Original Article

Assessment of type II diabetes mellitus drug therapy in diabetes clinic of a tertiary care teaching hospital in Addis Ababa

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ABSTRACT

Background: Prevalence of type II diabetes mellitus(T2DM) is substantially increasing in Ethiopia but there are no studies on its drug therapy. **Objective:** To assess drug therapy for T2DM and check association between fasting blood glucose levels with patient demographics, clinical characteristics and medications. **Materials and Methods:** A cross-sectional institution based study was conducted on T2DM patients over a 1 month period using patient chart review and key informant interview at the diabetes clinic of Tikur Anbessa Specialized Hospital (TASH). **Results:** Of 103 patients enrolled females accounted 59.2%. The mean age was 52.2 years and 96.12% of patients were from Addis Ababa. The mean fasting blood glucose (FBG) and body mass index (BMI) were 155.99 mg/dl and 26.4 kg/m^2 respectively. About 51.45% of the patients were overweight; and neutral protamine hagedorn insuline (NPH) (56.3%), metformin plus glibenclamide (19.4%) and metformin (10.7%) were the most common drug therapies. But there was no significant association of FBG levels of patients with either, gender, age, BMI or medications. **Conclusions:** The drug therapy at the diabetes clinic was in line with recommendations of International Diabetes Federation (IDF)despite lack of uniform guideline.

INTRODUCTION

Diabetes mellitus (DM) is estimated to have affected 284.6 million people in 2010, and is expected to reach up to 438.4 million by 2030; and the lion's share is expected to be from the developing world as its prevalence is substantially increasing.[1]

According to a recent study, about 14 million individuals are thought to have DM in Africa, which is expected to rise to 28 million by 2030; Sub-Saharan Africa is also being affected and experiencing increasing prevalence.[2] In Ethiopia, community based studies are not available at national level, based on extrapolation from similar countries prevalence of diabetes is estimated 4.36% and the number of DM related deaths was 34,262 in 2013.[3]

Since increased mortality and lack of control in DM patients' makes quality of treatment a major concern;[4] different studies underline the importance of glycemic control with different treatment modalities ranging from lifestyle changes to insulin.[5] However, recent advancements in pathophysiology of DM and pharmacological approaches are challenging physicians' choice of appropriate treatment strategy.[6,7] Moreover, the study by Holmer *et al*. indicates gaps and inconsistencies in quality within and across guidelines.[8]

Despite different studies on T2DM in Ethiopia;[9-11] a study focusing on drug therapy of T2DM is lacking.

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Furthermore, no specialized teaching hospital in the country has a specific guideline; as a result physicians rely on their personal experience and different guidelines. Thus, this study will assess T2DM drug therapy and association of clinical characteristics, demographics, and medications with fasting blood glucose (FBG) at the diabetes clinic of TASH.

MATERIALS AND METHODS

Study setting and study design

The study was conducted in the Diabetes Clinic of TASH. TASH is the largest specialized teaching hospital in Ethiopia that serves as a training center for undergraduate and postgraduate students. The diabetes service in TASH includes two diabetes clinics per week; one diabetes and pregnancy clinic per week, one foot clinic per week, diabetic retinopathy screening, laser treatment, twice per week-diabetes education and monthly diabetes education by the Ethiopian Diabetes Association. Approximately, 500 patients receive diabetic and endocrinology services per month. An institution based cross sectional study that used both quantitative and qualitative methods was conducted.

Data collection and management

All T2DM patients attending the diabetes clinic of TASH were used as a source population, 103 patients who obtained follow-up treatment in the diabetes clinic in April 2013 for T2DM were included in the study, while type I diabetes mellitus patients and T2DM patients with incomplete information were excluded.

Data were collected by trained final year nursing and pharmacy students using abstraction format from patient charts after physician consultation and key informant interview was also used to assess the experience and practice of the practitioners.

Data were cleaned, coded and entered into SPSS version 19 (SPSS Inc, Chicago, IL, USA) categorical variables were presented in numbers and percentages. Continuous variables were presented as complete data sets. Data for numerical variables were expressed as mean ± standard deviation and mean difference was determined using independent sample *t*-test. Association between FBG and sex, age, body mass index (BMI) and medications used was determined using bivariate analysis with Pearson correlation coefficient and Pearson Chi-square with significance set at $P < 0.05$.

