Published by
NIGERIAN SOCIETY OF PHYSICAL SCIENCES
Available online @ https://asr.nsps.org.ng/index.php/asr

African Scientific Reports 2 (2023) 63

African Scientific Reports

Determination of the Potency of Drugs used in Treatment of Type2 Diabete (A Case Study of Taraba State Specialist Hospital Jalingo)

Charity Ebelechukwu Okorie*, Martin Afam Nwaokolo

Department of Mathematics and Statistics, Federal University, Wukari, Nigeria

Abstract

Diabetes is a medical condition in which the body cannot produce enough insulin to process the glucose in the blood. Type 2 diabetes is mostly diagnosed in order adults but it is increasingly seen in children, adolescent and younger adult. It is discovered that the rate at which patients are diagnosed of diabetes has been on the increase despite the series of diabetic drugs that are available. This prompted the researchers to carry out this research so as to determine the potency of drugs used in the treatment of type 2 diabetes. Data were collected from Specialist Hospital, Jalingo Taraba State. The data were used to obtain the relative potency and pooled variance as well as analyzing the potency of the diabetes drug. The result for the relative potency which is > 1 (1.62), means that the test preparation is less potent than the standard test preparation. We also observed that their confidence interval lies between (-12.88,17.05). Analyzing the significance difference between the standard test preparation and the test preparation, using the student t test we obtain calculated t=1.93 and the t value from the table=1.96. We conclude that since t_{cal}= 1.93 <t_{tab}=1.96, we accept $H_{1,}$ and conclude that there is significant difference between Dji and Djk drugs (standard test preparation and test preparation respectively). This means that more effort is needed in the area of research for more diabetic drugs that will be highly effective in the treatment of diabetes.

DOI:10.46481/asr.2023.2.1.63

Keywords: Diabetes, Insulin, Diabetic-drugs, Variance, Potency

Article History :
Received: 29 September 2022
Received in revised form: 06 December 2022
Accepted for publication: 18 December 2022
Published: 21 February 2023

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Communicated by: Tolulope Latunde

*Corresponding author tel. no:
Email address: okoriec636@gmail.com (Charity Ebelechukwu Okorie)

1. Introduction

The term diabetes is the shortened version of the full name diabetes mellitus. Diabetes mellitus is derived from the Greek word *diabetes* meaning siphon - to pass through and the Latin word *mellitus* meaning honeyed or sweet. This is because in diabetes excess sugar is found in blood as well as in the urine [1]. Diabetes mellitus (DM) is defined as a group of metabolic disorders exerting significant pressure on human health worldwide [2]. Diabetes mellitus is a metabolic disorder with characteristics of hyperglycaemia and insufficiency of secretion or action of endogenous insulin [3]. [4]; In their work titled: Recent Trends in Blood Glucose Control Studies" introduced some important mathematical models of glucose insulin metabolism, followed by some representative blood glucose control systems, where most of them use model predictive control as control algorithm, developed to date and discuss their implications in the near future. Mathematical modelling has been used effectively to provide insight about incidence and prevalence of diabetes and help understand factors affecting disease development risk.

[5] formulated a Mathematical model to study the dynamics of diabetes mellitus and its complications in a population. Their model assumption is the constant rate of diabetes person developing complications. Diabetics populations were split into two groups: diabetics with complications and diabetics without complications. The model is a system of ordinary differential equations and the solution of the model was obtained using numerical method. The results show that the incidence of diabetes and occurrence of complications can be controlled with efficient and effective control strategies.

[6], proposed a mathematical model on the dynamics and control of diabetes mellitus and its complications. Their model is an improvement on the work of [7] and it was based on the size of diabetics without complications and diabetics with complications. Their study revealed that diabetes persists but its complications can be controlled. They investigated the sensitivity of each parameter to the model and the results obtained shows that the size of diabetics with complications can be reduced with adequate control measures.

According to [8]; in their work titled "Mathematical model for glucose regulation in the whole-body system" stated that the human body needs continuous and stable glucose supply for maintaining its biological functions. Stable glucose supply comes from the homeostatic regulation of the blood glucose level, which is controlled by various glucose consuming or producing organs. Therefore, it is important to understand the whole-body glucose regulation mechanism.

