Determinants of glycemic control among diabetic patients of the diabetic clinic at Jimma University Specialized Hospital, South-west of Ethiopia

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Abstract

BACKGROUND:

Diabetes mellitus is one of the most common metabolic disorders. Previously it was considered as the disease of affluent societies but currently its prevalence is increasing worldwide, especially in developing countries. Strict glycemic control is the corner stone of medical diabetes care to prevent diabetes related complications or early mortality. Thus poor glycemic control is associated with excess of diabetes-related morbidity and mortality. There is no study published on Jimma Hospital diabetes patients about their glycaemic control, using Hgb A1c, as an audit of diabetes care.

OBJECTIVE:

This study was designed to assess the degree of glycaemic control and associated factors among diabetes patients, served at Jimma University Specialized Hospital, South West Ethiopia.

METHODS:

A cross sectional study was conducted on June 2013 GC, among known diabetic patients attending outpatient department of diabetes follow up clinic of Jimma University Specialized Hospital.

Patients were stratified into Type 1 and type 2 diabetes based on their medication and then all patients who came for follow up, from both groups, during the study period were included. Participants were interviewed individually using pretested, predesigned questionnaire by trained data collectors. Data on socio-demographic status, clinically obtained parameters and laboratory (FBS and HgbA1c levels) were collected. The collected data was cleaned and entered into the SPSS for windows version 16.0 statistical software of the computer for analysis.

Work plan and budget:

The total budget required for this study was ~14,000 Eth. birr. The duration of this research project was 3 months (from proposal development up to final report).

RESULT

A total of 120 diabetes patients were enrolled from both type 1 and 2 diabetes in the study. Males constitued 53.8 %, most of the patients were Oromo by ethnicity (58.3%) and 65.5% of them were type 1 diabetes patients. The prevalence of poor glycemic control (A1c >7%) was 65.3% which was 72.2% in type 1 diabetes and 51.3% in type 2 diabetes. The determinants of poor glycemic were found to be, being type 1 diabetes patient ($p = 0.025$) and having diabetes for more than 10 years ($p = 0.026$). Those with longer duration of diabetes ($\geq$ 10 years) and type 1 diabetes had 2.66 ($p = 0.04$ confidence interval = 1.029 - 6.898) and 2.27 ($p = 2.274$ confidence interval = 1.007 – 5.134) times increased chance of having poor glycemic control, respectively, compared to relatively shorter duration of diabetes and type 2 diabetes.

Gender, Ethnicity, type of medication, compliance, exercise, hospitalization history and body mass index were not associated with poor glycemic control.

CONCLUSION

More than half of the diabetes patients, attending out patient department of diabetic follow up clinic of Jimma University Specialized Hospital, had poor glycemic control. Those with type 1 diabetes and duration of diabetes for more than a decade tend to have poorer control. Despite increased awareness of the benefits of tight glycemic control, few diabetes patients in Jimma Hospital met the recommended target value. This may contribute to increased rates of diabetes related complications. Our data clearly shows the magnitude of the problem, hence policy makers need to see the forthcoming problem and try to optimize diabetes care as per recommendation; that utilization of hemoglobin A1c for assessing degree of glycemic control.

Acknowledgement

I would like to thank my advisors, Dr. Ermias Habte and Dr. Mirkuzie Woldie, for their end less support and constructive feedbacks in developing the proposal as well as the final paper. I also wish to thank Jimma University for giving me the chance to conduct this research and for providing all the necessary resources.

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Acronyms and Abbreviations

BMI- Body Mass Index

DCCT- Diabetes Complication Trial

DM- Diabetes

DN- Diabetic Nephropathy

DR- Diabetic Retinopathy

FBS- Fasting Blood Sugar

HGB A1C- Glycated hemoglobin

IDF- International Diabetes Federation

NCD- Non Communicable disease

SSA- Sub- Saharan Africa

WHO- World Health Organization

DCCT UKPDS KUMATSO and ACCORD

Chapter 1

1.1 Background information

Diabetes is "a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or increased glucose production" (1). The classification of diabetes includes four clinical classes: 1) **Type 1 diabetes** (results from β-cell destruction, usually leading to absolute insulin deficiency) 2) **Type 2 diabetes** (results from a progressive insulin secretory defect on the background of insulin resistance), 3) **Other specific types of diabetes due to other causes**, e.g., ***genetic defects in β-cell function, genetic defects in insulin action, diseases of the exocrine pancreas, and drug- or chemical induced*** and 4) **Gestational diabetes mellitus (GDM)** (1).

The current criteria for the diagnosis of diabetes include, glycated hemoglobin A1C (Hgb A1C) $\geq$ 6.5% or FPG $\geq$126 mg/dl, or 2-h plasma glucose $\geq$ 200mg/dl during an OGTT or in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose $\geq$200 mg/dl (1). Type-I diabetes accounts for <10% of all cases of diabetes, tends to occur in younger subjects and is caused by severe insulin deficiency secondary to autoimmune destruction of the insulin-secreting beta cells of the pancreas (2).

Type-2 diabetes, the predominant expression of the disease, is usually seen in older adults but is being diagnosed with increasing frequency in younger age groups, including children and adolescents (2).

Diabetes is associated with both acute and chronic complications. Acute complications include; diabetic ketoacidosis (DKA), hyperglycemic hyperosmolar state (HHS) and hypoglycemia. Long-term hyprglycemia is associated with microvascular (Retinopathy, Neuropathy and Nephropathy), macrovascular (coronary heart disease, peripheral arterial disease and cerbrovascular disease) others including; gastrointestinal, genitourinary, dermatologic, infectious and periodontal disease (2).

Diabetes mellitus is a chronic illness that requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications (1).

Due to the high cost, it is rarely used in many developing countries, including Ethiopia. In most of the developing world, the old classical approach, fasting blood glucose determination, is still the standard method used for assessing the degree of glycemic control. Although, many reports show satisfactory correlation between Hgb A1c and FBS level, some authors have concluded that measurement of hemoglobin A1C is superior (4). Hence, knowledge on glycaemic control using the recommended technique, measurement of Hgb A1c, is of great relevance for planning healthcare programs targeting improved diabetes control.

