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## Data Analysis for Anti-Diabetic Treatment Regimen in DM Center in Basra, Iraq

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### ABSTRACT

**Objective:** Diabetes mellitus is one of the chronic diseases that carry a lot of complications on patients. This disease is not a curable condition, but by medications can minimize or retard the occurrence of such complication. Diabetes patients need to be followed continuously to control any disease development. This follow up is done through monitoring blood glucose level, glycated hemoglobin, lipid profile, macro-vascular complications (cardiovascular complications), microvascular complications (neuropathy, nephropathy, and retinopathy) and schedule a physical examination to control any development. **Methods:** In this study, 106 patients were involved. About 61 female and 45 male participated in the study. Mean age was  $35.1 \pm 16.65$  for diabetes mellitus type 1 and  $53.37 \pm 11.4$  for diabetes mellitus type 2. Their body mass index was  $23.9 \pm 5.84$  for diabetes type 1 and  $31.17 \pm 6.54$  for type 2. Estimation of lifestyle (healthy diet and exercise) and type of medications, study their effect on complications (neuropathy, blurred vision, decrease body weight) and the incidences are studied. **Results:** In this study, as the good lifestyle was maintained it was observed that there was a decrease in the incidence of diabetic complications; glycated hemoglobin shows decrease in its value if the patient follows good lifestyle. Also, a combination of medications (metformin+glibenclamide) gives better result on complication incidence than metformin alone and on the level of glycated hemoglobin. **Conclusion:** Good lifestyle, choosing good medication (especially combination medications) and continuous follow up to give a good prognosis and maintain a good level of health for diabetic patients.

**Keywords:** Blurred vision, Decrease body weight, Diabetes mellitus, Lifestyle, Metformin

### INTRODUCTION

Diabetes mellitus is the most spread worldwide endocrine disorders. The incidence of this chronic disease is increasing nowadays [1]. Diabetes mellitus popularity varies markedly around the world, and that is because of a variety of different factors like genetic or environmental factors. It is predicted that, in the year 2000, 171 million people had diabetic globally, and this is expected to double by 2030 [2]. In the last decade, the World Health Organization (WHO) showed increment in the incidence of diabetes and its association with obesity [3]. Lifestyle, age, diet, and associated conditions are an aid to increase the percentage of DM in society [4]. A clinical trial showed the necessity of patient with diabetes mellitus to take medication like a hypoglycemic agent, angiotensin-converting enzyme inhibitor and 3-hydroxyl-3-methylglutaryl coenzyme reductase inhibitor (statin) because of its efficacy [5]. Most of the Arab countries show high numbers of persons diagnosed with diabetes (20 million) and other 17 million diagnosed with prediabetes [6]. Tight glycemic control and target glycated hemoglobin (HbA1C) are the aims of using anti-diabetic agents, which in turn reduce the complications of a diabetic to present early [7]. American Diabetes Association (ADA) and others suggested guidelines for diabetic management and control. These guidelines were suggested using a combination of oral hypoglycemic agents and/or adding insulin therapy to reach the best target of HbA1C, reduce the resistance of insulin and minimize the cardiovascular combination [8]. Metformin, a biguanide anti-diabetic agent, is considered as the first choice for treatment of diabetes mellitus type 2 due to its high efficacy, well tolerance and vascular benefit effect. American Diabetes Association/European Association for the Study of Diabetes (ADA/EASD) consider in their guidelines that metformin is used as monotherapy or as combinations with other antidiabetic drugs because of good reduction for blood glucose level, its price and few side effects [9-11].

