Tanzania reported the mean HbA1c to be 10.65%.This poor control was attributed to lack of insulin supply, poor storage of insulin, inadequate dosing and lack of BGM(4).

2.3 Factors Associated With Poor Glycaemic Control

2.3.1: Socio-Demographic and Economic Factors

Socio-demographic and economic variables such as family income, level of maternal education and family structure have been found to be predictors of glycemic control. A study from Argentina found that single parent families and low levels of maternal education were predictive of poor glycaemic control(14). Similarly, a study from the UK found that patients from deprived areas had poorer glycaemic control as compared to those from affluent areas(15). In USA the study showed that, socioeconomic status (SES) and family structure were the primary risk factors to disease control. Children from low SES families were in poorer glycaemic control and experienced more episodes of hypoglycaemia-related loss of consciousness. In addition, children from middle-class, two-parent families were in better metabolic control than all other groups(16),another study from USA, Ortoland,OR,shows that Patients with parents who were single, separated, or divorced had an HbA1c value 0.47 higher than patients with married parents(17).

Similarly study from Belgium found parental marital and professional status to predict glycemic control(18).A study comparing glycaemic outcomes in children from single mother and 2 parent families found that those from single mother families had an average HbA1c of 1.2% higher than those from two parent families . This was attributed to the fact that single mothers had lower levels of education and lower SES(19).

2.3.2: Patient/Care Giver Related and Diabetic Specific Factors

Family support and involvement of parents and guardians in the care of diabetic children and adolescents has been found to promote adherence and hence result in better glycaemic control. A study in Boston ,Massachusetts,to investigate relationships between parental involvement in diabetes related tasks and glycaemic control found that more parental involvement in BGM improved adherence and this translated to better glycaemic control(20).

A study from Portugal found that support for female diabetics and those of lower social class resulted in higher adherence and better metabolic control while family conflict predicted poor glycaemic control in patients of upper social class(17).In a study among Hispanic youth, better adherence was associated with lesser adolescent independent responsibility and more family support for diabetics(18).

The dose of insulin has been found to be associated with level of glycemic control. Several factors influence the initial daily insulin dose per kilogram of body weight. The dose is usually higher in pubertal children. It is higher in those who have to restore greater deficits of body glycogen, protein, and fat stores and who, therefore, have higher initial caloric capacity. On the other hand, most children with new-onset diabetes have some residual β-cell function (the honeymoon period), which reduces exogenous insulin needs. Children with long-standing diabetes and no insulin reserve require about 0.7 U/kg/day if prepubertal, 1.0 U/kg/day at mid puberty, and 1.2 U/kg/day by the end of puberty. A reasonable dose in the newly diagnosed child, then, is about 60-70% of the full replacement dose based on pubertal status. The optimal insulin dose can only be determined empirically, with frequent self-monitored blood glucose levels and insulin adjustment by the diabetes team. Residual β-cell function usually fades within a few months and is reflected as a steady increase in insulin requirements and wider glucose excursions(1).

Studies from Australia, New Zealand and France found a higher dose of insulin per kg body weight to be associated with poor glycemic control (8, 9, 19). However, a study from Sudan demonstrated no difference in glycemic control with a higher dose of insulin (21).

Even if there are some contradicting findings, age of the patient, age at onset of DM and diabetes duration have been found to be significantly associated with glycemic control. Older age and longer duration of DM was associated with poorer control in studies from UK and France (9, 15).However, age was not associated with poor control in studies from Australia, New Zealand and France (8, 15, 19, 22)). In other study in Tanzania Children aged < 10 years were found to have a significantly better glycemic control as compared to 10 – 14 year olds and year olds(4). Similarly study from USA, Ortoland,OR; found patients between 14 and 18 yr of age had an

HbA1c value 0.56 higher than children between 2 and 8 yr of age. They explain the poorer glycemic control there is high opportunity for non-compliance with increasing age because many parents stop supervising blood testing, insulin adjustment, and injections by this times combined with changing hormonal milieu during adolescents, which places them at risk for higher HbA1c levels(22).

On contrary to the study in Ortolan, study from Saudi showed younger patients were significantly had higher mean HbA1c than older children. Patients with diabetes duration more than 10 years were significantly had lower mean HbA1c than patients with diabetes duration between 5 and 10 years and less than 5 years(23). Similar to this study from Sudan showed an inverse relationship; with older age and longer duration of diabetes being associated with better control(24).Possible explanations for this were that older patients with longer duration of DM may have more knowledge and experience to deal with their diabetes.

Adherence to the treatment regimen has been found to play a major role in promoting optimal glycemic control. A recent meta-analysis by Hood et al of studies in type 1 diabetic children and adolescents demonstrated a negative correlation between adherence and HbA1c levels and this was found to be independent of socio-demographic and other diabetes specific variables(25).Mehta et al demonstrated that greater dietary adherence was associated with lower HbA1c levels in youth with diabetes(26).

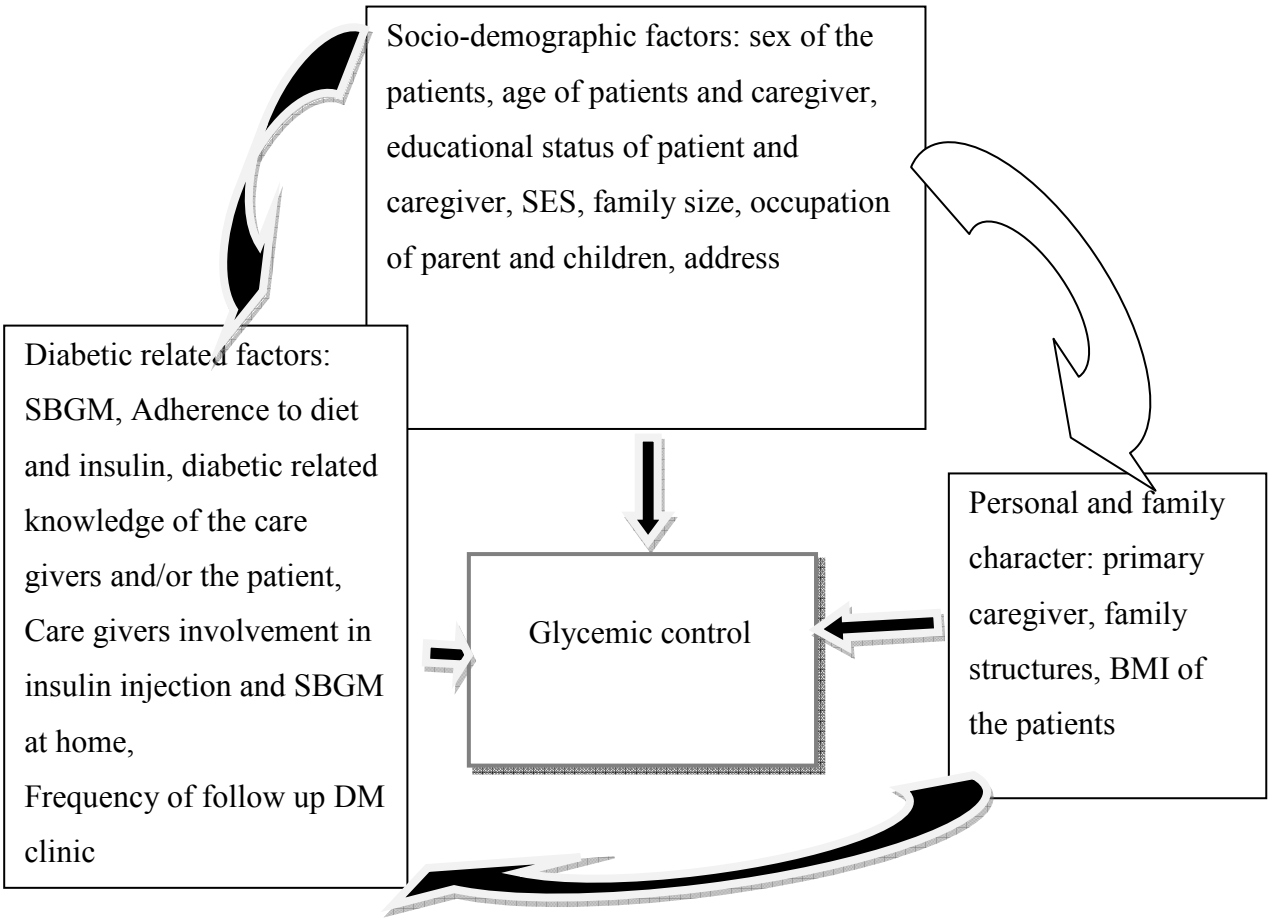
Self-monitoring of blood glucose is recommended 3 to 4 times a day for diabetics on intensive treatment(25). Less frequent blood glucose monitoring has been found to be a predictor of poor glycemic control(8, 9). A study in Denmark showed improved glycemic control with more frequent self-monitoring of blood glucose(10).Similarly, in Sudan, self-monitoring in type 1 diabetics was associated with significantly better glycemic control(21).