1.2 Statement of the problem

Diabetes affects people worldwide and poses major public health and socioeconomic challenges (5). The worldwide prevalence of DM has risen dramatically over the past two decades (especially type 2 diabetes), from an estimated 30 million cases in 1985 to 285 million in 2010. Based on current trends, the International Diabetes Federation (IDF) projects that the number of adults with diabetes in the world will expand by 54%, from 284·6 million in 2010 to 438·4 million in 2030 (4.4% of population worldwide) (2, 5, 6).

From this emerging epidemic; populations of developing countries and minority groups around the world faced the greatest risk (5). Furthermore diabetes arise at younger ages in African than in European populations making the economic burden even worse (5, 8).

According to World Health Organization's (WHO) 2010 prediction, Africa will have the highest relative increase of diabetes over the coming decade (27%) (8). By the year 2025, more than three quarters of all persons with diabetes will reside in developing countries and the projected growth of diabetes and impaired glucose tolerance for sub-Saharan Africa (SSA) is 98% (from 12·1 - 23·9 million) and 75.8% (from 26·9 - 47·3 million), respectively in 2030 (3, 8). And the prevalence of overweight (an important risk factor for diabetes and hypertension) is expected to increase from 24% to 30% and from 38% to 41% in men and women, respectively (9). The estimated prevalence of diabetes in Africa is 1% in rural areas, up to 5% to 7% in urban sub-Saharan Africa, and between 8% and 13% in more developed areas such as South Africa and in populations of Indian origin.

There is considerable geographic variation in the incidence of both type 1 and type 2 DM. Scandinavia with the highest incidence of type 1 DM (~ 57.4/100,000 per year), Northern Europe and the United States have an intermediate rate (~ 8–20/100,000 per year) and the Pacific Rim has a much lower rate of type 1 DM (~0.6–2.4/100,000 per year). The prevalence of type 2 DM and IGT, is highest in certain Pacific islands and the Middle East and intermediate in countries such as India and the United States (2).

The top five countries with the highest number of people affected by diabetes in Sub-Saharan Africa are Nigeria (about 1.2 million people), South Africa (841,000), the Democratic Republic of Congo (552,000), Ethiopia (550,000), and Tanzania (380,000) (5).

In SSA, although the majority of patients (70% to 90%) present with typical type 2 diabetes, up to 25% are considered to have type 1 diabetes. Among the latter group, it is currently estimated that approximately 15% may represent atypical presentations of diabetes, especially type 1B or ketosis-prone atypical diabetes, and tropical diabetes (10). In SSA, prevalence rate of impaired glucose tolerance (IGT) in 2003 was 7.3% (21 million) (5).

Markers of the early stages of a diabetes epidemic are suggested to be high in SSA; for example, in individuals from Tanzania and Cameroon with low diabetes prevalence, rates of impaired glucose tolerance were raised with a high epidemicity index of 88·4% and 83%, respectively. In both of these populations, diabetes prevalence has increased over the past two decades (5).

In Tanzania, the prevalence of diabetes has risen from 2·3% in the 1980s to 4·6% in 1996 with a three to seven times rise in the 35—54 years age-group. In urban areas of Cameroon, a four times escalation from 1·5% in the 1990s to 6·6% in 2003 was noted. The prevalence of type 2 diabetes between nineteen sixties and eighties in Africa was lower than 1%, except in South Africa (0.6-3.6%) and Côte d'Ivoire (5·7%); however, it is the most common form of diabetes currently. (5) for example, recently reported data disclosed that among West African countries, Ghana has the highest rate of prevalence at 6% and in parts of South Africa, type 2 diabetes prevalence was 4.8% in semi-urban community in the Orange free state, 6% in urban community of Orange free state, 5.5% in Durban and 8% in Cape Town (11).

Moreover, the prevalence of undiagnosed diabetes is huge, in SSA, which accounts for 60 % in Cameroon, 70 % in Ghana and over 80 % in Tanzania (5). This is associated with prolonged hyperglycemia which is an important risk factor for diabetes related chronic complication. Furthermore this allows the complications to ensue at an earlier age (5).

Although there is no nationwide study done in Ethiopia, the prevalence of diabetes is increasing as in the case of most SSA. IDF estimated the prevalence of type 1 and 2 in Ethiopia to be 4.95 and 252.6 per 1000 population, respectively, in 2000 (9).

In SSA, although the classic symptoms of diabetes are similar to those seen elsewhere in the world, the majority of patients usually present with sepsis and/or acute diabetes complications (11, 12).

In some cohorts, infection is the mode of presentation of diabetes in up to 22% of cases, sometimes with mucormycosis and deep palmar infections that are rarely seen in developed countries. Neuropathic symptoms, foot ulcerations, and stroke are frequent presenting problems that lead to the diagnosis of type 2 diabetes. Approximately 20% to 25% of type 2 diabetic patients at diagnosis already have retinopathy (10).

DKA is a common diabetic emergency in developing countries, which accounts for about 71% of all diabetes related acute complications (31%) followed by hypoglycemia, 19.4%, in JUSH, Jimma, Ethiopia (13).

In SSA, the prevalence of diabetic retinopathy and nephropathy ranges from 13-55% from 32-57%, respectively. DN accounts for a third of all patients who are admitted to dialysis units (11), in SSA. A progressive rise in the incidence of DN in Nigeria from 19% in 1971 to 28.4% in 2003 has been observed (15). In Sudan, the prevalence of diabetic nephropathy, retinopathy and neuropathy was 11.6%, 18.5% and 28.1%; respectively (11).

According to a study done in Ethiopia, 52% of DM patients had one or more of the chronic complications, the major ones were neuropathy in 29.5%, nephropathy in 48 15.7%, visual disturbance in 33.8% (13). The prevalence of microalbuminurea in Ethiopia is 33% and 36% in type and type 2 diabetes patients, respectively in 1997 (11).