[9], presented a new mathematical model for Blood Glucose Regulatory System (BGRS). Their result showed that the glucose concentration returns to normal level within a shorter time.

Diabetes has two common classifications namely;

Type 1 Diabetes (T1D), previously called insulin dependent diabetes mellitus (IDDM), or juvenile diabetes, is usually diagnosed in children and young adults. In T1D, the body does not produce insulin, a hormone needed to carry glucose (sugar) from the bloodstream into the cells. Insulin is not produced because the body's immune system attacks insulin-producing cells from the pancreas called beta -cells. Type 1 indicates the processes of beta–cell destruction that may ultimately lead to diabetes mellitus in which "insulin is required for survival. Type 1 includes those cases attributable to an autoimmune process, as well as those with beta– cell destruction and who are prone to ketoacidosis for which neither an aetiology nor a pathogenesis is known. Risk factors for type 1 diabetes are not as well understood as those for type 2 diabetes. Family history is a known risk factor for type 1 diabetes. Other risk factors can include having certain infections or diseases of the pancreas [10].

Different kinds of diabetes can occur, and how people manage the condition depends on the type. Not all forms of diabetes stem from a person being overweight or leading an inactive lifestyle. Some are present from childhood The problem with diabetes is that diabetes often causes mild or no symptoms, until blood sugar levels become extremely high. Undetected/ untreated diabetes causes further complications such as Loss of limbs, vision etc. The effects of diabetes mellitus include long– term damage, dysfunction, and failure of various organs. Diabetes leads to systemic alterations, thereby damaging all parts of the body [11].

[12], stated that between 60% and 70% of people with diabetes have diabetic neuropathy (nerve damage), and feet and legs are most often affected. Nerve damage can cause lose feeling in the feet which can make one to gets cut or blister without knowing. Without treatment, a small sore can become a hard-to-heal infection, that can threaten one's health. Daily foot checks can help to stop these problems in their tracks

[13]. People with diabetes are 2 to 3 times more likely to have depression than people without diabetes. Only 25% to 50% of people with diabetes who have depression get diagnosed and treated.

Diabetes affects nearly 422 million people in the world, some of whom don't even know about the problem. In 90% of cases, diabetes appears when body cells become resistant to normally produced insulin. The estimated worldwide prevalence of diabetes among adults in 2010 was 285 million (6.4%) and this value is predicted to rise to around 439 million (7.7%) by 2030. Specialists say that those who are overweight or obese, don't manage high blood pressure, have high cholesterol levels and are physically inactive, and have dramatically high risks for developing this type 2 diabetes. Diabetes doesn't treat men and women the same. Diabetes increases the risk of heart disease (the most common diabetes complication) by about four times in women but only about two times in men. Women are also at higher risk of other diabetes complications, like blindness [14]

When a person has diabetes, the lack of insulin or the body's inability to use it properly, causes sugar to stay in the blood rather than entering the cells to be used for energy. This excess sugar in the blood results in higher-than-normal blood sugar levels [15].

[16], studied glucose–insulin dynamics in T1D patients using nonlinear ODE and generalized smoothing. They obtained good approximation of global glucose–insulin dynamics and physiologically meaningful parameter estimates.

[17], stated that, to control glucose levels, simple and effective intervention measures like regular exercise, eating healthy, eating on time can turn out to be a large contribution in preventing this chronic disorder diabetes mellitus. Mathematical modelling deals with abundance of literature. These models have provided a simpler way to get proper knowledge of Diabetes dynamics. Several exciting mathematical models including glucose-insulin interaction and epidemiology of diabetes are based upon totally unique aspects of diabetes during the last decades in general.

[18], formulated by first five -order ordinary differential equations that describe glucoregulatory dynamics. They applied the localization of compact invariant sets and Lyapunov's direct methods to obtain their results and then concluded that the model can be used to understand the long-term dynamics of the system.

[19], stated that Mathematical modelling has established itself as a theoretical tool to understand fundamental aspects of a variety of medical-biological phenomena. The predictive power of mathematical models on some chronic conditions has been helpful in its proper prevention, diagnosis, and treatment. Such is the case of the modelling of glycaemic dynamics in type 2 diabetes mellitus (T2DM

[20], proposed the method of Homotopy Perturbation to solve a system of equations of model of diabetes mellitus disease. Analytical solution was obtained, and graphical profile of the solution was shown using Maple software. The results showed that model parameters play a very important role in determining the size of diabetic's population and the number of diabetics with and without complications at time t.