Study from USA,Ortoland, founds increased frequency of clinic attendance is associated with worse control likely reflects the practice of following those in poor control more closely. More frequent follow-up in these patients is therefore a marker of poor control and not a cause of it. As sited by Stacey the relationship between fewer clinic visits and poorer control has been

described by Kaufman et al.in a sample of children followed at diabetes centers in Southern California (22).

Knowledge of diabetes and attitude of parents and care givers towards the care of children with diabetes have been found to predict glycemic control. Better caregiver knowledge results in lower HbA1c levels as demonstrated by Tahirovic et al in Bosnia and Stallwood et al in USA(27, 28)Similarly, Butler et al found that higher parental diabetes knowledge and less parental perceived burden towards the care of diabetic children were predictive of lower HbA1c levels(29).In India, however, it was found that a planned educational intervention program on the knowledge, attitude and practices of type 1 diabetics resulted in significant improvements in the knowledge and attitude but no change in the practice domain and hence no improvement in HbA1c levels(30).

2.4. Conceptual Frame Work (Prepared By Principal Investigator)



Chapter Three: Significance of the Study

This study was done to identify the factors associated with glycaemic control in children and adolescents with T1DM in Jimma and the surrounding areas. The findings from this study will provide valuable information to guide targeted interventions aimed at improving glycaemic control in the region hence reducing the risk of complications at a young age.

In addition, this study may put a baseline data for further research into the field of diabetes in our setup and help improve the overall care and the quality of life in patients with T1DM.

Chapter Four: Objectives

4.1: General objective

- Assessing serum HbA1c and its associated factors in children and Adolescents with type 1 DM at JUSH,2014

4.2: Specific objective

4.2.1. To determine the mean serum HgA1c in children and adolescents with T1DM at JUSH, 2014.

4.2.2. To assess the prevalence of poor glycemic control in children and adolescents with T1DM at JUSH

4.2.3. To assess factors associated with poor glycemic control in children and adolescents with T1DM at JUSH

Chapter Five: Methodology and Materials

5.1: Study Setting and Period

The study was conducted in Jimma University Specialized Hospital Diabetic Clinic; located in Jimma Zone, Jimma town 350 km southwest of Addis Ababa. It provides services for approximately 14000 inpatient and 123000 outpatient attendances each year.

There are a total of 2,062 diabetic patients on follow up at JUSH from which 160 are children 18yrs old and below. All the diabetic children less than18 years inclusive have regular follow-up at DM clinic for adherence, complications and monitoring of RBS by pediatric and medical residents. A total of 60 children were seen during the study period.

All children and adolescents attending the clinic are provided with insulin at no cost through the Ethiopian Diabetic association (EDA). In addition, they are provided with glucose monitors, test strips, lancets and told to record their blood glucose. Ninety three of the participants have their own glucometer. They are encouraged to monitor their glucose at least once daily.

Almost all patients are on a 2 daily injection regimen that consist of NPH and regular insulin both given at the same time in the morning and evening except some time the patient may took only NPH when regular insulin run out of hospital. Patients and guardians are also given advice on appropriate nutrition. Data was collected from April 01, 2006 to May 30, 2006 E.C.

5.2: Populations:

5.2.1. Source Population**:**

All children and adolescents up to 18 years inclusive who were attending the diabetes clinic at JUSH and their caregiver/guardian

5.2.2. Study population: All children and adolescents 3mon up to 18 years inclusive and their caregiver/guardian attending the diabetes clinic at JUSH

5.3: Sample Size Determination and Sampling Technique**:**

All children and adolescents attending the clinic who met the inclusion criteria were included into the study after obtaining written informed consent from the parent/guardian. Adolescents who were unable to come with a parent/guardian were enrolled after obtaining agreement.

5.4: Inclusion Criteria:

1. Children and adolescents between 3mon and 18 years inclusive on follow up presumed to have T1DM and taking insulin.

2. Informed consent by the parents/guardians or assent by the adolescent.

5.5: Exclusion Criteria

Newly diagnosed type 1 diabetes or those on insulin treatment for less than 3 months.

5.6: Study Variables**:**

5.6.1: Independent Variable

Primary care giver (biologic parent or others), Family structure, Adherence to BGM regimen meal and insulin , insulin dose, Diabetes knowledge of caregiver and children , Age of patient, Duration of DM, Per capita monthly income,

5.6.2: Dependent Variable**:** glycemic control **(**serum HgA1c) status

5.7: Data Collection Process and Tools

Data were collected by two trained BSc clinical nurses using a structured questionnaire. This was administered to the child and caregiver together. The questionnaire assessing diabetes knowledge was administered separately to the child/adolescent and parent/guardian. The questionnaire had the following three major components: Sociodemographic and background information, Diabetes knowledge of children/adolescents and caregivers, Diabetes related practices.

Weight and height of the patients were taken on the day of visit. All of them came with FBS of the day and it was also recorded.