Macrovascular complications of diabetes are considered rare in Africa (10,13,14,15). Prevalence of CAD in Ethiopia, Kenya, Nigeria and Tanzania was 1%, 15.6%, 1% and 23%, respectively (10). However, both population- and hospital based studies now provide evidence for an increasing burden of cardiovascular disease in sub-Saharan Africa, with diabetes mellitus as a

major contributor (10). The prevalence of ischemic heart disease in diabetic subjects on ECG stress testing is between 5% and 8% (10). According to studies done in Ghana, Cameroon, Kenya, Senegal and Egypt; diabetes was present, in 23%, 26%, 39%, 40% and 32% of CAD patients, respectively. Recent data from Tanzania disclosed that, coronary heart disease may affect 5 to 8 % of type 2 diabetic patients and cardiomyopathy up to 50 % of all patients (11).

Peripheral vascular disease prevalence varies across sites from 4% to 28% (10). In Ethiopia, Nigeria and South Africa, the prevalence of PAD is 0.6%, 0.2% and 2%, respectively. Lower-extremity amputation varies from 1.5 to 7 %, and about 12 % of all hospitalized diabetic patients have foot ulceration (11). Close to 15% of patients with stroke have diabetes, and up to 5% of diabetic patients present with cerebrovascular accidents at diagnosis (10). Prevalence of stroke in Ethiopia, Nigeria and Tanzania is 1.3%, 6% and 1.4%, respectively. Seven percent of patients with cerebrovascular disease have diabetes in Burkina Faso (10). In a South African study, subjects with diabetes were 3 to 4 times more likely to present with a stroke than nondiabetic subjects.

The DCCT UKPDS KUMATSO and ACCORD's report provided definitive proof that reduction in chronic hyperglycemia can prevent many of the early complications of type 1 DM. Improved glycemic control also slowed the progression of early diabetic complications and reduced nonproliferative and proliferative retinopathy by, microalbuminuria, clinical nephropathy by, and neuropathy by. Previously, optimal glycemic control had no significant effect on improving macrovascular events; however, recent report from DCCT shows that there is significant 42% reduction in CVD outcomes and a significant 57% reduction in the risk of nonfatal myocardial infarction (MI), stroke, or CVD death (1,2).

Experience from our neighboring country; Eritrea, shows that, after introduction of Hgb A1c determination at the beginning of 2003, HbA1c values improved significantly (16).

Nearly all developing countries including Africa don't adopt the recommended techniques because of their high expense; therefore, diabetes patients of this nations are managed sub-optimally with the resultant poor glycemic control and diabetes related complications to ensue

earlier (10,11,). According to one study done in this region, diabetes related complications like diabetic retinopathy and diabetic nephropathy, are significantly associated with poor control of HbA1c (d1). Also there was a poor agreement between poor control of HbA1c and poor glycemic control in the presence of DR.

Audits of diabetes care carried out in Cape Town, South Africa; Dar es Salaam, Tanzania; and Yaoundé, Cameroon, have demonstrated poor glycemic control and inadequate foot care as risk factors for diabetic foot. Poor glycemic control is seen 83% of diabetic patients in Sudan (11).

There is only one single study done in Makele Hospital, Northern Ethiopia, assessing degree of glycemic control using Hgb A1c level and found that glycemic control was poor at mean level of 11.3% with strong association between poor glycemic control and diabetes related chronic complication (14).

Diabetes was the fifth leading cause of death worldwide and was responsible for almost 4 million deaths in 2010 (6.8 and 6% of deaths were attributed to diabetes worldwide and SSA, respectively) (2,5). In the United States, diabetes was listed as the seventh leading cause of death in 2007 (2).

In Africa, chronic diseases are projected to account for ~23% of all mortality and over the next 10 years, 28 million people will die from a chronic disease and deaths from chronic diseases will increase by 27%, most markedly, deaths from diabetes will increase by 42%. Moreover, the absolute and relative mortality rates from DM are highest in the 20—39 year age-group—i.e., the most economically productive population (8,11).

Seventy five percent of all diabetes-related deaths are from cardiovascular disease (DCCT). By 2020, mortality from ischemic heart disease in developing countries is expected to increase by 120% and 137% for women and men, respectively. (10) Over the next 2 decades, mortality attributed to IHD and stroke will be tripled, in Latin America, the Middle East, and sub-Saharan Africa (10).

In Tanzania, stroke mortality is three to six times that of England and Wales and that 4.4 % of type 2 diabetic patients presented with stroke at the diagnosis of diabetes. And five years from

diagnosis, 40% of those on insulin would die, whereas in Europe 40 percent of similar patients would survive more than 40 years (11).

In Zimbabwe, in-patient mortality is 8 %, and the survivors have a mortality rate of 41 % within six years of follow-up. Most deaths are due to infection, hyperglycemic emergencies (ketoacidosis and nonketotic coma), or hypoglycemia (10,11).

Mortalities due to acute complications like diabetic ketoacidosis range from 25 % in Tanzania to 33 % in Kenya (10).

End-stage renal failure secondary to diabetes nephropathy is the first cause of hospital mortality in diabetic patients in Africa. In South Africa, 50 % of all causes of mortality in type 1 diabetic patients may be due to renal failure (10,11,18).

The major contributing factors to such high mortality in SSA; are the chronic lack of availability of insulin, delays in seeking medical assistance by newly diagnosed type 1 patients presenting in DKA, misdiagnosis of diabetes, poor glycemic control, nonstandardized diagnostic procedures , late diagnosis of diabetes and poor health care in general and diabetic care in particular (10,11,19).

Once diabetes has developed, it is expensive to treat because of the costs associated with routine medications, endless clinic visits, laboratory testing, supplies for home glucose monitoring, and treatment of complications.

The cost of health care for patients with Type 2 diabetes rises by up to 25% over the next 30 years; however, because of reductions in the economically active age groups, the relative economic burden of the disease can be expected to increase by 40−50%. The total annual cost of patients with Type 2 diabetes in the UK rises to a maximum of about £2.2 billion over the next 30-40 years (an increase of nearly 25% from 2000) (19).

The top five countries with the highest costs of diabetes care, in SSA are South Africa, Kenya, Zimbabwe, Nigeria, and Ghana. The total cost required to take care of diabetes patients in Tanzania is US$ 138/patient/year (US$4 million) and in Cameroon US$ 489/person/year. In

Malawi, type 1 and type 2 diabetes patients spend on average US$100/person/year and US$ 25/person/year, respectively, to purchaise insulin and OGLA (10).

