

Effect of Drugs and Combination of Diets with Exercise on Biochemical Parameters in Patients with Type 2 Diabetes Mellitus in Barishal, Bangladesh: A Follow up Study

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Abstract: Diabetes Mellitus is a chronic metabolic disorder associated with an increased rate of glucose which can be reduced by diets, drugs, lifestyle changes and physical activity. The present study aimed to investigate the comparison of the effectiveness of drugs and combination of diets with exercise on biochemical parameters of Type 2 Diabetes mellitus patients. A follow up study of 150 diabetes patient's biochemical test >30 years of age were conducted in two phages before and after three months from Diabetes Hospital, Barishal. The investigator categorized two groups of diabetes patients where intervention of diets with exercise was given to 75 respondents and on the other hand 75 respondents by drugs to find out which intervention was more effective. This study found the incidence of reduced blood glucose from 50% to 13.33% by diets with exercise and 50% to 10.67% by drugs during fasting after three months of intervention. After 2 hours eating, blood glucose reduced to 14% and 18% respectively. Analyst established diets with exercise and drugs both had a great effect on fasting glucose, after two hours glucose and serum creatinine which was statistically significant between two phages of same respondents ($P < .05$). Drugs over fasting glucose, after 2 hours glucose and serum creatinine were statistically significant. Diets with exercise over fasting glucose, after 2 hours glucose, LDL and serum creatinine were also highly significant. Combination of diets and physical activity targeting this factor has proven to be superior to conventional drug use for reducing blood glucose of diabetic patients.

Keywords: Effect, Drugs, Diets, Physical Exercise, Biochemical Parameters and Type 2 Diabetes Mellitus Patients

1. Introduction

Diabetes Mellitus is a chronic metabolic disorder that prevents the body to utilize glucose completely or partially with an identified increased rate of glucose in blood after execution of proper biochemical test which can be controlled by diets, drugs, lifestyle changes and physical activity [1]. It is a metabolic disorder characterized by chronic hyperglycemia with disturbances of carbohydrates, fat and protein metabolism that prevents the body to utilize glucose

completely or partially [2]. The prevalence of Type 2 diabetes mellitus is threatening the global health showing worrying indication due to ageing of the population, urbanization and physical inactivity [3-4]. It increases healthcare use and expenditure and imposes a huge economic burden on the healthcare systems [5]. Moreover, the socio-economic status of all income level countries in both urban and rural populations are affected adversely [6].

It was estimated that in 2014 there were approximately 387 million individuals with the type 2 diabetes mellitus. Despite the fact, this number is likely to double by 2035 [7].

Among them the number of adults with type 2 diabetes mellitus will be more than 8 million by the year 2030 [8]. On the other hand, by 2013 in Bangladesh diabetes percentage increased from 4.5% to 35%. The International Diabetes Federation revealed that 7.1 million people were suffering from type 2 diabetes and almost an equal number with undetected diabetes in Bangladesh. This number was estimated to double by 2025 [5]. Out of this 90% of people having non-insulin dependent Type 2 Diabetes Mellitus, while remaining 10% having insulin dependent Type 1 Diabetes Mellitus [9]. Although, prevalence of Type 2 diabetes is increasing in Bangladesh in both urban and rural areas but rapid urbanization with sedentary lifestyle, high calorie intake and lack of physical exercise is the associated factor for Type 2 diabetes mellitus [5, 10].

Although there is no treatment to cure type 2 diabetes mellitus but it can be controlled by diets, drugs and physical activity [11]. Evidence from previous study showed diets can control almost 62% of diabetes condition and the effect of drugs minimizes 45% and 60% respectively [5, 12, 13]. Drug use helps to combine with receptor protein on pancreatic β -cells to stimulate insulin release and control glucose in blood quickly [14]. Moreover, most patients prefer oral medication along with physical activity rather than diets and lifestyle changes [15]. Though drug use daily provide appropriate glycemic control but it also affects adversely causing the weight gain [16, 17]. Worldwide approximately 50% patients were treated with diets including lifestyle changes like regular physical exercise, 20-30% patients were prescribed antibiotics and rest 20-30% patients with insulin. Therefore, combination of diets and physical exercise improved physical function by controlling the blood glucose more effectively [18, 19].