The Diabetes knowledge of children and their care givers were assessed by use of the Michigan Diabetes Research and Training Center's brief diabetes knowledge test(31).It was a multiple choice questionnaire and true/false simplified questionnaire which was attempted to be modified for our set up. Specific knowledge of the patient`s and the caregivers` about diet locally used was tried to be included in the questions .The diabetes knowledge test was a valid and reliable measure for estimating patients general understanding of diabetes(32).The true/false simplified questionnaire validity and reliability was also done in UK and found to be valid and reliable(33). This validity and reliability test was done in patients who were older than 18yrs old and in those who have completed 6^{th} grade of education. Even though our population`s age is $\leq$18 yrs old and their care giver and the educational status of the clients may not allow us to self-administer the questionnaire still we could use this instrument as interview by health professionals .Still we need to test the validity and reliability of this question in our set up and converting to the local language may also be needed to use in the future. The results of the test were scored based on percentage of correct responses.

The Diabetes related practices evaluated were frequency of clinic visit, adherence to insulin dosage blood glucose monitoring, caregiver involvement in diabetes related tasks and insulin storage. Insulin adherence was assessed by the number of insulin doses missed in the last 3month.None, between 1 and 3 and greater than 3 doses. Adherence was then graded as: Good – no missed doses; Average – between 1 and 3 missed doses; Poor - > 3 missed doses.

The Dietary adherence was assessed by use of a 24 hour dietary recall. All meals and snacks eaten in the last 24 hours prior to the clinic visit were documented and adherence was graded. The frequency adherence was scored depending on the WHO recommendation for any children at least 3 meals each day. The child should also be given 2 or more extra feedings between meals each day. The meal content was scored depending on the general principle diabetic children should eat from all components of major diet(carbohydrate, protein and vegetables).Diabetic patients should also avoid diets rich in simple sugar. Both dietary adherence of meal content and

frequency was scored as follow: The following tool was used at muhimbili national hospital,Dar Es Salaam but there is no evidence whether this tool was tested(4)

Table 1: The score of adherence to meal frequency and content muhimbili national hospital,Dar Es Salaam

Component	score	Interpretation ®
Meal frequency:		
3 meals and 3 snacks OR 3 meals and 2 snacks	4	< 4 – poor
3 meals and 1 snack	3	
3 meals only	2	4-6– average
< 3 meals	1	
Meal content:		
All components (carbohydrates, proteins, vegetables)	4	
Carbohydrates and vegetables	3	> 6 – good
Carbohydrates and protein	2	
Only carbohydrates	1	

® Maximum score: 8

The BGM adherence was classified as: 3 or more times a week, 1 – 2 times a week or none. This was graded as: those who test their blood glucose ≥ 3 was scored as good;1-2 tests a week was graded as average and those who did not do blood glucose test was scored as poor. Involvement in BGM was determined by the degree of participation of the caregiver in the taskThe level of

involvement of parents or caregivers in insulin administration and blood glucose monitoring was assessed by using a scale graded as minimal, moderate or optimal involvement. This was modified from the scale used in the study by Anderson et al.(20) Involvement in insulin injections was determined by the number of doses in the last 24 hours injected or supervised by the caregiver.

Table 2: Involvement of care givers in injection with in 24hr prior to data collection and blood glucose minitoring at home(BGM).

Degree of Involvement	**Number of Participation**
Insulin Injection	
Minimal	None
Moderate	1
Optimal	All injections
BGM	
Minimal	No participation
Moderate	Reminds the child to check blood glucose
	Enters glucose level in the diary
	Asks child about the blood glucose level
Optimal	Sets up the meter
	Does the finger prick
	Supervises the task

5.8: Operational Definition

Children: all Children and adolescents between 3mon and 18yrs inclusive

Insulin adherence: Good – no missed doses; Average – between 1 and 3 missed doses; Poor - > 3 missed doses.

Dietary adherence: scored out of 8; < 4 – poor, 4-6– average, > 6 – good

BGM adherence :graded as those who test their blood glucose ≥ 3 was scored as good;1-2 tests a week was graded as average and those who did not do blood glucose test was scored as poor

5.9: Lab Investigation

Glycemic control was determined by measurement of HbA1c. Blood was obtained by finger prick using a sterile lancet and directly entered into a reagent cartridge from prick site. Then cartridge immediately inserted into the in2it (A1C Analyzer, Bio-Rad Laboratories, Inc., Hercules, California). Automated results were recorded from the machine after a processing time of 10 minutes.

Quality control of analyzer (machine) was done routinely with system check cartige prepared for this purpose each day before starting to analyze the actual sample. The machine is said to be normal if it reads between 6.0 and 11.0 %(value on the cartage itself).

Data were double entered, cleaned and analyzed using Epidata software version 3.1 and SPSS (Software Package for Statistical Sciences) version 16. Patients' socio demographic characteristics and diabetes specific variables were summarized using frequency distribution tables. Mean and median was calculated for continuous data. Association between variables was tested by linear regression. Multivariate linear regression analysis was performed to determine factors independently associated with glycaemic control. A p value of less than or equal to 0.05 was considered statistically significant.

5.10. Ethical consideration

The ethical approval and clearance for the study before data collection was obtained from the Jimma University College of Medical Sciences and Public Health. An official letter from the college was obtained to the hospitals.

The aims of the study and expected outcomes and utility of knowledge derived from this study was explained to patients and guardians. Study participants were interviewed after obtaining oral informed consent from the guardian or assent from the adolescent in the absence of a guardian.

All data collected during the study was treated with strict confidentiality.HbA1c values were communicated to the patients/guardians and the managing team and the results were explained to them.

5.11. Data quality control

The quality of data was ensured through training of data collectors, close supervision and immediate feedback, reviewing each of completed data collection tools daily. Data consistency and completeness was checked throughout the data collection, double data entry and analysis.

During HbA1c determination the in2it System Check Cartilage (SCC) checks that the optical and the operating systems of the Analyzer are working correctly. The SCC was run once a day before samples were to be tested; or if error message reported. The result was validated by doing HbA1c of some patients by in2it analyzer and the hospital machine at same day and compares the results. The results obtained from both machines were almost same.

5.12: Limitations of the study

Adherence to treatment modalities could be overestimated by the self-reporting method used. In addition, assessment of dietary adherence and scoring was difficult because there is no dietary guide in our DM clinic .The 24 hours diet prior to the study may not represent the overall dietary adherence of the patients. The budget allocated for the study was very low which limited the study duration which affect the sample size, in turn the results and the conclusion from the study may not represent the study population.

5.13: Plan for Dissemination of Findings

The findings of this study will be reported to JUSH, Oromia Regional Health Bureau, the Federal MOH, Ethiopian Diabetic association. Findings will also be presented on the annual students'

research conference, different seminars and workshops. The results will be published in a peer-reviewed scientific journal.