Many of the core paradigm of optimal diabetes management, including SMBG and routine measurement of Hgb A1c, are not feasible in poorer countries. In SSA, the majority of DM patients, because of economic constraints, cannot implement SMBG. Similarly, Hgb A1c, the gold standard test for evaluating glycemic control, is not available in most laboratories due to lack of reagents, and many patients cannot afford measurement in a private laboratory (10).

Tragically, the lack of day-to-day (SMBG) or long-term (HgbAlc) feedback information on glycemic trends renders the state of diabetes control unknowable in most patients. As a result of inadequate health care infrastructure and socioeconomic limitations, the degree of glycemic controlnecessary to prevent blindness, renal failure, amputation and heart disease are beyond reach for patients in many developing countries. Therefore, poor glycemic control is pervasive, and the complications of diabetes are almost inevitable.

Despite the current human and economic burden of diabetes, and its impending escalation, most countries do not have a national diabetes program. Well-structured and appropriate diabetes education is lacking. Wide disparities in the distribution of healthcare resources leave huge numbers of people acutely vulnerable and underserved. Hospitals do not have well organized standard guideline for diabetes care (10,11). And to develop standard guideline and to improve diabetes care and quality of life of diabetes patients, knowledge of degree of glycemic control has invaluable information; however, there is no such study conducted in JUSH. Furthermore; these study will be a base line for future investigation of diabetes related complications and the level at which these complications develop in our own nation, since it has racial variation.

Chapter 2

2.1 Literature review

SSA will have the greatest increase in prevalence of diabetes in the next three decades, moreover it affects the younger generation with an indirect impact on the already crippled economy. Furthermore, diabetes related mortality is very high in this region, due to the chronic lack of availability of insulin, delays in seeking medical assistance by newly diagnosed type 1 patients presenting in DKA, misdiagnosis of diabetes, poor glycemic control, nonstandardized diagnostic procedures , late diagnosis of diabetes and poor health care in general and diabetic care in particular (10,11).

One of the medical component of diabetes care is glycemic control. Epidemiologic studies first showed an association between poor glycemic control and microvascular complications. Then clinical trials showed that optimizing glycemic control for patients with diabetes reduces the risk of complications of the disease. Based on the results of these trials, standard clinical practice guidelines recommend that patients target Hgb A1c to be below 7% and preprandial capillary plasma glucose between 70 and 130 mg/dl and if there is discrepancy between Hgb A1c and preprandial glucose level, postprandial capillary plasma glucose below 180 mg/dl (1)

The investigation of hemoglobin A1C and patient SMBG are presently accepted as tools for the evaluation of the glycemic control in the diabetic patients. American Diabetes Association 2012 recommends to determine Hgb A1c level twice a year in patients with stable glycemic control and every three months for those not meeting glycemic goal or whose therapy has been changed (1).

Although considered the “gold standard” for diagnosis, measurement of glucose in the blood is subject to several limitations, many of which are not widely appreciated. There are many factors that affect the results of any blood test. These factors can be categorized into three, namely biological, preanalytical and analytical. Biological variation comprises both differences within a single person (intaindividual) and between two or more people (interindividual). Preanalytical issues pertain to the specimen before it is measured. Analytical differences result from the measurement procedure itself.

FBS determination is inexpensive assays on automated instruments that are available in most laboratories worldwide. Nevertheless, FPG is subject to some limitations. One study reported that FBS lacks of reproducibility, on the study, FBS ≥126 mg/dL on the first test had FPS ≥126 mg/dL when analysis was repeated ~2 weeks later in only 70.4%. The sources of variation are determined to be the above mentioned factors.

FBS is subject to Preanalytical variations, which include medications, venous stasis, posture, sample handling, food ingestion, prolonged fasting, and exercise. Inter-current illness is associated hyperglycemia as well as acute stress. The requirement that the subject be fasting is a considerable practical problem as patients are usually not fasting when they visit the doctor, and it is often inconvenient. In addition, blood drawn in the morning as FPG has a diurnal variation.

Glucose concentrations decrease in the test tube by 5–7% per hour due to glycolysis. Therefore, a sample with a true blood glucose value of 126 mg/dL would have a glucose concentration of ~110 mg/dL after 2 h at room temperature. Moreover, glycolysis increases if there is leukocytosis, erytrocytosis or thrombocytosis.

The nature of the specimen analyzed can have a large influence on the glucose concentration. Glucose can be measured in whole blood, serum, or plasma, but plasma is recommended by both the ADA and WHO for diagnosis. However, many laboratories measure glucose in serum, and these values may differ from those in plasma. The source of the blood is another variable associated with variation.

The other limitation of FBS measurement is biologic variation. This includes both inter-individual and inta-individual variation at12.5% and 5.7–8.3%, respectively. Although a bit lower than biologic variation, FBS is also subjected to analytical variation, according to the method of determination of the FBS used (38).

In comparison with FBS measurement, intra-individual variation of A1C in non-diabetic people is minimal, with CV <1%; however, inter-individual variation is greater. Most pre-analytical variations that alter FPG do not significantly affect A1C concentrations. Acute illness, short-term lifestyle changes (e.g., exercise), recent food ingestion, and sample handling do not significantly alter A1C values. Importantly, whole blood samples are stable for 1 week at 4°C and for at least 1 year at −70°C or colder (38).

The interpretation of A1C depends on the erythrocytes having a normal life span. Patients with hemolytic disease or other conditions with shortened erythrocyte survival have a substantial reduction in A1C. Similarly, individuals with acute blood loss have spuriously low A1C values because of an increased fraction of young erythrocytes. Individuals with iron deficiency anemia have increased A1C and fructosamine concentrations, both of which are reduced by therapy with iron (38).

Analytical variations are said to be low when Hgb A1c is measured as compared to FBS determination (38).

Cases of diabetes related complications will increase rapidly to peak 20−30% above present levels between 2035 and 2045 (11). The incidence of diabetic nephropathy (DN) has increased by 150% in the past 10 years in the United States, with similar trends in Europe and Japan. DM remains the leading cause of ESRD in the United States and Japan, accounting for 45% and 37% of cases, respectively (9).