Sulfonylureas (SUs) are agents used for management of type 2 diabetic patients. Good glycemic control, minimize

cardiovascular events by an increase in the insulin secretion and ability to use monotherapy or combination with other group agents make this group good choice for type 2 DM, especially thin patients due to increased body weight [12,13]. Dipeptidyl peptidase-4 (DPP-4) inhibitors are unique agents acting as antidiabetic. The less hypoglycemic adverse effect and change in the body weight when compared to other agents make them the right choice for DM2 treatment [14]. Thiazolidinedione (TZD) introduce a new advantage for treatment of DM2 patients by several good effects on body systems in addition to its action on insulin resistance and good improvement in HbA1C [15]. Meglitinides are well tolerated, good efficacy in lowering blood glucose level, rapid-acting agents and less hypoglycemic side effect when compared to SUs. These properties make them the most considered agents for the treatment of DM2 [16]. Glucagon-like peptide-1 mimetics (GLP-1) are agents related to incretins, which are hormones responsible for secreting insulin postprandial period, and this mechanism of action provides a beneficial effect on blood glucose level and improvement in DM treatment [17]. All that mention above is for treatment of DM2 patients. People with DM type 1 are managed by insulin. Good glycemic control and lowering in HbA1C are required, either insulin or oral agents are used to delay the onset of diabetes complications that are listed in Table 1 [18]. Good treatment choosing, controlled diet, and exercise and scheduled checking for the disease development will give a good result on diabetes patients either on the disease or on their daily life. In our study, we would like to analyze several clinical data of diabetes patients using different types of anti-diabetic agent, continue on specific lifestyle based on data collection from patients. Through this information, the best regimen for diabetic patients can be confirmed.

**Table 1 Some complications of diabetes mellitus**

<b>Microvascular Complications</b>	<b>Macrovascular Complications</b>	<b>Miscellaneous Complications</b>
Neuropathy	Atherosclerosis	Diabetic cardiomyopathy
Nephropathy	Myocardial infarction	
Retinopathy		

#### **PATIENTS AND METHODS**

In our study, the retrospective design of the study was used for collecting information. We assumed data from 106 patients affected with diabetes during February 2018 in Faiha Specialized Diabetes, Endocrine and Metabolism Center (FDEMC). Gestational diabetes, the presence of other hormonal disorders was excluded in this study.

All patients were randomly selected either during their visit to the medical center or in a health institution. DM1 or DM2 was included in this study, and other types, if present, were excluded. Several demographic data were collected including age, DM duration, risk factors, disease complications, risk factors, and others. The questionnaire was designed with full information from the patients. The agreement was taken from each patient before collecting data and an ethical committee was obtained to start with this research as it is applied to a human. Data is calculated statistically by using SPSS version 22 program.

#### **RESULTS**

In Table 2, several parameters were listed for diabetes patients type 1 and diabetes patients type 2. Age, gender, body mass index and other parameters were listed. Mean age of diabetes mellitus 1 is 35.1 years while for type 2 diabetes is 53.37 years, due to the onset of each one. DM1 mostly occur before 35 years of age, while type 2 diabetes occurs after 35 years. For the same reason, the duration of DM1 was 12.19 years and DM2 duration was 5.47 years. HbA1C was high for both groups (8.37 for DM1 and 8.17 for DM2). HbA1C was indicated for the glycemic state of a diabetic person for the previous 3 months, that is because it depends on the lifespan of red blood cell and is considered one of the 1<sup>st</sup> markers for diagnosing diabetes. Body mass index of participated patients was measured by dividing body weight that was measured in kg and height measured in the meter. Body mass index (BMI) is an important marker in new studies to confirm the health status of individuals. Only 10 patients were smokers and only one was a drinker.

In Table 3, diet and exercise were chosen to estimate their effect on glycated hemoglobin (HbA1c), some of the diabetic complications (neuropathy, blurred vision, and decrease body weight) and body mass index (BMI) on the participated patients. Here, both diet and exercise give a good effect on HbA1c in spite of non-significance difference is observed and the best effect observed when both diet and exercise is applied (Figures 1 and 2).