Chapter Eight: Results

A total of 60 children aged up to 18 years inclusive was visited the diabetic follow up clinic during the study period. Eleven (18.33%) adolescents came alone for follow up; hence the parent component of the diabetes knowledge test was not administered.The mean age was 11.81±3.5 yrs. The most frequent age group is 10-13.9 yrs 30(50%); with 33(55%) male sex. Thirty one (51.7%) of the primary caregivers` had no formal education. Most of the children, 38 (63.3%) were 1-6thgrade students. Concerning the residence of the patients, 33(55%) of them, were from rural.

Table 3:Socio_ demographic characteristics of children with type 1 diabetes mellitus and the caregivers

	n(%), mean ± SD median (25th, 75th)	n
Age (in yrs.)	12.0 (9,14)	60
0.25-9.9	18 (30.0)	
10.0-13.9	30 (50.0)	
14.0+	12 (20.0)	
Male Sex	33 (55.0)	60
BMI (kg/m^2)	16.7 (14.8,18.2)	
<18.5	50 (83.3)	
18.5-25.0	7 (11.7)	
>25.0	3 (5.0)	
Child lives with		60
Both Parents	48 (80.0)	
Single parent/Relatives	12 (20.0)	
Primary caregiver		60
Mother	16 (26.7)	
Father	37 (61.7)	
Relatives	7 (11.6)	
Care giver's Educational grade		60

No formal education	31 (51.7)	
1-6	14 (23.3)	
7-12	10 (16.7)	
>12	5 (8.3)	
Educational status of children [b]		58
No formal education	8 (13.3)	
1-6	38 (63.3)	
7-12	12 (20.0)	
Rural residence	33 (55.0)	60
Occupation of family/care giver		
Farmer	39 (65.0)	
Merchant	7 (11.7)	
Employee	7 (11.7)	
Others[*]	6 (10.0)	
Occupation of children [b]		58
Student	48 (82.8)	
others [#]	10 (17.2)	
Family size		60
<5 family members	7 (11.7)	
≥5 family members	53 (83.3)	

[b] only for children > 5yrs old

[*] One diver, three-housewife, two-student

[#] six of them reports they didn`t have any identified job except they simply involved in their parents daily activities, three of them are engaged in farming, one is merchant.

The mean±sd of HbA1c is 10.4±2.6%. Thirty four (56.7%) of them have poor (HbA1c:10.0+ %) glycemic control; 16(26.7%) of them have fair glycemic control (HbA1c:8.0-9.9); only 10

(HbA1c16.7%) of them have good (<7.9%) glycemic control. The mean duration with DM is 3yrs± 2.8yrs; 41(68.3%) being between 1-5yrs with DM. Thirty seven (61.3%) of them follow the DM clinic every 2-3months. Table 4

Adherence to the insulin regimen is found to be good in majority of study participants (85%). Only 9(15%) reported to have missed 1-3doses in the past three months; the reasons being run out of insulin (44.44%) before the next appointment, forgot the doses (33.33%), one lack the prescribed insulin from hospital and the other one skipped the dose because the blood glucose was very low.Twenty percent of children reported good adherence to the BGM while 35% and 33.3% reported average and poor adherence respectively. The most common reason for poor adherence was difficulty of using glucometer (57.90%).The meal adherence is good only in 4(6.7%) of children, average in 38(63.3%) of children and poor in 18(30.0%) children. Parent involvement in blood glucose monitoring (BGM) is optimal in only 15(25.0%) of cases; while that of insulin injection is good in 34(56.7%) of them (Table 4).

Table 4: Frequency distribution of diabetic related characteristics of children with type 1 diabetes mellitus (T1DM) and the caregivers (n=60)

Characteristics	n(%)
Mean HgA1c level (%) ± SD	10.4±2 .6
Diabetic control using HbA1c (%)	
Good (<7.9)	10 (16.7)
Fair (8.0-9.9)	16 (26.7)
Poor (10.0+)	34 (56.7)
Mean insulin (U/kg) ± SD U/kg	0.8 ± 0.33
Duration of DM (yr.) ± SD	3± 2.8
<1	8 (13.30)
1-5	41 (68.30)
>5	11 (18.30)

Mean FBS mg/dl) on day of visit ± SD	201.25 ± 113
Frequency of DM clinic follow up	
Every month	23 (38.30)
Every 2-3months	37 (61.70)
Missed dose of insulin in the past three months(n=60)	9 (15.00)
Adherence to insulin doses*	
Good adherence	51 (85.00)
Average adherence	9 (15.00)
Reason for missed dose(n=9)	
Forgot	3 (33.30)
Lack of prescribed insulin	1 (1.10)
Run out of insulin	4 (44.40)
Others (jump dose while BG is very low)	1 (11.10)
Test blood glucose(BG) at home	41 (68.30)
Frequency of testing BG per week	
None (Poor)	19 (31.70)
1-2/wk. (Average)	21 (35.00)
>=3/wk. (Good)	20 (33.30)
Record the result of BG test	14 (34.15)
Reason for not testing BG at home	
Difficulty to use glucometer	11 (57.90)
Lack of glucometer	4 (21.10)
Lack of lancet	2 (10.50)
Lack of test strip	2 (10.50)
Meal adherence [c]	

Good	4 (6.70)
Average	38 (63.30)
Poor	18 (30.00)
Parent involvement in insulin injection [d]	
Optimal	34 (56.70)
Moderate	3 (5.00)
Minimal	23 (38.30)
Parent BGM involvement [e]	
Optimal	15 (25.0o)
Moderate	24 (40.00)
Minimal	21 (35.00)
Change site of insulin injection every	
Every injection	33 (55.00)
Every day	10 (16.70)
Every 2-3days	3 (5.00)
Every 4-7days	5 (8.33)
Every >7days	5 (8.33)
Not changed	4 (6.67)

[a] *Values in cell are n(%), mean ± standard deviation, median (25, 75th),N*

**Insulin adherence was assessed by the number of insulin doses missed in the last 3month: Adherence graded as: Good – no missed doses; Average – missed between 1 and 3 missed doses; Poor - > 3 missed doses*

[C] *meal adherence scored out of 8points from meal content and meal frequency each having 4 points. Maximum score is 8.those who score < 4(poor), 4-6(average),> 6 (good)*

[d] *Involvement in insulin injections was determined by the number of doses in the last 24 hours injected or supervised by the caregiver: Minimal- None, Moderate-once, Optimal- All injections*

[e] *Parent BGM involvement was determined by the degree of participation of the caregiver in the task:Minimal:No participation ,Moderate: Reminds the child to check blood glucose/Enters glucose level in the diary/Asks child about the blood glucose level; Optimal Sets up the meter-Does the finger prick/Supervises the task*