Although, Type 2 Diabetes Mellitus scenario in Bangladesh is going to take a monster shape but the different study extracted a follow up report with only one intervention either by drugs nor diets and physical exercise. Published reports were lacking in finding the more effective intervention to reduce the blood glucose of diabetes patients. The study is of existential value because there are little study ever like ours carried out in Bangladesh previously. Therefore the present study was designed to investigate the comparison of the effectiveness of drug and combination of diets with exercise on serum glucose (fasting and also after 2 Hrs.), Cholesterol, High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Serum creatinine, Serum Glutamic Pyruvic Transaminase (SGPT).

2. Materials and Methods

2.1. Study Setting

The Study was conducted in Diabetes and General Hospital of Diabetes situated in Barishal town. Total population of Barishal was 3, 39,308 as per census of 2011

[20]. Among the population 11.6% were suffering from type 2 diabetes [21]. People from all (lower and upper) classes' socioeconomic condition attend this hospital for biochemical tests and receives doctor supervision. Therefore, the researcher considered this hospital as a representative of study population.

2.2. Study Design

This was a follow up study which was conducted in diabetes hospital during July-August 2019 to obtain the biochemical tests results of 150 diabetes patients >30 years of age having type 2 diabetes mellitus in 1st phage. The inclusion criteria was to take the data of patients >30 years of age by excluding pregnant mother. Moreover, presence of diseases other than diabetes were also excluded. Diabetic patients received the intervention of drug medication and combination of diets with exercise in 1st phage. Data of same 150 diabetic patients test results were collected in the 2nd phage by December 2019-January 2020 after three months of intervention. Categorization of two groups of diabetes patients where intervention of diets with physical exercise was given to 75 respondents and on the other hand 74 respondents by drugs to find out the more effective intervention between the two. The minimum required sample size was calculated by using single population proportion formula $n_0 = z^2 pq / e^2$, where n_0 =the required sample size, z =standard normal deviate usually set at 1.96, which corresponds to the 95% confidence level, p =the estimated proportion of diabetes patients in Barishal division was 11.6% [21], $q=1-p$; and e =desired level of precision 0.05. This yielded a sample size of 157.

2.3. Determination of Biochemical Parameters

The estimation glucose level during fasting were determined by the conventional technique of reduction method in the laboratory of Barishal Diabetes Hospital, where blood glucose were measured in plasma by direct reading electrode system in mmol/kg water, e.g. plasma glucose concentration and after 2 hours eating glucose were inspected by glucose tolerance test. Adults were given a drink containing 75 g of glucose after two hours of fasting. Timing was begun when the patient begins to drink the glucose solution. Blood samples were obtained every 30 minutes for 2 hours [22]. Cholesterol, LDL and HDL were analyzed in Roche Diagnostics which was a cholesterol high performance reagent. On the other hand triglycerides were analyzed enzymatically simultaneously with cholesterol using reagent from the same manufacturer. The investigator found serum creatinine as an indicator of kidney by Jaffe's reaction where creatinine and picric acid react in alkaline medium forming complex to indicate the presence of serum creatinine [23]. Moreover, serum glutamic-pyruvic transaminase (SGPT) was determined by alanine transaminase test to check the effect of it in liver.

2.4. Diets

Table 1. Food Groups Suggested For the Diabetic Patients.