Despite the numerous advances achieved in diabetes control and evaluation, the management of such a complex disease remains challenging. Recent epidemiological data from various regions of the world show most patients with diabetes are not controlled to recommended HbA1c targets (3). According to studies done in UK, France, Finland, Spain, Estonia, Brazil, Venezuela, Jordan, Malaysia, South Africa, Congo, Ghana, Kenya and Ethiopia glycemic control was 76%, 41%, >50%, 46.9%, 50%, 76%, 76%, 65.5%, 73%, 79.9%, 68%, 83.3%, 60.5% and >68%, respectively.

Younger patients (age group < 50 years) had significantly higher mean A1C than elderly patients (32) and those with poor glycemic control were approximately 2 years younger (24). However

age did not attain statistically significant proportions according to studies done in Minnesota, US and Kenya (22,36) as well as gender (22,30).

Physical inactivity, obesity and low educational level were associated with poor glycemic control, according to one study done in Jordan (31). However, a study enrolled in Congo found that poor glycemic control was more common in underweight.

Poor glycemic control was also more common among patients who were not adherent for medications (20,23 and 31) and longer duration of diabetes(4-7years) (29,32,33and34).

According to some studies, degree of glycemic control varies with the type of diabetes and type of therapy. Poor control was more common in Type1 Diabetes patients (87%) than in those with Type 2 Diabetes (75%) (29,30) and insulin treated type 2 diabetes patients tend to have poor control (27,29,31).

2.2 Significance of the study

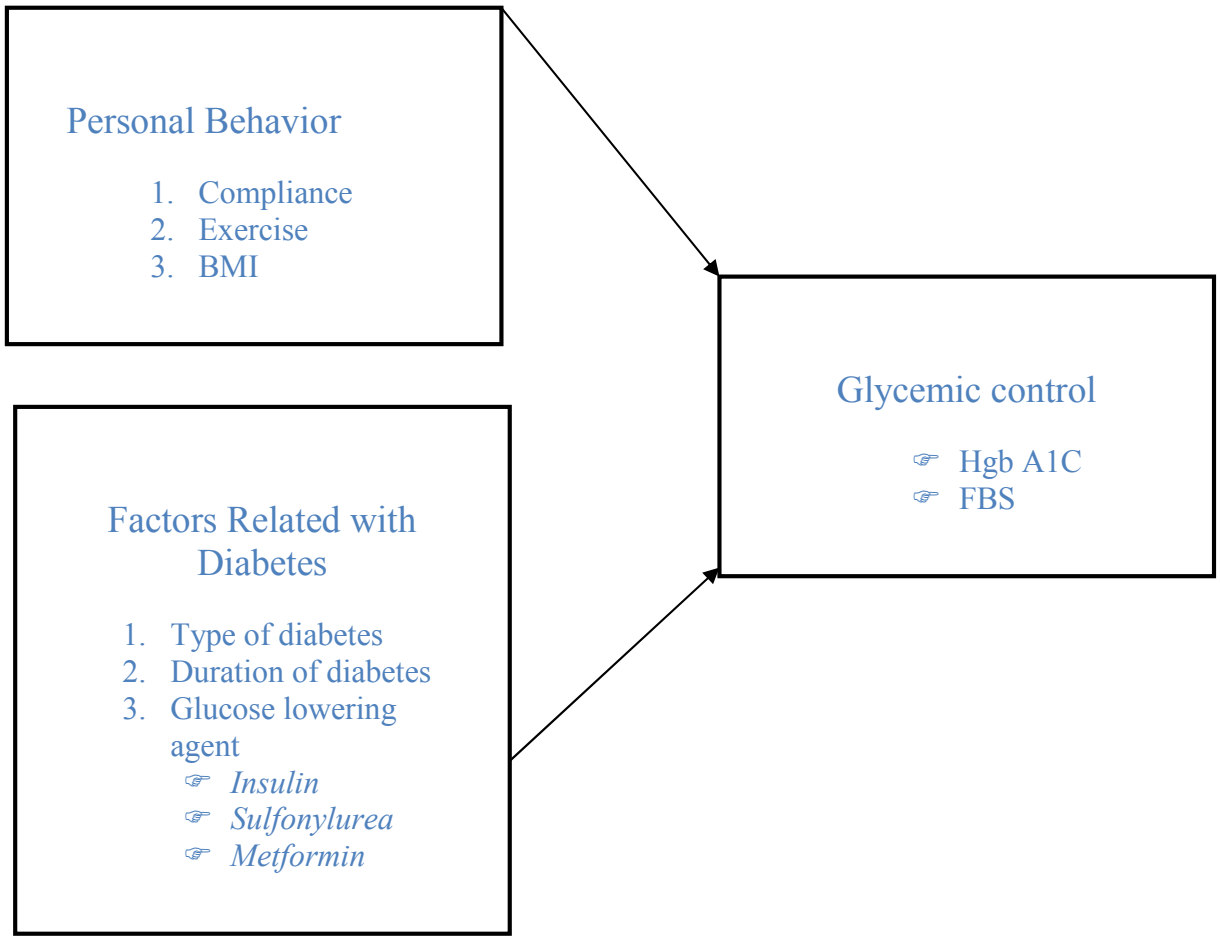
Diabetes mellitus is a chronic illness that requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of diabetes related chronic complications. One of the components of diabetes care is glycemic control and there are two standard techniques to assess the glycemic control namely, SMBG and Hgb A1c level.

Ethiopia is one of the poorest countries in the world, even in Africa. It is difficult to provide adequate diabetes service especially in rural parts of the country due to limited resources and inadequacy of health services and personnel. In almost all parts of the country, glycemic control is assessed with fasting blood glucose at the time of visit while the standard recommendation is different.

Nowadays it is becoming a common scenario to see relatively young patients admitted with acute and chronic complications of diabetes obviously, as a result of poor glycemic control. Currently there are few data in the country assessing degree of glycemic control with only one study done utilizing Hgb A1c.