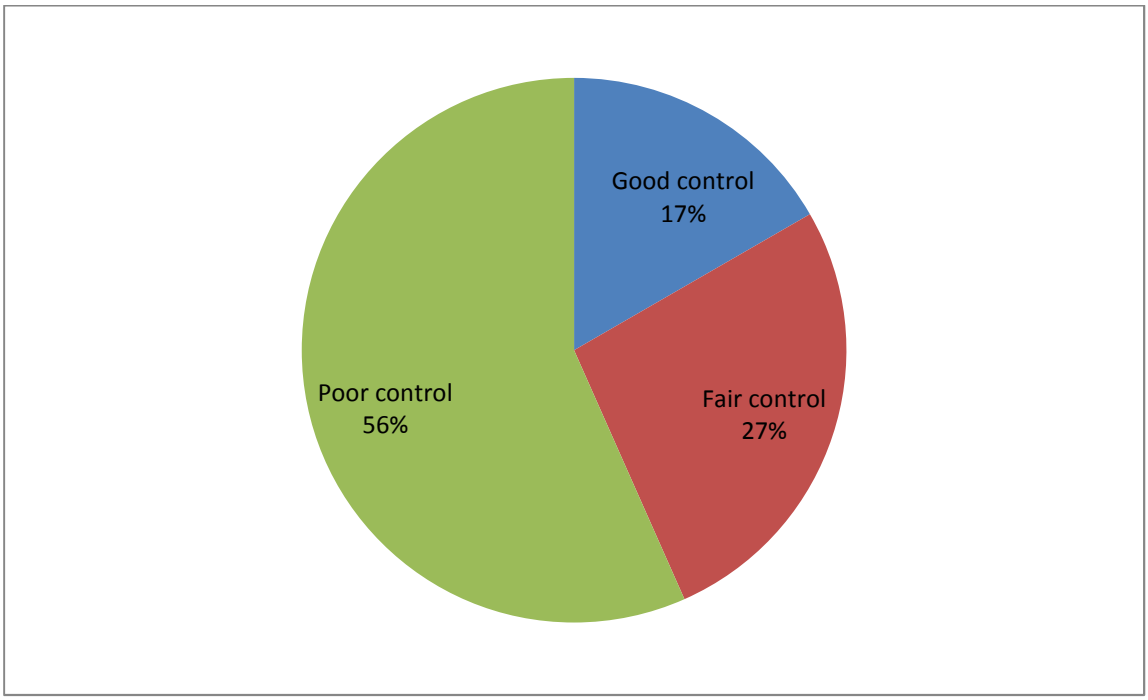


Figure 1: Patterns of glycemic control in children with type 1 DM treated in Jimma university specialized hospital, Jimma Ethiopia, July 2006 E.C

Most of the children and families believe that diabetic patient should not take Bread made of wheat, Food prepared from maize, Macaroni, Mango, Banana and Pasta. Only 17(44.7%) of children and 15(32.6%) of the care givers know to adjust insulin while the blood sugar is high. Most of the interviewed children and the care givers know the Symptoms of excessive glucose in the blood (hyperglycemia) but most of them also identify symptoms of hypoglycemia as that of hyperglycemia. Only minorities of the children 2(4.8%) and the care givers 6(12.2%) know correctly what to do if they remembered at lunch time the child forgot to take the morning insulin. nineteen (45%) of the children and 19(38.8) of the care givers do not know whether DM

can affect different body parts; and almost less than 50% of them know the effect of DM on different body parts. Thirty three (78.6%) and 28(66.7%) of the children and 38(77.6%) and 29(40.8%) of the care givers respectively know the effects of exercise and infection on blood glucose level. (Table 5& Table 6)

Table 5: Proportion of correct answer to diabetic knowledge test of diet in children with T1DM and the caregivers.

DKT questions	**N**	**Children**		**Parent/caregiver(n=49)**	
Diabetic Patient Can take	42	N	%	N	%
Bread made of wheat		14	33.3	10	20.40
Food prepared from maize		21	50.0	18	36.70
Food prepared from teff		41	97.6	47	95.90
Macaroni		14	33.3	15	30.60
Pasta		14	33.3	15	30.60
Sugar		40	95.2	48	98.00

Banana	21	50.0	17	34.70
Mango	19	45.2	23	46.90
Avocado	33	78.6	40	81.60
Lean meat	36	85.7	40	81.60
Fat meat	34	81.0	40	81.60
Packed biscuit	39	92.9	43	71.70
Soft drinks	42	100	47	95.90
Milk	32	76.20	38	77.60
Vegetables	40	95.20	47	95.90

Table 6: Proportions of correct answers to diabetic knowledge test of in children with type I Diabetes Mellitus (T1DM) and the Care Givers

DKT questions	N	Children		Parent/caregiver(n=49)	
Know how to adjust insulin dose to blood sugar level	37	17	44.70	15	32.60
Symptoms of excessive glucose in the blood (hyperglycemia)	42			49	
Shaking		33	78.60	39	79.60
Sweating		29	69.00	34	69.40
Loss of consciousness		31	73.80	34	69.40
Frequent urination, bed wetting, nocturia		38	90.50	44	89.80
Excessive thirst and dry mouth		37	88.10	43	87.80
Sites of insulin injection	42			49	

Upper arm		41	97.80	47	95.90
Peri-umbilical		30	78.60	27	55.10
Anterior thigh		36	85.70	37	75.50
Buttock area		-	-	1	2.00
Insulin storage	42	36	85.30	45	91.80
If forgot to take insulin; What to do		2	4.80	6	12.20
Body part affected by diabetes mellitus					
Eye		22	52.40	23	46.90
Kidney		12	28.60	13	26.50
Nerve problems		9	21.40	13	26.50
Foot		17	40.50	20	40.80

Do not know	19	45.20	19	38.80
Causes of High blood glucose	33	78.60	38	77.60
Effect of exercise on blood glucose	33	78.60	38	77.60
Effect of infection on blood glucose	28	66.70	29	48.33
Mean percentage of DKT	65.79±1.11		64.00 ± 1.16	

The linear regression shows there is no significant association between age of the patients and the mean HbA1c.Being female shows trends of decreased the mean HbA1c. BMI lower than and above 18.5-25kg/m^2 shows trends to increase by1.9% and 1.6 % respectively.

Lower educational status of the care givers and rural residence are associated with significant increased mean HbA1c level. Less frequent follow up and missing doses associated with increased mean HbA1c.More frequent home blood glucose monitoring shows trend of decreasing mean HbA1c.Decreased meal adherence, parent involvement in BGM and parent involvement in insulin injection generally shows increment of HgA1c level.(table 5&6).