Sl. No.	Food Group	Food Items
1	Cereals	Rice, Bread, Potato, Sugar, Flatten rice, Puff rice, Semolina, Unripe Banana, Noodles, Corn, Sweet Potato etc
2	Meat & Fish	Small fish, Catfish, Horn fish, Prawn, Ruhi fish, Chicken, Beef, Egg, Milk and milk products etc.
3	Dark green Vegetable	Spinach, Gard leaf, Juite leaf, Colossian leaf, kolmi leaf, unripe papaya, cataract etc.
4	Legumes	Mug dal, musur dal, khesari dal, buter dal, maskolai dal, peas, beans etc.
5	Nuts & Oils	Cina badam, kat badam, til, sorisa, kalo jira, pesta badam, kaju badam, sun flower seed, etc.
6	Other vegetables	Brinjal, cabbage, coli flower, mula, lal sakh, chal kumra, deros, cucumber, beans etc.
7	Other fruits	Peyara, boroi, kul, jam, anaros, amloki, chalta, angur, bedana, anar etc.

*The Patients should take at least 4/4+ food groups daily to meet up the daily needs of 24 hrs.

2.5. Physical Exercise

Regular physical exercise for 30 minutes/day, 5 days per week was highly recommended in this study which will ultimately improve insulin sensitivity, glycemic control, lipid profile, blood pressure, fibrinolysis, weight loss and quality of life and self-esteem [24]. The Suggested physical exercise were as follows:

- 1) Walking/ by-cycling if the patients able to move (outdoors).
- 2) Arm Jumping along with toes (indoors).
- 3) Side body reach (indoors).

- 4) Back Stroke of hands by opening up the shoulder (indoors).
- 5) Side toe moving along with hands (indoors).
- 6) Single toe twisting again and again for leg muscle by having support to chair by hands (indoors).
- 7) Sitting and standing randomly in chairs (indoors).

2.6. Drug Use

The different types of drugs which was used for controlling diabetes their names and functions were as follows [25]:

Table 2. Drugs Suggested For the Diabetic Patients

Serial No:	Drugs Names	Functions
a.	Glybenclamide, glipizide, glicazide, repaglinide, nateglinide	Increases insulin secretion.
b.	Metmorfin, Paoglitazon	Increases the working capacity of insulin.
c.	Acarose	Resist the glucose absorption in the intestine.
d.	Sitagliptin, Vindagliptin	Increases insulin secretion and protect the human cells.

2.7. Data Collection Procedure

The questionnaire was furnished according to the objectives and the report of biochemical test results. Data were collected before and after three months of biochemical test which includes age, fasting glucose, after 2hrs glucose, cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL), pyruvic transaminase (SGPT), Serum Creatinine, treatment (Drugs and Diets including physical exercise) during three month. The biochemical test were done by the medical assistant of Diabetes hospital according to the regular basis per day. The report were published by the Diabetes hospital and after the publication the data were collected from chief secretary office.

2.8. Ethical Approval

All study procedures were carried out following the guidelines of the Helsinki Declaration, 1975. Written ethical approval was obtained from the Research Ethical Committee, Department of Environmental Sanitation, Patuakhali Science and Technology University (Ref. ENS/REC/2019/01). The chief Secretary of the Hospital was informed with written application for the collection of the data so that the respondent

co-operate with us and the secretary announced to help us in this regard. The respondents were also assured about the confidentiality and anonymity of the data.

2.9. Statistical Analysis

Collected data were scrutinized and summarized for the purpose of tabulation using the Statistical Package for Social Sciences (SPSS) version 20. Statistical analysis was used to show the demographic data. Effect of drugs and also diets with physical exercise on biochemical parameters were shown by ANCOVA, One Way ANOVA, and Independent T Test.

3. Results

The table 3 provides the salient features of our study which indicates the biochemical parameters of same diabetes patients after three month of intervention by drugs and diets with physical exercise. Collection of both tests results before and after three months of intervention explored glucose in blood during fasting was decreased from 50% to 13.33% by diets with exercise and 50% to 10.67% by drugs during fasting after three months of intervention. After 2 hours eating, blood glucose reduced to 14% and 18% respectively. Moreover, Cholesterol percentage decreased from 16.7% to

10%, Triglycerides 28% to 8.7%, LDL 48% to 13.3%, HDL from 41.3% to 32% respectively.
17.3% to 10.7%, serum creatinine 42.7% to 24% and SGPT

Table 3. Characteristics of Diabetes Patients Test Results before and after Three Months of Medication by Drugs and Combination of Diets with Exercise.