Table 2 Demographic data of patients participated in this study

Parameter	Type of DM	
	DM1	DM2
Age	35.1 ± 16.65 (18)	53.37 ± 11.4 (88)
Gender	14 (female)	47 (female)
	4 (male)	41 (male)
BMI*	23.9 ± 5.84	31.17 ± 6.54
Duration of DM*	12.19 ± 8.36	5.74 ± 3.49
HbA1C%*	8.37 ± 2.03	8.17 ± 1.67
Smoker	0	10
Alcoholic	0	1

\*BMI: body mass index which measured by weight/(height)<sup>2</sup>; Duration measured by years; DM: Diabetes mellitus; HbA1C: Glycated hemoglobin

Significance effect of both diet and exercise on neuropathy involved blurred vision and decrease body weight (1.88%, 0.94%, and 1.88%), respectively. BMI, when a healthy diet and exercise were applied it showed a decrease (26.68) if compared to that of diet and exercise alone (30.9 and 28.94) respectively. The p-value shows the non-significant difference (0.43) (Figure 3).

Table 3 Estimate the effect of lifestyle (diet and exercise) on Hba1c% and complications (neuropathy, blurred vision, and a decrease in the body weight)

Parameter	Factor				p-value
	Diet	Exercise	Both	None	
HbA1c	8.33 ± 1.93 (27)	8.23 ± 1.42 (15)	7.58 ± 1.24 (6)	8.27 ± 1.81 (6)	0.790*
Complication-neuropathy	10.37% (11)	7.54% (8)	1.88% (2)	26.41% (28)	0.017**
Blurred vision	14.15% (15)	7.54% (8)	0.94% (1)	27.35% (29)	0.300*
Decreased body weight	12.26% (13)	7.54% (8)	1.88% (2)	30.18% (32)	0.020**
BMI (kg/m <sup>2</sup> )	30.90 ± 7.79 (20)	28.94 ± 5.25 (15)	26.68 ± 4.17 (6)	29.38 ± 7.00 (57)	0.430*

\* Non-significance different between means, p>0.05, \*\*significance different when p<0.05