Table 7: Bivariate association between socio-demographic characteristics of children with T1DM and the caregivers and HbA1c

Characteristics	**β(95%CI)**	**P values**
Age(in yrs)(n=60)	0.09(-0.10,0.29)	0.347
0.25-9.9	-0.66 (-2.58,1.27)	.498
10-13.9	0.52 (-1.25,2.28)	.559

14+	Ref	
Female Sex	-1.06 (-2.39,0.26)	0.114
BMI(kg/m2)	-0.11(-0.31,0.09)	0.265
<18.5	1.90(-0.195,3.94)	0.075
18.5-25	Ref.	
>25	1.60(-1.94,5.13)	0.370
Child live with other relatives	0.65 (-1.03,2.33)	0.440
Primary caregiver		
Mother	Ref.	
Father	0.37 (-1.14,1.87)	.625
Others caregiver:	-0.78 (-3.05,1.49)	.493
Care givers education		
No formal education	2.08 (0.23, 3.92)	0.028
1-6grade	2.00 (-0.12, 4.10)	0.062
7-12grade	Ref	
>12 grade	1.95(-0.831,4.73)	0.166
Educational status of children (n=58)		
No formal education	0.44(-1.99,2.87)	.720
1-6	0.77(1.00,2.54)	.383
7-12	Ref.	
Rural residence	1.40 (0.08,2.68)	0.038
Occupation of family/care giver(n=60)		
Farmer	-0.25(-2.42,1.93)	0.819
Merchant	-0.03(-2.86,2.80)	0.984
Employee	Ref.	
Others	-0.95(-3.69,1.79)	0.490
Occupation of children [q]	0.03(-1.80,1.86)	0.974
Student		
Others		

Table 8: Bivariate association between diabetic related characteristics of children with type 1 diabetes mellitus and the care givers, and mean serum HbA1c

Characteristics	**β(95%CI)**	**P values**
Diabetic knowledge of care givers	-0.11(-0.31,0.09)	0.268
Diabetic knowledge of children	-0.21 (-0.43,0.02)	0.071
Family size 5+ (n=60)	0.14(-1.96,2.24)	0.89
Duration with DM	-0.12(-0.36,0.12)	0.333
<1yr	Ref	
1-5yrs	1.557(-0.42,3.54)	0.121
5yrs	0.53(-1.85,2.91)	0.655
Mean insulin (U/kg)	0.61(-1.46,2.68)	0.560
FBS mg/dl) on day of visit	0.01(-0.00,0.01)	0.121
Frequency of DM clinic follow up		
Every month	Ref.	
Every 2-3months	1.32 (-0.02,2.67)	0.053
Adherence to insulin doses		
Not missed (good)	Ref.	
Missed1-3doses (average)	2.1(0.28,3.90)	0.024
Frequency of testing BG per week	-0.21 (-.48,0.06)	.125
None (Poor)	0.178 (-1.87,2.23)	.861
1-2/wk (Average)	0.78 (-1.46 ,3.02)	.484
>=3/wk (Good)	Ref.	
Record the result of BG test	0.67(-0.97,2.32)	0.415
Meal adherence		
Good	Ref.	

Average	1.32 (-1.43,4.07)	0.341
Poor	1.34 (-1.55,4.23)	0.356
Parent involvement in insulin injection		
Optimal	Ref.	
Moderate	1.22	0.443
Minimal	0.18	0.802
Parent involvement in BGM		
Optimal	Ref.	
Moderate	1.032(-.67 ,2.73)	0.230
Minimal	1.217(-.53 ,2.96)	0.169
Frequency of changing injection site		
Every injection	Ref.	
More than every injections	-0.37(-1.78,1.05)	0.605
Not change	-1.58(-4.34,1.17	0.255

q Children older than 5yr

To determine predictors of glycemic control, a multivariate regression analysis was performed using variables that had a significant association with HbA1c ($p < 0.05$) and those that approached statistical significance ($P < 0.25$) in bivariate analysis .The variables tested in the multivariate analysis were: educational status of the caregiver rural residence ,duration with DM, FBS on day of visit ,frequency of follow up of clinic ,adherence of insulin, frequency of BGM at home and parent involvement BGM. Only rural residence and missed dosses of insulin associate with increased mean HbA1c independently. Even if it is not statistically significant, the HbA1c increment in this model is very significant

Table 9: Predictors of HbA1c in multivariate analysis

VARIABLE	B (unstandardized coefficients)	P VALUE	95% Confidence Interval for B	Adjusted R^2
Rural residence	1.14	0.085	(-0.163,2.434)	.101
Missed1-3doses of insulin	1.79	0.053	(-0.023,3.60)	

Chapter Nine: Discussion

Overall, the glycaemia control among the study population was poor.There is also high prevalence of illiteracy among the caregivers. Most of the study populations are from rural; most of the children live with their biologic parents from which most of the primary caregivers are fathers. Majority of the caregivers and the children are farmers and students respectively. Adherence of the insulin regimen is found to be good in vast majority of the participants. Even though 56 of the participant have glucometer at home only forty one of them test blood glucose at home within a week of data collection; only 12 of them record their results. Meal adherence is poor in very high number of the participants. Generally there is low percentage of diabetic related knowledge in both the care givers and the children.

The mean glycemic control (HbA1c) in this study is 10.4±2.6%SD. This is almost similar with the study done in Tanzania in which the mean of 10.65 ± 2.09 was reported in 2006(34).But the previous study was done in the setting of very poor insulin supplies and unavailability of BGM at home. This high mean HbA1c in this study is alarming because poor glycemic control is associated with increased risks of chronic complication of DM. Despite major progress in the availability of insulin and blood glucose monitors, glycemic control is poor .This point to the existence of other underlying factors which have yet to be identified that are contributing to poor glycemic control.

This study revealed that more than half (56.67%) of the patients have poor glycemic control (HbA1c=10.0+), and only 10 (16.7%) of them have good (<7.9%) glycemic control. Similar to the current study, various published studies have shown that glycemic control is often poor in children with Type 1 diabetes mellitus despite easier home monitoring of blood glucose, the introduction of pen devices for insulin injection, and the introduction of new insulin types and regimens during the last decade For instance , in the study done in Bashar, Iraq the age specific

target HbA1c was achieved in only 12.4%(11), only 18% of the patients achieve target HbA1c in Kuwait(12); fewer than 15% of children and young people with diabetes in England and Wales achieve an HbA1c of <7.5(13, 35).

Though not significant, the current study showed, age of children younger than 10yrs old and duration with DM less than one year showed lower level of HbA1c when compared to those older than 10+yrs and longer duration of DM respectively. Similar to this study, older age and longer duration of DM was associated with poorer control in studies from UK and France (9, 15). Similarly study from USA, Ortoland, OR; found patients between 14 and 18 yr of age had an HbA1c value 0.56 higher than children between 2 and 8 yr of age .The poorer glycemic control could be explained by high opportunity for non-compliance with increasing age because many parents stop supervising blood testing, insulin adjustment, and injections by this times combined with changing hormonal milieu during adolescents, which places them at risk for higher HbA1c levels (22).

In contrary, age was not associated with poor control in studies from Australia, New Zealand and France (8, 15, 19, 22). On contrary to the current study, study from Saudi showed younger patients were significantly had higher mean HbA1c than older children. Patients with diabetes duration more than 10 years were significantly had lower mean HbA1c than patients with diabetes duration between 5 and 10 years and less than 5 years (23). Similar to the study in Saudi, study from Sudan showed an inverse relationship; with older age and longer duration of diabetes being associated with better control. Possible explanations for this were that older patients with longer duration of DM may have more knowledge and experience to deal with their diabetes (24).