Patients Information	Patients (Before Three Months)		Patients (After Three Months)	
Fasting Glucose	Numbers	Values	Numbers	Values
Diabetes (≥ 7.0 mmol/l)	150	100%	36	24%
Diets with exercise	75	50%	20	13.33%
Drugs	75	50%	16	10.67%
After 2Hrs Glucose				
Diabetes (≥ 11.1 mmol/l)	150	100%	48	32%
Diets with exercise	75	50%	21	14%
Drugs	75	50%	27	18%
Cholesterol				
Normal (≤ 200 mg/dl)	125	83.3%	35	90%
Abnormal (≥ 200 mg/dl)	25	16.7%	15	10%
Triglycerides				
Normal (≤ 150 mg/dl)	70	46.7%	132	88%
High Triglycerides (150-200 mg/dl)	38	25.3%	05	3.3%
Abnormal (≥ 200 mg/dl)	42	28%	13	8.7%
LDL				
Normal (≤ 130 mg/dl)	78	52%	120	86.7%
Abnormal (≥ 150 mg/dl)	72	48%	30	13.3%
HDL				
Normal (≥ 40 mg/dl)	124	82.7%	134	89.3%
Abnormal (≤ 40 mg/dl)	26	17.3%	16	10.7%
Serum Creatinine				
Normal (≤ 1.2 mg/dl)	86	57.3%	114	76%
Abnormal (≥ 1.2 mg/dl)	64	42.7%	36	24%
SGPT				
Normal (≤ 40 U/L)	88	58.7%	102	68%
Abnormal (≥ 40 U/L)	62	41.3%	48	32%

*All Parameters are expressed in percentage to show the decrease of biochemical parameters by the intervention of drugs and diets along with exercise individually.

Table 4. Comparison between Diabetes Patients before (1st Phage) and after Three Months (2nd Phage) of Biochemical Test in presence of Covariate Drugs Given to the Patients.

Patients Information	Patients (Before Three Months) 1 st Phage	Patients (After Three Months) 2 nd Phage	P-Value
Fasting Glucose (mmol/l)	10.04 \pm 2.98	7.38 \pm 2.72	.036
After 2Hrs Glucose (mmol/l)	14.10 \pm 4.62	12.90 \pm 3.92	.047
Cholesterol (mg/dl)	208.56 \pm 26.40	197.87 \pm 34.17	.636
LDL (mg/dl)	144.91 \pm 45.41	134.64 \pm 54.08	.137
HDL (mg/dl)	42.87 \pm 12.64	41.68 \pm 10.93	.530
Serum Creatinine (mg/dl)	0.94 \pm 0.22	0.88 \pm 0.18	.038
SGPT (U/L)	41.07 \pm 14.15	33.95 \pm 6.42	.490

* mean \pm SD units (blood glucose-mmol/l, cholesterol-mg/dl, LDL/HDL/S. creatinine-mg/dl, SGPT-U/L)

Bolded *Italic* values indicate statistical significance $p < 0.05$

Table 5. Comparison between Diabetes Patients before (1st Phage) and after Three Months (2nd Phage) of Biochemical Test in presence of Covariate Diets with Exercise Given to the Patients.

Patients Information	Patients (Before Three Months) 1 st Phage	Patients (After Three Months) 2 nd Phage	P-Value
Fasting Glucose (mmol/l)	10.82 \pm 3.08	7.08 \pm 2.99	.008
After 2Hrs Glucose (mmol/l)	13.51 \pm 4.31	11.01 \pm 4.15	.000
Cholesterol (mg/dl)	203.21 \pm 30.83	172.84 \pm 31.35	.803
LDL (mg/dl)	139.77 \pm 50.04	118.27 \pm 51.87	.456
HDL (mg/dl)	42.27 \pm 11.59	52.54 \pm 12.11	.581
Serum Creatinine (mg/dl)	0.91 \pm 0.20	0.90 \pm 0.20	.000
SGPT (U/L)	37.51 \pm 11.52	36.86 \pm 6.66	.000

* mean \pm SD units (blood glucose-mmol/l, cholesterol, LDL/HDL/S. creatinine-mg/dl, SGPT-U/L)

Bolded *Italic* values indicate statistical significance $p < 0.05$

Table 6. Comparison of their Mean Along with the Different Subjects to Test the Significant Level.