Ethical consideration

Ethical clearance was obtained from the Ethics Review Committee of the School of Pharmacy; College of Health Sciences, Addis Ababa University and from Institutional Review Board of TASH. Patient and health care provider related data was confidential and was destructed after constructing database.

RESULTS

Demographic characteristics

Of the total 103 patients, 59.20% were females patients and mean age was 52.20 ± 10.90 with a minimum of 25 and maximum of 82. For 96.12% of the patients the area of residency was Addis Ababa as shown in Table 1.

Clinical characteristics

Fasting blood glucose

Mean FBG was 153.99 ± 44.32 mg/dl with a minimum of 58 mg/dl and a maximum of 287 mg/dl. About 72.80% were above the diagnostic reference of 126 mg/dl with a mean difference of 27.99 mg/dl. Mean female FBG was 158.75 ± 45.75, whereas the mean male FBG was 133.33 ± 47.90 but there was no significant difference ($P = 0.325$).

Body mass index

26.40 ± 3.05 kg/m^2 was the mean BMI with a minimum of 19.50 kg/m^2 and a maximum of 35.20 kg/m^2. 34.95%, 51.45% and 13.59% of patients' BMI was normal, overweight, and obese respectively, while none were underweight.

Medications used

Majority of the patients were on NPH followed by metformin and glibenclamide as shown in Figure 1. Mean age of patients receiving NPH was

Table 1: Sociodemographic profile of diabetic patients treated at the diabetes clinic of TASH, April 2013

Demographic characteristics	*N* (%)
Sex	
Male	42 (40.80)
Female	61 (59.20)
Age	
25-39	11 (10.68)
40-54	53 (51.46)
55-69	29 (28.15)
70-82	10 (9.71)
Area of residency	
Out of Addis Ababa	4 (3.88)
Addis Ababa	99 (96.12)

TASH: Tikur Anbessa Specialized Hospital

50 ± 9.80 years and; 24.14% and 75.86% of patients on NPH were switched from metformin and metformin plus glibenclamide, respectively.

Factors affecting fasting blood glucose

Gender (P = 0.600) and age (P = 0.803) showed no significant association with FBG. BMI depicted a linear relation with FBG with no significant association (P = 0.970). Similarly medications used and FBG showed no significant relation (P = 0.081) as tabulated in Table 2.

Key informant interview

The interview included two fellows in diabetes and endocrinology who were involved in treating and teaching for the past 2 years in the diabetes clinic of TASH. Routine assessments including glycemic and lipid level, blood pressure, current complaint, diet, exercise and medications used were conducted. Retinal and foot exams and discussion on pregnancy plans in female patients were carried out when appropriate. However after assessment, their management strategies were different, while one preferred the American Diabetes Association and Canadian Diabetes Association guidelines, the other had predilection to IDF guideline. Trainings given by the fellows were comprehensive and were not directed to a specific guideline. With regard to influence of age, gender and BMI on medication choice one fellow stated "no effect," while the other indicated use of individualized approach.

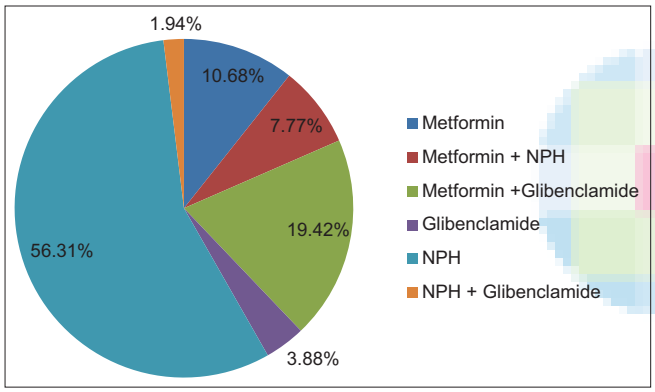

Figure 1: Percentage of medications prescribed to diabetic patients treated at the diabetes clinic of Tikur Anbessa Specialized Hospital, April 2013

Table 2: Association of FBG levels with age, BMI and medication used in the diabetes clinic of TASH, April 2013