Therefore it is worth investigating the degree of glycemic control and indentifying the factors that preclude from achieving the target glucose level in the management of diabetes patients. The information gathered from this study might open the eyes of the policy makers and help them plan and implement strategy in order to provide standard diabetes care in the country. Moreover, this will serve as a baseline for future researchers interested in the area.

2.3 Conceptual Framework



Chapter- 3

3. Objectives of the study

3 - 1General objective

- To assess the degree of glycaemic control and associated factors among diabetes patients served at Jimma University Specialized Hospital, South West Ethiopia.

3 – 2 Specific objective

1. To determine the degree of glycemic control using glycosylated hemoglobin
2. To identify predictors of degree of glycemic control

Chapter- 4

4. Methods and Materials

4.1 Study Area and Period

Study area

The study will be conducted in Jimma University Specialized Hospital from September 2012 to Mar. 2013. The hospital is located in Jimma town of the Oromia Regional State in the Southwest of the country. In addition to the JUSH, there is one primary hospital (Shenen Gibe Hospital) and 4 health centers. There are also nongovernmental health facilities (NGO's) and private clinics. Most of patients with chronic diseases are referred to JUSH for chronic care and follow up. Jimma University hospital is a teaching center for both undergraduate and post graduate medical doctors, health officers and para-medics.

JUSH, outpatient department provides diabetic follow up service for a total of ~ 2000 type 1and 2 diabetes patients coming from Jimma town and its surroundings.

On average, 160 patients are seen in the follow up clinic schedule of two days per week. The follow up clinic is run by the department of internal medicine and patients in the clinic are attended by internists, internal medicine residents, and medical interns.

4.2 Study design

A prospective, cross sectional, study was employed.

4. 3 Source Population

The source population of this study was all diabetes patients attending the diabetes follow up clinic of Jimma University Specialized Hospital, south-west of Ethiopia.

4. 4 Study population

Inclusion criteria

- Diabetes patients above the age of 15 years.
- Patients who are already on drug treatment for diabetes for more than 3 month were taken.
- Participants who are willing to give informed and written consent and are willing to participate were taken for the study.

Exclusion criteria

- Individuals below 15 years of age.
- Those diagnosed with diabetes, 3 months back.
- Pregnant women.
- Participants who did not give informed and written consent or were not willing to participate were not taken for the study.

4. 5 Sampling

4.5.1 Sampling technique

There are a total of 2000 patients attending JUSH diabetic follow up clinic

Diabetic patients attending JUSH were classified into type 1 and type 2 diabetes based on their medication, that is, those taking insulin only were considered as type 1 and the rest as type 2.

Based on this information from JUSH diabetes clinic data base, the patients were stratified into type 1 and type 2 diabetes and then all patients were taken from both types of diabetes that came for their routine follow up visit to the diabetic clinic during the month of June 2013.

4.5.1 Sample size

All patients were taken from both types of diabetes that came for their routine follow up visit to the diabetic clinic during the month of June 2013.

4.6 Measurement

4.6.1 Variables

- Dependent variable
    - Hgb A1c level
- Independent variable
    1. Age
    2. Sex
    3. Ethnicity
    4. Type of diabetes
    5. Duration of diabetes
    6. History of admission to the ER due to very high glucose level in the past 1 year

7. Exercise
8. BMI
9. Type of Medication

4.6.2 Instruments and Data procedures

Participants were interviewed individually using pretested, questionnaire by trained data collectors. The questionnaire contains information about socio-demographic status, diabetes related questions (eg, duration of illness, medication and so on) and clinically obtained parameters. Medication adherence was assessed by **morisky score.**

Height was measured without shoes, and weight recorded while wearing indoor clothing.

Laboratory results of FBS and HgbA1c levels.

FBS and HgbA1c will be measured by blood glucose meter and Ion-exchange Resin Separation Method, Human, Germany, respectively.

4.7 Data quality control

The measures that were undertaken to ensure quality of data, include pre-testing of the data collection instrument on 5% of the sample, training on data collection for data collectors 2 days prior to data collection for 1 day, supervision of the data collection process and data was stored in a safe cabinet and data was managed properly.

4.8 Data Analysis Plan

The collected data was cleaned, entered in to SPSS version 16.0 and Epi Info version 3.3.2 software programs for analysis.

Frequencies, proportions, and mean values were calculated. Uunivariate and multivariate regression analysis were employed to identify predictors of degree of glycemic control. Statistical significant associations were determined using confidence interval at 95% and P-value <0.05.

The HbA1c level was used as the primary indicator of glycemic control; the number and percent of diabetic patients with HbA1c value <7% and ≥ 7% were labeled as adequate and inadequate

glycemic control, respectively as defined in the American Diabetes Association standards of medical care for persons with diabetes (1). Basic descriptive statistics and frequency calculations were performed on all variables; a chi-square test was used to assess differences in answers by categories of stratifying variables.

The results were presented using tables, figures, charts and statements. Appropriate discussions, sound conclusions and recommendations were made.

4.9 Ethical consideration

Official written approval was obtained from the ethical review committee of Jimma University, College of Public Health and Medical Sciences. A written consent was obtained from the patients who participate in the study.

The written consent form, prepared both in Oromifa and Amharic languages, were provided to study subjects describing the aims, benefits and reason for conducting the study, how their involvement will contribute, and what their rights are within the study.

During the investigation, all patient records will be kept confidential such that each patient will be coded. The right of the patient not to participate or refuse to give blood sample for the purpose of the study or to withdraw at any time from the study will be respected. Refusal to participate or withdrawal from the study at any point will not affect the care to be received by the patient. A letter which addresses the reason and importance for conducting this research will be communicated to the Clinical Director of JUSH.

4.10 Limitations

The limitation of this study was record incompleteness and small sample size. The need for reducing our sample size was scarcity of reagent, which was very expensive (Eth 56 birr per patient) and made it difficult to rectify some of the determinants of poor glycemic control.

4.11 Result Dissemination Plan

The findings of this study will be presented to the Jimma University scientific community. After approval by the University, it can also be communicated to health policy makers and

Implementers at regional and national level. Publication in peer reviewed, national or international, journals will also be considered.