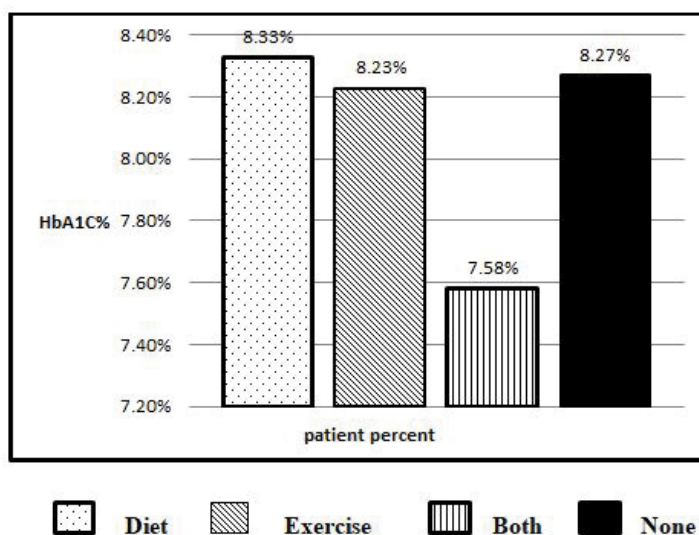


Figure 1 Estimate of diet and exercise on HbA1c

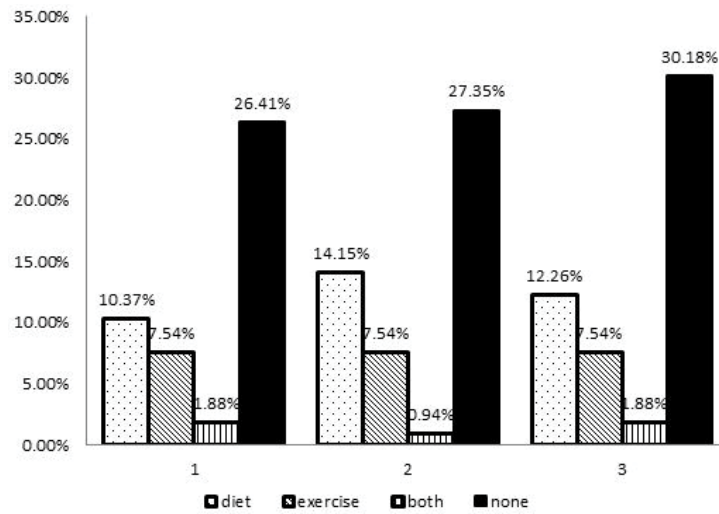


Figure 2 Estimate of lifestyle on complication incidence

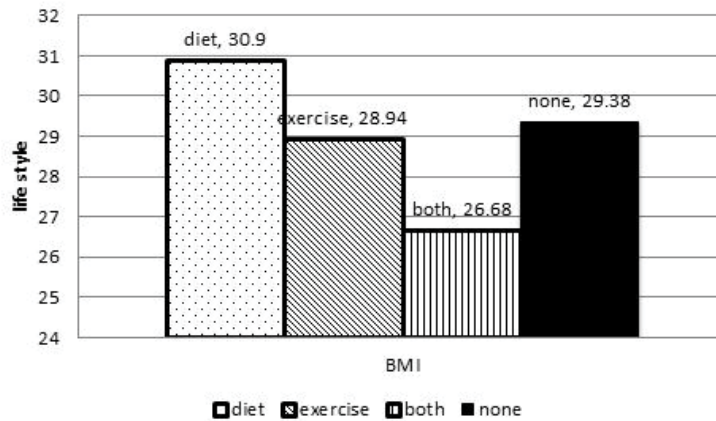


Figure 3 Estimate of lifestyle on BMI

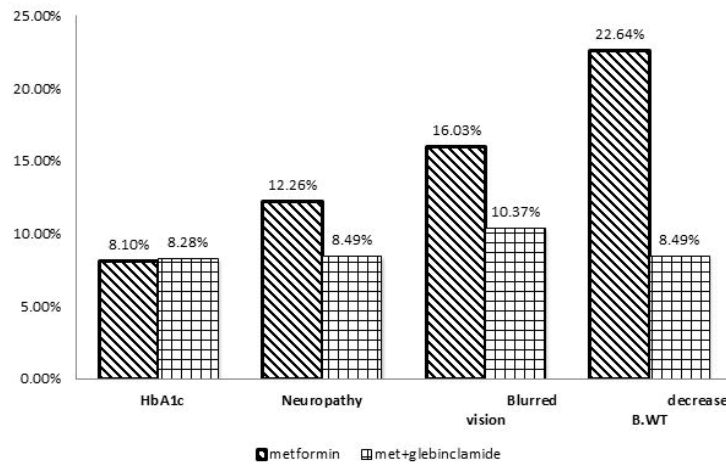
Table 4 estimates the effect of metformin alone and as a combination with glibenclamide on HbA1c and on diabetic complications.

Table 4 Estimate the Effect of metformin and (metformin+glibenclamide) on Hba1c% and complications (neuropathy, blurred vision, and a decrease in the body weight)

Parameter	Drug		p-value
	Metformin	Metformin+Glibenclamide	
HbA1c	8.1 ± 1.6 (48)	8.28 ± 2.1 (20)	0.510*
Complications-neuropathy	12.26% (13)	8.49% (9)	0.002**
Blurred vision	16.03% (17)	10.37% (11)	0.034**
Decreased body weight	22.64% (24)	8.49% (9)	0.054**

\*Non-significant if p>0.05, \*\*Significant if p<0.05

HbA1c level shows the non-significance difference between metformin-treated patients and metformin+glibenclamide treated patients. This may be related to the difference in a number of treated groups. Diabetic complications show a decrease in their incidence if both diet and exercise are followed by the patients. About 12.26%, 16.03%, and 22.64% are percents of neuropathy, blurred vision and decrease body weight, respectively if the drug that is used for DM treatment is metformin, in comparison with 8.49%, 10.37% and 8.49% are percents of neuropathy, blurred vision and decrease body weight, respectively which are complications if drug combination is used. As seen in the table, a combination of medications gives a significant decrease in the appearance of diabetic complication (neuropathy, blurred vision, and decrease body weight) when compared to metformin only. From this, to get the best result in diabetic patient health, a combination of medication is preferred (Figure 4).