	FBG
Patient age	
Pearson correlation	−0.025
P value	0.803
N	103
BMI	
Pearson correlation	−0.004
P value	0.970
N	103
Medication used	
Chi-square (*P* value)	0.081
N	103

TASH: Tikur Anbessa Specialized Hospital, BMI: Body mass index, FBG: Fasting blood glucose

Both confirmed metformin and glibenclamide as the most commonly prescribed medications with the use of NPH when oral hypoglycemic agents failed. One fellow stated obesity as a factor to poor glycemic control due to insulin resistance. But both stated that glycemic control on repeated visits guided changes in medications; but before any change or addition, attempts were made to achieve the desired outcome with medications patients were on. Further the fellows pointed out sub-optimal monitoring, patient load, lack of adopted guideline for the setting, lack of self-care practice and resources, reliance on free medications and resistance to initiate insulin as major reasons for the inadequacy of treatment.

DISCUSSION

With regard to patient demographic characteristics, it is important to know the source of the problem, either with age, sex or area of residency, because knowing these factors could affect the choice of appropriate treatment. The mean age in this study was 52.20 ranging between 25 and 82, which was in line with self-care practice study among T2DM patients in TASH (55.03) ranging from 30 to 85 years; and 53.50 ranging from 14 to 88 years study in Gondar University Teaching Referral Hospital (GUTRH).[10,11] In Ghana, the mean age was 54.70,[12] while in Eritrea more than half of the patients were older than 50 years with a mean of 57.40.[13] The age group ranging from 40 to 54 accounted for the greater proportion of patients and enclosed the mean age of the study participants, which was expected and gave an idea about the most affected section of the population; similar to Eritrea.[13]

In this study, 59.20% were females close to figures from the self-care practice study in TASH (52.2%) and 51% in GUTRH.[10,11] A study in Rwanda and India also reported a higher incidence of T2DM in females;[14,15] while another study in India indicated

higher number in males.[16] Higher incidence in females is associated with limited physical activity as many females remain in house, which make them prone to obesity. Plus 84.6% of obese patients were females which relates with obesity as a risk factor for developing T2DM.

The area of residency of most patients (96.12%) was Addis Ababa. Besides the fact that the hospital is located in the city, obesity associated with a sedentary life style in urban areas as compared to the rural areas could be a plausible reason. Urbanization and city life has been associated with a rise in T2DM. Moreover, a study by Hall *et al*. suggested, comparatively higher prevalence of T2DM in urban areas associated with a higher prevalence of obesity.[2]

With regard to clinical characteristics, mean FBG and BMI were 153.99 mg/dl and 26.37 kg/m^2, respectively. The minimum BMI in this study was 19.50 kg/m^2 lower than that of GUTRH of 24.20 kg/m^2.[11] Mean FBG was above IDF recommendation and mean BMI was within overweight category. In similar studies, a mean FBG of 149.88 mg/dl was found in Ghana[12] and 24.20 of BMI in India.[17]

Most of the patients were on NPH, which could be due to failure to achieve glycemic control with oral hypoglycemic agents; supported by the mean age of patients on NPH being 50 years when compared to the mean age of the total participants. Further, a study among T2DM patients in TASH indicated that the mean duration of T2DM to be 12.3 years.[10] Re-evaluation of patient charts of those on NPH indicated metformin and metformin plus glibenclamide as first and second most commonly used oral agents, which was in line with the IDF guideline. However, disparity in medication choice was observed; which could be due to personal experience and choice, availability and cost based preference or lack of uniform guideline.

Age, gender, BMI, and medications used had no significant effect on FBG, pointing the problem of elevated FBG to lack of self-care practice and resources. Furthermore, a self-care study done in TASH, revealed 84% non-adherence to self-blood glucose monitoring and 78.8% non-adherence to recommended diet management practices;[10] in line with the reasons for the inadequacy of treatment forwarded by the fellows.

CONCLUSION

Though the study was conducted for a period of a month due to budget limitation, it gives a general picture about T2DM drug therapy in diabetes clinic at TASH: drug therapy was congruent with IDF's recommendations despite higher FBG levels and obesity. Patient education on lifestyle modification, development of uniform guideline and involvement of clinical pharmacists is strongly recommended. Because studies have illustrated pharmacists' role as educators and in establishing patient specific goals to increase medication effectiveness, adherence, and safety.[18,19]

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