4.12 Operational definition

The Morisky score

The Morisky score is a 4-item questionnaire that predicts patient medication-taking behavior. The Morisky score is calculated by adding the number of no answers to the 4 questions of non-adherence:

1. *Do you ever forget to take your medicine?*
2. *Are you careless at times about taking your medicine?*
3. *When you feel better, do you sometimes stop taking your medicine?*
4. *Sometimes if you feel worse when you take the medicine, do you stop taking it?*

A higher score on the scale of 0 to 4 indicates better adherence to treatment. When any response is missing, a yes response will be implied.

BMI (Body Mass Index)

Was calculated by dividing weight in kilograms with height, in meters squared. The following labeling were made based of the BMIs:

- *<18.5 are considered underweight,*
- *18.5–24.9 are normal,*
- *25–29.9 are overweight, and*
- *≥30 are obese.*

Glycemic control

<7 is good control

>7 poor control

Chapter 5

Results

Prevalence of poor Glycemic control

Both random blood glucose and hemoglobin A1c% level were markedly elevated with mean values of 261.85 (SD 140.8) and 7.94 (SD 2.28). Only 27.8% of type 1 diabetes patients had A1c level below 7% where as 48.7% of type 2 diabetes patients had A1c below 7%. Random blood glucose measurement detected 89.6% (69) of the patients with glycated hemoglobin value of ≥ 7 with value of ≥130 mg/dl. There was statistically significant disagreement between the measured random blood glucose and hemoglobin A1c% value as determined by kappa (p = 0.087).

Base line characteristics of the study population

Of the 120 patients enrolled, 53.8% (64) were male, the majority 34.2% (41) were between 18-45 years of age and 58.3% (70) were oromo, 13.3% (16) amhara and 24.2% (29) debub by ethnicity.

Type of Diabetes

Arbitrarily defining type 1 diabetes as those taking insulin only, 67.5% (81) were considered to be type 1 diabetes and the rest as type 2 diabetes.

Table 1 Socio-demographic characteristics of diabetes patients, in Jimma Specialized Hospital, Jimma, South West Ethiopia, 2012 - 13 GC.

Socio-demographic characteristics		**Type of diabetes**		**Total (%)**
		Type 1 (%)	**Type 2 (%)**	
Sex	Male	42 (52.5%)	22 (56.4%)	64 (53.8%)
	Female	38 (47.5%)	17 (43.6%)	55 (46.2%)
Age in years	18 - 44	35 (43.8%)	6 (15.4%)	41 (34.6)
	45 - 54	19 (23.8%)	8 (20.5%)	27 (22.7%)
	55 -65	15 (18.8%)	16 (41%)	31 (26%)
	66 - 75	11 (13.8%)	8 (20.5%)	19 (16%)
	≥ 76	-	1 (0.3%)	1 (0.08%)
Ethnicity	Oromo	48 (60%)	22 (56.4%)	70 (58.8%)
	Amhara	9 (11.3%)	7 (18%)	16 (13.4%)
	Tigre	2 (2.5%)	2 (5%)	4 (3.4%)
	Debub	21 (26.3%)	8 (20.5%)	29 (24.4%)
	Others	-	-	-

Table 1-2 Degree of glycemic control, correlation between FBS and Hgb A1c and difference in glycemic control between type 1 and tyep2 diabetes patients, in Jimma Specialized Hospital, Jimma, South West Ethiopia, 2012 - 13 GC.

Type Of Diabetes	Glycemic Control			
	FBS		Hgb A1c	
	<130	≥130	< 7%	≥7%
Type 1	8 (10.3%)	70 (89.7%)	22 (27.8%)	57 (72.2%)
Type 2	9 (23.7%)	29 (76.3%)	19 (48.7%)	20 (51.3%)
Total	17	99	41	77

Determinants of Glycemic control

The frequency distribution for hemoglobin A1c level and different patients characteristics is summarized in table 2. Most of the patients had their diabetes for less than 10 years (68.9%) and 14.3% for more than 15 years. Among type 2 diabetes patients only 3.3% (4) patients take insulin in addition to their oral glucose lowering agent and 20.1% (28) take combination oral glucose lowering agents. Majority of type 1 and type 2 diabetes patients [57.1% (68)] do not exercise at all in any day of the week with only 21.1% (25) fulfilling the exercise criteria as recommended by ADA. Forty-nine percent (58) of patients had no history of hospitalization due to poorly controlled hyperglycemia and only 5 patients were admitted for this condition. The distribution of Morisky score were 21.8% (26) for score of 0 or 1, 33.6% (40) for 2, 31.9% (38) for score of 3 and 12.6% (15) for score of 4. According to the BMI, most type 1 and type 2 diabetic patients [53.3% (64)] were in the ideal range and 34.7% (41) were more than 25 kg/m^2.

There was no statistically significant association between poor glycemic control gender, ethnicity, compliance, hospitalization history, type of medication and body mass index. However there was statistically significant association between poor glycemic control and longer duration of diabetes (≥ 10 years) ($p = 0.026$) and type 1 diabetes ($p = 0.025$).

Those with longer duration of diabetes (≥ 10 years) and type 1 diabetes had 2.66 ($p = 0.04$ confidence interval = 1.029 - 6.898) and 2.27 ($p = 2.274$ confidence interval = 1.007 – 5.134)

times increased chance of having poor glycemic control, respectively, compared to relatively shorter duration of diabetes and type 2 diabetes.

Table 3 Factors affecting glycemic control in type 1 and tyep2 diabetes patients, in Jimma Specialized Hospital, Jimma, South West Ethiopia, 2012 - 13 GC.