**Figure 4** Estimate the effect of metformin and metformin+glibenclamide on the HbA1c level and complications incidence

## DISCUSSION

Present study enrolled 106 patients complaining from diabetes mellitus, 61 female (14 suffered from DM 1 and 47 suffered from DM 2) and 45 male (4 has DM 1 and 41 has DM 2) with a mean age (35.1%) had DM 1 and (53.37%) had DM 2. Mean BMI was (23.9 kg/m<sup>2</sup>) for DMI and (31.17 kg/m<sup>2</sup>) for DMII patients. Table 2 showed that 23.9% is the mean duration of DM 1, while 5.47% is related to DM 2. This high difference in this value related to that DM 1 affect people who are less than 35 years old and people with DM 1 with a mean age was 35.1% and this speech is also applicable for patients with DM 2. Table 3 also showed HbA1c in which its values were high in both DM 1 and DM 2 patients (8.37% and 8.17%, respectively). Good controlling for diabetes and tight glyceimic control aid in lowering HbA1c% and reaching it near normal values.

Table 2 showed the relationship between patients' lifestyle (if they were following specific diet regimen or exercise program) and the rate of HbA1c and complication incidence (neuropathy and blurred vision were taken because they are high incidence among patients included in the study). The table explained the effect of diet, exercise, both of them or none on HbA1c%, which was (8.33%, 8.23%, 7.58%, and 8.27%, respectively). Both diet and exercise give a good result on the HbA1c level. So, diabetes patients must encourage continuing on good diet regimen and regular exercise schedule.

In the same table, the lifestyle affects the incidence of some diabetic complications (neuropathy and blurred vision). There is a high rate of their occurrence if the patient was not following any regimen for diet or exercise (26.41% of neuropathy and 27.35% for blurred vision). While 1.88% and 0.94% are the incidences of neuropathy and blurred vision if the patient follows both diet and exercise programs. This result put in mind how the effectiveness of a good lifestyle on the percent of diabetic complications.

BMI of diabetic patients was measured and a relation was made between BMI and if the patients follow diet or exercise program. The average of BMI was overweight if the patient follows a diet regimen while is consider healthy if the patient follows both diet and exercise regimen. From the results that are listed in Table 2, shows the importance of taking a healthy diet and continues on exercise on several factors of the human body. Type of eating is very important in controlling diabetes and prevents disease development and the important aim of good diet regimen is to reduce body fat. This gives a benefit in reducing BMI and helping in control diabetes [19].

Table 3 showed the effect of treatment use on HbA1c% and percent of diabetic complication incidence. In our data, almost all patients were using metformin only as an oral treatment for diabetes (48 patients) while 20 patients were using metformin+glibenclamide. Other patients were using metformin+glimepiride, others were using sitagliptin but small number size make us not included in this comparison. HbA1c% values were not different in high percentage. On the other hand, there is a difference in the percent of patients receiving metformin and who were receiving

combination in the incidence of neuropathy and blurred vision. This may be due to the good glycemic control which results in a decreased incidence of complications. Combination of treatment (by adding antidiabetic agent into metformin therapy) give good outcome on HbA1c, blood pressure, body weight (either decrease or increase depends on the adding agent) and this will give a good effect on the disease prognosis [20].

Therefore, diabetes patients should be instructed about their disease and what complications on short term and long term period that they may face if not controlled their glycemic state. Also, all medical team members should participate in this program to get the good result about health care which will reflect its outcome on whole society [21].

### CONCLUSION

Diabetes patients have a chronic disease, which requires continuous follow-up and healthy diet and activities. Good lifestyle and the combination of metformin and glibenclamide give a good prognosis on HbA1c, the incidence of complications and on BMI. Thus, a good quality of life can be obtained by these patients.

### DECLARATIONS

#### Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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