Variables	Mean \pm Std. Deviation	P-value
Drugs over Fasting Glucose		
Insulin	1.68 \pm 0.92	.000 ^a
Antibiotics	2.49 \pm 0.85	
Both	2.95 \pm 0.21	
Drugs over glucose After 2Hrs		
Insulin	1.88 \pm 0.95	.000 ^a
Antibiotics	2.52 \pm 0.84	
Both	3.00 \pm 0.00	
Drugs over Serum Creatinine		
Normal (\leq 1.2 mg/dl)	1.38 \pm 0.54	.004 ^b
Abnormal (\geq 1.2 mg/dl)	1.59 \pm 0.74	
Drugs over SGPT		
Normal (\leq 40 U/L)	1.45 \pm 0.62	.847 ^b
Abnormal (\geq 40 U/L)	1.47 \pm 0.64	
Diets over Fasting glucose		
Maintained	1.23 \pm 0.63	.000 ^b
Not Maintained	2.40 \pm 0.89	
Diets over glucose after 2Hrs		
Maintained	1.58 \pm 0.90	.000 ^b
Not Maintained	2.43 \pm 0.86	
Diets over LDL		
Maintained	1.22 \pm 0.41	.003 ^b
Not Maintained	1.40 \pm 0.49	
Diets over HDL		
Maintained	1.15 \pm 0.36	.686 ^b
Not Maintained	1.17 \pm 0.37	
Diets over Serum Creatinine		
Maintained	1.09 \pm 0.29	0.000 ^b
Not Maintained	1.51 \pm 0.50	

Note: ^aP value for One way ANOVA Test^bP value for Independent T Test

The table 4 exhibits comparison of diabetes patients before and after Three Months of Biochemical Test in presence of Covariate Drugs given to the patients and we had come to the conclusion that the drugs had an effect on fasting glucose, after two hours glucose and serum creatinine respectively which showed a statistically significant results $P < .05$ but other parameter were not statistically significant.

The table 5 displays comparison of diabetes patients before and after three months of biochemical test in presence of Covariate Diets with exercise given to the patients and we had come to the conclusion that the diets had a great effect on fasting glucose, after two hours glucose, serum creatinine and SGPT respectively which showed a statistically significant results $P < .05$ but other parameter were not statistically significant.

The mean value of different subject comparison with different test variables and dependent variables which was done by Independent T test and one way ANOVA test along with their P values. Here, drugs over fasting glucose, after 2 hours glucose and serum creatinine were statistically significant $P < .05$ but over other parameter it was not. Again, diets with exercise over fasting glucose, after 2 hours glucose, LDL and serum creatinine were also statistically significant $P < .05$ (Table 6).

4. Discussion

This interventional study explored the incidence of reduced

blood glucose from 50% to 13.33% by diets with exercise and 50% to 10.67% by drugs during fasting after three months of intervention. After 2 hours eating, blood glucose reduced to 14% and 18% respectively. The study conducted by Gunngu revealed the diabetes condition had been decreased from 80.4% to 21% fasting and 86% to 37% after 2 hours of eating in Malaysia due to age, sex and ethnicity where blood glucose decreases after intervention which was consistent with this study [15]. Another study conducted by Akter and Xu et al revealed the diabetes condition changed in China from 89.1% to 10% due to diets and drugs maintaining [21, 26]. Drugs used for controlling diabetes worked as reducing the amount of glucose released by liver and but diets with physical exercise burn calories and uptake glucose from blood to the muscle and fat cells [5]. Finding of this study displayed cholesterol level along with Low density Lipoprotein (LDL) and High Density Lipoprotein (HDL) level improved automatically, diabetes condition often lower the cholesterol level by misbalancing LDL and HDL level. So, in our study diabetes condition had been controlled by medication and the parameters of cholesterol, LDL and HDL graduated to normal [27].