Clinical Parameters		**Type 1 Diabetes**				**Type 2 Diabetes**			
		FBS (mg/dl)		**Hgb A1c**		**FBS (mg/dl)**		**Hgb A1c**	
		< 130	≥ 130	< 7%	≥ 7%	< 130	≥ 130	< 7%	≥ 7%
Duration of Diabetes In Years	< 2	2	10	7	6	5	3	4	4
	2 – 4.9	5	14	7	12	1	13	9	5
	5 - 9.9	0	20	5	15	1	6	2	6
	10 – 14.9	0	12	0	12	2	4	2	4
	≥ 15	1	13	3	11	0	3	2	1
History of admission to the ER, in the past 1 year	None	5	24	8	22	5	22	15	13
	1 - 3	3	38	12	29	4	6	4	6
	≥3	-	7	2	5	-	1	-	1
Exercise	None	2	39	11	31	4	20	12	12
	1- 2	2	4	1	5	3	1	2	2
	≥3	4	26	10	20	2	8	5	26
BMI	Underweight	1	10	2	10	0	1	1	0
	Ideal Weight	5	34	11	28	4	18	13	10
	Overweight	1	16	7	10	1	8	3	6
	Obese Or Morbidly Obese	1	8	1	8	4	2	2	4

Chapter-6

Discussion

Even though we were limited by the smallness of the sample size to reveal some associations; our study discovered the prevalence of poor glycemic control as well as some of the predictors of this poor glycemic control among type 1 and type 2 diabetes patients of diabetic clinic at Jimma University Specialized Hospital. The study included all diabetes patients attending follow up at diabetic clinic that came for their routine check up during the study period, to study the prevalence and predictors of poor glycemic control. We believe that the results of this study will provide base line information about the degree of inadequate glycemic control, as well as aid in planning a strategy to address this problem.

We also tried to identify modifiable factors associated with poor glycemic control that can be adjusted in order to improve the quality of care of diabetes patients.

In our study the over all prevalence of inadequate control was high (65.3%) which is comparable with previous studies done both in Western countries and SSA.

We found out that poor glycemic control was associated with type 1 diabetes and longer duration of diabetes which is consistent with previous studies done in (23,34,31,33)

In our data, there was no significant difference in glycemic control by gender, ethnicity, compliance, hospitalization history, type of medication and body mass index. In contrast a study done on type 2 diabetes in north America, Detroit showed that high Morisky score, which shows good compliance, was associated with lower hemoglobin A1c level (23). This may be explained by the fact that our study included both types of diabetes and the proportion of type 1 diabetes was significantly higher and type 1 diabetes patients are more likely to be compliant to their medication, since they are aware of the acute complication associated with skipping their routine dose of insulin.

In terms of associations between poor glycemic control and gender, hospitalization history and body mass index, there are conflicting results from different studies, some showing associations and others showing no significant association (14, 34 31 33). Large scale study needs to be conducted to settle this issue, till then it is difficult to infer any conclusion regarding these associations.

Our study did not find statistically significant association between poor glycemic control and inadequate level of exercise, however; more than half of patients do not exercise at all in any day of the week.

Chapter 7

Conclusions and Recommendations

Conclusion

1. Prevalence of poor glycemic control among type 1 and type 2 diabetes patients attending their follow up at, Jimma University Specialized Hospital, diabetic clinic is 65.3%.
2. Duration of diabetes longer than ten years and type 1 diabetes were predictors of poor glycemic control.

Recommendation

1. Following diabetes patients utilizing hemoglobin A1c level is recommended in order to achieve the target level set by the ADA to prevent diabetes related complications. We also suggest studying, in the future, any relations between poor glycemic control, assessed by hemoglobin A1c level, and diabetes related complications.
2. Type 1 diabetes patients tend to have poorer glycemic and most of the studies found consistent result in preventing diabetes related complications with tight glycemic control in type 1 diabetes patients than type 2 diabetes patients. Furthermore we suggest conducting a study, why type 1 diabetes patients had poorer glycemic control, till then it is recommend optimizing insulin therapy by combining short and long acting insulin regimen.
3. We also recommend encouraging diabetes patients to exercise for a total of 150 minutes per week in order to gain invaluable benefits of exercise.
4. Duration of diabetes longer than ten years is associated with poor glycemic control, however; it is difficult to recommend any thing since it is non-modifiable factor. Nevertheless, optimizing diabetic care as per standard protocol using hemoglobin A1c level to assess glycemic control might benefit this sub-group of diabetes patients in achieving the target.

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Annexes

Annex I. Data Collection Instrument

QUESTIONNAIRE FOR DATA COLLECTION

Jimma University Specialized Hospital, Department of Internal Medicine, Study on Pattern of Glycemic Control.

Socio-demographic characteristics

Age of patient (y)

(1) 18–44
(2) 45–54
(3) 55–65
(4) 66–75
(5) ≥76

Sex
(1) M
(2) F

LNMP (in days)

Ethnicity
(1) Oromo
(2) Amhara
(3) Tigre
(4) Debub
(5) Others

Clinical Information

Duration of diabetes
(1) < 2 years
(2) 2 - 4.9 years
(3) 5 – 9.9 years
(4) 10 -14.9 years
(5) 15 years

Medication
(1) Insulin
(2) Metformin
(3) Sulfonylurea
(4) Others

Compliance

1. Do you ever forget to take your medicine? Yes No
2. Are you careless at times about taking your medicine? Yes No
3. When you feel better, do you sometimes stop taking your medicine? Yes No
4. Sometimes if you feel worse when you take the medicine, do you stop taking it? Yes No

Total "No" answers

(1) 0 and 1
(2) 2
(3) 3
(4) 4

Exercise

- Do you exercise? Yes No.
- If yes, on how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

(1) 0
(2) 1
(3) 2
(4) 3
(5) 4
(6) 5
(7) 6
(8) 7

Hospitalization history

(1) 0
(2) 1
(3) 2
(4) 3
(5) >4

BMI (Kg/M^2)

(1) < 18.5
(2) 18.5 -24.9
(3) 25- 29.9
(4) 30

Investigation

FBS

(1) 70 -130
(2) 131 – 200
(3) 200

A1C

1. < 6.5
2. 6.5 - 6.9
3. 7 – 7.9
4. > 8

I am _____, collecting data in the behalf of Dr. Dagmawi Tewolde, who is a final year resident of Jimma University, department of internal medicine. He is going to study the pattern of glycemic control in diabetes patients, as partial fulfillment of the requirements for his specialty certificate in internal medicine.

This kind of research, has never been conducted before, in this hospital. We believe that, the results of this study will provide us with information, that is important in the management of diabetes, and help us strengthen diabetes care. So, are you willing to participate in this study? (You have the right not to participate, if there is any doubt!)

- YES, I want to participate ☐
- No, I don't want to participate ☐