Despite the fact that from the various literature reviewed, it was discovered that diabetes could be controlled with the use of drugs, exercise, good food etc. In order to control diabetes, there are various diabetic drugs which the diabetic patients are exposed to, yet, diabetes has become a deadly disease that affects both young and old. It has taken so many people all over the world to their early grave and has left some in constant pain as a result of disability caused by it. Based on this, we intend to determine the potency of drugs used in the treatment of type 2 diabetes

2. Research Methodology

In this research work, we will determine the potency of the drugs, using the relative potency method, determine the significance difference between the standard test preparation and test preparation. To be able to do these, three standard drugs and three test preparation drugs, administered on 100 diabetic patients were collected from the hospital records at Specialist Hospital, Jalingo Taraba state.

2.1. Relative Potency of the Drugs used in the Treatment of Diabetic Patients

The term relative potency is used to express the biological activity of a sample preparation compared to a standard preparation.

We shall calculate the relative potency of the drugs used in the treatment of diabetes and then compare our results, using the formula below

$$\text{Relative potency} = \frac{D_{ij}}{D_{kj}} \tag{1}$$

where
D_{ij} is standard test preparation
D_{kj} is the treatment test preparation

2.2. Decision rule

If the relative potency is < 1, then it means that test preparation is more potent.
If it is = 1, then the two products produce the same result at the same dose.
If it is > 1, it means that a test preparation is less potent.
We will also calculate the variance of the relative potency, using the pooled variance with this formula

$$Var(S_T^2) = \frac{1}{n_T - 1}[\sum X_T^2 - (\sum X_T)^2] \tag{2}$$

$$Var(S_T^2) = \frac{1}{n_S - 1}[\sum X_S^2 - (\sum X_S)^2]$$

$$S_p^2 = \frac{(n_1 - 1)S_T^2 + (n_2 - 1)S_S^2}{n_T + n_S - 2}$$

S_p^2 is the pooled variance
$S^2 = S_P^2\left(\frac{1}{n_S} + \frac{1}{n_T}\right)$
The variance R,

$$var(R) = \frac{S^2}{Z_1^2}(\frac{1}{N_2} + \frac{R^2}{N_1}) \tag{3}$$

where z is the mean and $R = \frac{\bar{x}_s}{x_t}$
where $\bar{x}_s$ is the mean drugs dosage for standard and $\bar{x}_t$ the mean drugs dosage for treatment.
T test

$$t_{cal} = \frac{\bar{y}_1 - \bar{y}_2}{\sqrt{S_p^2(\frac{1}{n_1} + \frac{1}{n_2})}} \tag{4}$$

Hypothesis

$$H_0 : \mu_1 - \mu_2 = 0$$

$$H_A : \mu_1 - \mu_2 \neq 0$$

Decision rule
Reject H_0 if t_{tab} at $\alpha = 0.05 > t_{cal}$
Confidence interval

$$\bar{y_1} - \bar{y}_2 \pm t_{\frac{\alpha}{2}}, n_1 + n_2 - 2\sqrt{S_p^2(\frac{1}{n_1} + \frac{1}{n_2})} \tag{5}$$

3. Results and presentation

We seek to present the results of the analysis carried out to determine the relative potency of the drugs using the relative potency method and then determine the significance difference between the standard preparation and the test preparation. We also present the descriptive statistics Statistical packages used for running the analyses are Minitab 19.0, E-VIEW and SPSS 21.0. Below are the results and their respective interpretations.