Moreover, the percentage of serum creatinine and Serum Glutamic Pyruvic Transaminase (SGPT) came back to normal due to regular proper diets maintained during three months of medication. The kidney functioned properly for which the Serum Glutamic Pyruvic Transaminase (SGPT) percentage became normal in the blood [7, 28]. Nevertheless, the proper

diets and drugs could maintain all the parameters of biochemical test which will fall back the reading to normal [29].

Instantaneously effect of diets with exercise and drugs on fasting glucose and after 2 hours eating, of the same respondents before and after three months of medication were highly significant. The study of Wong done in Singapore exhibited most patients prefer oral medication then diets along with which increased drug resistance and made the patients permanently dependent on drugs [30-31]. Although, proper counselling on diets and physical activity had a great importance in a regular basis to overcome the situation revealed in the study of Malaysia [32] conducted by Shelina and Rozali. In addition, diets and drug on serum creatinine had a significant observation which was following the study of Nicolas UK [33] as a result the glucose in the blood will be shown normal due to proper medication by diets and drugs during three month and that's why the activity of the kidney will be as usual and the percentage of enzyme Serum Glutamic Pyruvic Transaminase (SGPT) will be normal in the blood which will ultimately reduce the serum creatinine level due to the proper activity of the kidney [34].

Similarly, our study demonstrated the effect of diets with exercise and drugs over fasting glucose and after 2 hour eating glucose exploring a statistically significant results which was alike result obtained by Wong [30], deriving the condition of awareness of the respondents before and after the medication. Although, the awareness of medication was acceptable after checkup but earlier it was almost unsatisfactory due to the lack of awareness revealed in the study of Rahman and Premkumar [35-36] done in Bangladesh and India respectively. Moreover, diets with exercise and drugs over serum creatinine was also statistically significant which was forensic to the study of in UK, it was maintained due to healthy diets and physical activity along with alternative way of medication by drugs maintained during three month which kept the kidney working well to denote serum creatinine normal [33]. Though awareness build up for both diets with exercise and drugs for controlling diabetes should be made but dependency on drug use could cause drug resistance against Type 2 Diabetes mellitus, focus on diets with physical exercise rather than drug use [37].

Justification and Strength

The present study was not without its limitation. Firstly, the respondent data we had collected was 150, but according to the sample size calculation yield was 157. The condition occurred due to the missing of 7 respondent in the 2nd slot because the patients didn't come for the test that's why we have excluded 7 respondent to make it 150. Secondly, the baseline and follow-up data were collected at an interval of only three months. We were unable to follow up study participants for longer periods because of limited resources. Thirdly, the location for the collection of data was only one hospital, if we could collect the data from different hospital of Barishal, Bangladesh then it could denote the total scenario of the town.

Findings of this study will be helpful for the health promotional authority and national policy maker to take intervention programs on patients having diabetes with proper

diets and physical exercise by minimizing the use of only drugs use to control diabetes and eradicate antibiotic resistance to fulfill sustainable development goals.

5. Conclusion

Nowadays, type 2 diabetes mellitus is an international health burden. After performing our research we can conclude the intervention of diets and physical exercise is more effective than the conventional drugs in case of reducing the blood glucose during fasting and after 2 hours of eating. Appropriate lifestyle changes and diets with physical activity targeting this factor has proven to be superior to drug use for reducing blood glucose of diabetic patients.

6. Recommendation

The present study provides novel benchmark data for other future studies to replicate and extend by enriching this sector. It is possible to show the comparison of the effect of the intervention of drugs solely and the combination of drugs with physical exercise to show the effective intervention by the follow-up study around the different countries of the world. Eventually, it will help to discourage the only drug use and manage this comorbidity.

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