In contrary to the study done in USA, Portland, OR, in which gender was not associated with metabolic control(22), this study showed a trend for poor control among females. This could be explained that females are more submissive than male children

Compared with those who have normal BMI (18.5-25), wasted (<18.5) and over weight (>25) participants showed increment of mean HbA1c by 1.9% and 1.6% respectively. Wasting in the current stud may be the reflects of poor glycemic control. This is in contrast to the study done in

Tanzania in which there was no significant difference of mean HbA1c between normal weight and wasted patients but those with BMI >25 had lower mean HbA1c by 1.12% than those patients with normal BMI (18.5-25).The same study also showed educational status of the care giver was not significantly associated with mean HbA1c (3), but in the current study showed lower educational status of the care givers is associated with increased mean HbA1c level. This agrees with the study done in Argentina and Belgium that found the low level of maternal education were predictor of poor glycemic control(18, 36).

Rural residence was associated with significant increased mean HbA1c level. This can be explained those from rural have lower educational status and also less frequent follow up due to distance from the hospital; and as well those from rural are more likely to have lower educational status which may affect the appropriate use of orders and educations provided by health care providers .So far it was not possible to found literature which compare effects of residence in rural or urban on glycemic control.

Less frequent follow up and missing doses associated with increased mean HbA1c. More frequent home BGM shows trend of decreasing mean HbA1c.Even if statistically not significant (but clinically significant) decreased meal adherence, parent involvement in BGM and parent involvement in insulin injection generally shows increment of HgA1c level almost at least by 1%.These findings agree with the studies done in Sudan ,Colorado, Denver; Australia, Ortoland (USA), California and Texas which showed HbA1c lower in those who had good insulin adherence, good dietary adherence , more frequent BGM, more frequent follow up associated with decreased mean HbA1c level (8, 26, 28, 30, 37). In contrast, another Study from USA, Ortoland, founds increased frequency of clinic attendance is associated with worse control likely reflects the practice of following those in poor control more closely. More frequent follow-up in these patients is therefore a marker of poor control and not a cause of it (22).

There was a negative correlation between the percentage of diabetic related knowledge of the care givers and the children and glycemic control in this study. Better caregiver knowledge results in lower HbA1c levels as demonstrated by Tahirovic et al in Bosnia and Stallwood et al in USA(27, 28). Similarly, Butler et al found that higher parental diabetes knowledge and less

parental perceived burden towards the care of diabetic children were predictive of lower HbA1c levels(29).

The dose of insulin has been found to be associated with level of glycaemic control. Several factors influence the initial daily insulin dose per kilogram of body weight. The dose is usually higher in pubertal children(1).This study showed increasing dose of insulin per kg of the children showed pattern of increasing HbA1clevel.This could be the explained by insulin dosage increment as the age increase and this may be consistent with higher HbA1c seen in children ten years old and above. Studies from Australia, New Zealand and France also found a higher dose of insulin per kg body weight to be associated with poor glycaemic control (8, 9, 19). However, a study from Sudan demonstrated no difference in glycaemic control with a higher dose of insulin (21).

9.1: Conclusion and Recommendations

Glycemic control was poor in children and adolescents with T1DM attending the JUSH clinic despite availability of insulin and self-monitoring of blood glucose at home. There was also a deficit in the diabetes knowledge of both caregivers and children with lack of knowledge on diet specific to DM. Poor adherence were common especially to dietary guidelines. Rural residence and missed dose of insulin were found to be independent predictors of glycemic control.

So, it is better if Caregivers of children and adolescents with T1DM receive regular diabetes education by health professions who have adequate knowledge of diabetic education. The children with T1DM need close follow up with emphasis on adherence counseling. It will be better if DM clinic decentralized to nearby health center to make the follow up closer for those who come from rural areas

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Appendix II: Data Collection Material

Questionnaire Prepared for a Study Entitled "Serum HgA1c and Determinants of Glycemic Control in Children and Adolescents following treatment in Jimma University Specialized Hospital"

Informed Consent form

My name is Dr. Diriba Fufa, a 3rd year resident in the department of Paediatrics and Child Health at JUSH.I am conducting a study with the above title as part of my study program.

Aims of the study:

This study aims to determine the average blood sugar control in children and adolescents with type 1 diabetes and to find out what factors are associated with poor control of blood sugar.

Participation in this study:

Your child can participate in this study if he/she is 18 years old or less and has been on insulin treatment for type 1 diabetes for at least 3 months.

The study mainly involves responding to a questionnaire which has general questions about the child's demographic characteristics, your family's socioeconomic status and a section on questions related to diabetes. Both you and your child will answer the questions together if your child is less than 10 years and separately if the child is older than 10 years. In addition, the child's HbA1c level will be measured and this level will be used in the study.

If you choose not to participate in this study, your child will continue to receive the normal care at the diabetic clinic and will not be compromised in any way.

Risks:

We do not anticipate any risks involved in participating in the study.

Benefits:

By participating in this study, you will know your child's glucose control as measured by HbA1c and the level will be interpreted for you and hence you will be able to take measures to improve the control or maintain it if it is within normal levels.

Confidentiality:All information collected during this study will be kept strictly confidential and will not be revealed to anybody outside the research team.

Cost: You will not be required to make any payments to participate in this study and no payment will be made to you. For further information, questions or queries, you can contact:

Dr.Diriba Fufa

Department of Paediatrics and Child Health,

Mobile No: 0932285770 Email: hord_gro@yahoo.com or diribafuf@gmail.com

SOCIODEMOGRAPHIC DATA AND BACKGROUND INFORMATION

1. Card number _____

2. Serial number _____

3. Address:_____ A. Urban B. Rural

4. Age of the patient in yr. _____

5. age of the primary care giver _____

6. Sex a) Male b) Female

7. Weight of the patient in kg_____

8. Height of the patient in Centimeter_____

9. Duration with DM(in yrs)_____

10. Access to insulin a) free b) paid c) both

11. Daily Insulin dose (IU) _____

12. Primary caregiver of the patient : a) Mother b) Father c) Sibling d) Other _____

13. Educational status of primary care giver: a) illiterate b) can read only

    c) can read and write d) 1-6 grade e) 7-12 f) > 12

14. Educational status of the patient: (For > 5yrs old). a) illiterate b) can read only

    c) can read and write d) 1-6 grade e) 7-12 f) > 12

15. Family structure : a) Both parents living together b) Single parent

c) Not living with either parent d) Orphan

16. Occupation of care taker : a)farmer b) merchant c) daily laborer

e) Governmental employee f) others specify)_____

17. Occupation of the patient (for >5yrs old). a) Student b) farmer

c) Merchant d. others_____

18. Approximate monthly income of the family in Ethiopian birr_____

(List types and amount of the source of income_____ _____

19. Size of family member living together _____

20. HgA1C_____ RBS(mg/dl)_____ FBS(mg/dl) on day of visit_____

I. KNOWLEDGE ASSESSMENT OF PATIENTS AND CAREGIVERS:

A. Knowledge Assessment Of Caregivers

1. Diabetic patient can eat :

1.1. Brea made of wheat. A. true B. False C. not sure

1.2. Food prepared from maize. A. true B. False C. not sure

1.3. Food prepared from teff. A. true B. false C. not sure

1.4. Macaroni. A. true B. false C. not sure

1.5. Pasta. A. true B. False C. not sure

1.6. Sugar A. true B. False C. not sure

1.7. Banana. A. true B. false C. not sure

1.8. Mango. A. true B. false C. not sure

1.9. Avocado. A. true B. False C. not sure

1.10. Lean meat. A. true B. False C. not sure

1.11. Fat meat. A. true B. False C. not sure

1.12. Packed biscuit. A. true B. False C. not sure

1.13. Can drink coca cola. A. true B. false C. not sure

1.14. Can drink milk. A. true B. False C. not sure

1.15. Vegetables. A. true B. false C. not sure

2. Do you know how to change (arrange) insulin dose on the basis of blood sugar level?

A .No B. Yes

3. From the following which is /are Symptoms of excess glucose in the blood (can be more than one

A. Shaking B. Sweating D. loss of consciousness E. Excessive thirst and dry mouth

F. Frequent urination, bed wetting, nocturia G.I do not know

4. Where are Sites of insulin injection do you know? (Can be more than one)

A. Upper arm B. peri umbilical C. anterior thigh D. buttock area

5. Insulin can be stored anywhere in living room. A. true B. false C. not sure

6. You realize just before lunch time that your child forgot to take his/her insulin before breakfast. What should you advise him /her to do now?

A. Skip lunch to lower blood glucose B. Take the insulin that he/she usually takes at breakfast

C. Take twice as much insulin as he/she usually takes at breakfast

D. Check his/her blood glucose level to decide how much insulin to tak

E .I don`t know what to do.

7. High blood glucose may be caused by: A. Not enough insulin B. skipping meal .

C. delaying your food D. I don`t know

8. From the following which body part do you think is possibly affected by diabetes (can be more than one)

A. Eye B. Kidney C. Nerve problems D. foot E. I don`t know

9. What effect does exercise have on blood glucose?

A. Lowers it B. raises it C. Has no effect D. I don`t know

10. What is the effect of infection on blood glucose?

A. Lowers it B. raises it C. Has no effect D. I don`t know

B. KNOWLEDGE ASSESSMENT OF CHILDREN/ADOLESCENTS(for >10years old)

1. Diabetic patient can eat:

1.1. Bread made of wheat. A. true B. False C. not sure

1.2. Food prepared from maize. A. true B. False C. not sure

1.3. Food prepared from teff . A. true B. false C. not sure

1.4. Macaroni. A. true B. false C. not sure

1.5. Pasta. A. true B. False C. not sure

1.6. Sugar A. true B. False C. not sure

1.7. Banana. A. true B. false C. not sure

1.8. Mango. A. true B. false C. not sure

1.9. Avocado. A. true B. False C. not sure

1.10. Lean meat. A. true B. False C. not sure

1.11. Fat meat. A. true B. False C. not sure

1.12. Packed biscuit. A. true B. False C. not sure

1.13. Can drink coca cola. A. true B. false C. not sure

1.14. Can drink milk. A. true B. False C. not sure

1.16. Vegetables. A. true B. false C. not sure

2. Do you know how to change (arrange) insulin dose on the basis of your blood sugar level? A .No B. Yes

3. From the following which is /are Symptoms of excess glucose in the blood (can be more than one) A. Shaking B. Sweating D. loss of consciousness

E. Frequent urination, bed wetting, nocturia

F. Excessive thirst and dry mouth g. I do not know

4. Where are Sites of insulin injection do you know? Can be more than one)

A. Upper arm B. peri umbilical C. anterior thigh D. buttock area

5. Insulin can be stored anywhere in living room. A.true B.false C. not sure

6. If you realize just before lunch time that you forgot to take your insulin before breakfast. What Will you do now?

A. Skip lunch to lower blood glucose

B. Take the insulin that usually you takes at breakfast

C. Take twice as much insulin as you usually takes at breakfast

D. Check your blood glucose level to decide how much insulin to take

E .I don`t know what to do.

7. High blood glucose may be caused by: A. Not enough insulin B. skipping meal C. delaying your food D. I don`t know

8. From the following which body part do you think is/are possibly affected by diabetes mellitus (can be more than one)? A. Eye B. Kidney C. Nerve problems D. foot E. I don`t know

9. What effect does exercise have on blood glucose?

A. Lowers it B. raises it C. Has no effect D. I don`t know

10. What is the effect of infection on blood glucose?

A. Lowers it B. raises it C. Has no effect D. I don`t know

II. PRACTICES OF PATIENT/CAREGIVER ON DIABETES:

1. How frequent do the patient follow DM clinic? A. every 1months B. every 2-3mon. C.> 3mon.

2. How many doses of insulin have you missed in the last three months? _____

3. If missed what is the reason? A. Forgot the dose B. Lack of getting prescribed insulin from the hospital C. Lack of syringe D. Others_____

4. In the last 3 months, have you ever missed getting prescribed insulin /syringe from the hospital? A. Yes B. No

5. If yes to number 4, how frequently have you missed your supplies?

A. Every month B. Once or twice in 3 months C. Others

6. When you miss the supplies of insulin or syringes, what do you usually do?

A. Buy your own

B. Wait till supplies are available from the hospital

C. Others_____

7. How frequent do you change the injection site? A. Every injection B. Every day

C. not changed D. other_____

8. Do the blood sugar test of the patient done at home in the past three months?

A. yes B.No

Q8a. How many days a week do you test your blood sugar? _____ (days / week)

Q8b.if not tested, what is the reason? A. lack of lancet B. lack of test strip

C. lack of glucometer E. others (specify)_____

Q8c. do you record the result of your blood glucose tests? A. yes B. no

9. What will you do if you find abnormally high blood sugar?

A. Nothing till the next appointment B. Took additional insulin

C. Visit and consult health care professional as soon as possible

D. Other_____

10. What did you eat in the last 24 hours?(please write main component; example injera made of---------;wot(ወጥ)----------; butter or oil added?)

- Breakfast _____ Lunch _____
- Dinner_____
- Snacks (how many times) _____ _____

11. Where do you store the insulin?

a) Refrigerator b) Pot of cold water c) Room temperature d) others _____

12. How involved is the parent/caregiver in the monitoring of the child's blood glucose?

A. No involvement

B. B. Reminds the child to monitor glucose or logs in the level in the diary or ask about the blood glucose level

C. Sets up the meter and does the finger prick

13. In the last 24 hours, how many times did the parent/caregiver inject or supervise the insulin injection?

A. None B. Once or twice C. all the injection

14. Does the patient performing physical activity? A. Yes B. No

15. If yes, what kind of activity? A. Working in the field (farming, fetching water..)

B. going school C. Play with peer groups such as football or hand ball

D. Others (specify)_____

16. For how long does the patient do physical activity each day? _____

17. Are feet of the patient checked for signs of problems such as ulceration? A. YES B. NO

18. IF YES for Q .No14; how frequent ? A. daily B. not daily but at least once a week

C. others_____

Name of data collector _____sign _____

Thank You!