Table 1. Descriptive Statistics

Variable	TotalCount	N	N*	CumN	Percent	CumPct	Mean	SE Mean	TrMean	StDev	Variance
Dij	100	100	0	100	100	100	5.450	0.450	5.000	4.500	20.250
Dkj	100	100	0	100	100	100	3.370	0.982	2.400	9.822	96.478

Variable	CoefVar	Sum	Sum of-Squares	Minimum	Q1	Median	Q3	Maximum	Range	IQR
Dij	82.57	545.000	4975.000	5.000	5.000	5.000	5.000	50.000	45.000	0.000
Dkj	291.46	337.000	10687.000	1.000	1.000	2.000	3.000	100.000	99.000	2.000

Variable	Mode	N for-Mode	Skewness	Kurtosis	MSSD
Dij	5	99	10.00	100.00	10.227
Dkj	2	30	9.81	97.43	49.939

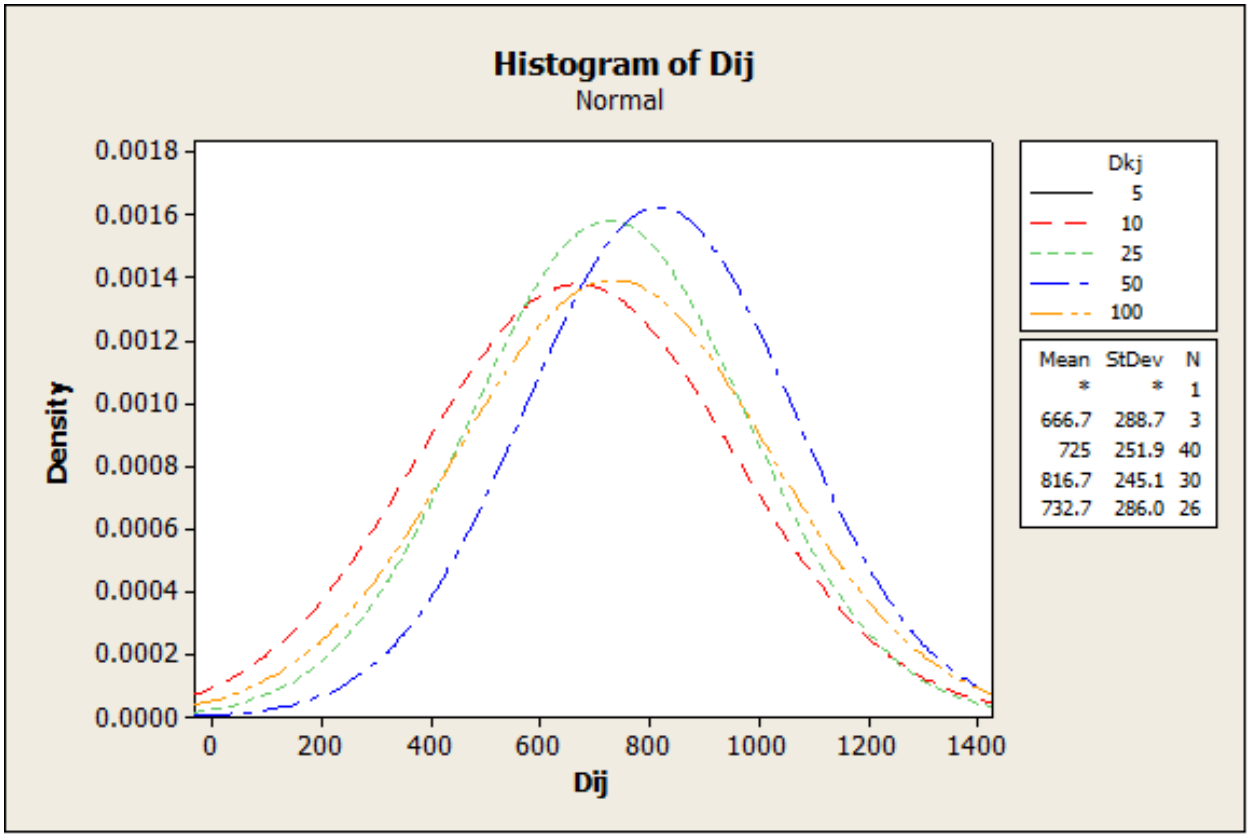

Figure 1. Graph for the standard preparation

3.1. Potency of the drugs used in the treatment of diabetic patient's analysis.

From table 1 above, it shows that the variance and the standard deviation of the standard preparation are 20.250 and 4.500 while the variance and standard deviation of the test preparation are 96.478 and 9.822

Looking at figure1 above, it is observed that the data is normally distributed. This is because of the bell shape which is the curve for normal distribution.

Figure 2 shows that the test preparation is normally distributed.This is because, looking at the graph, we observed

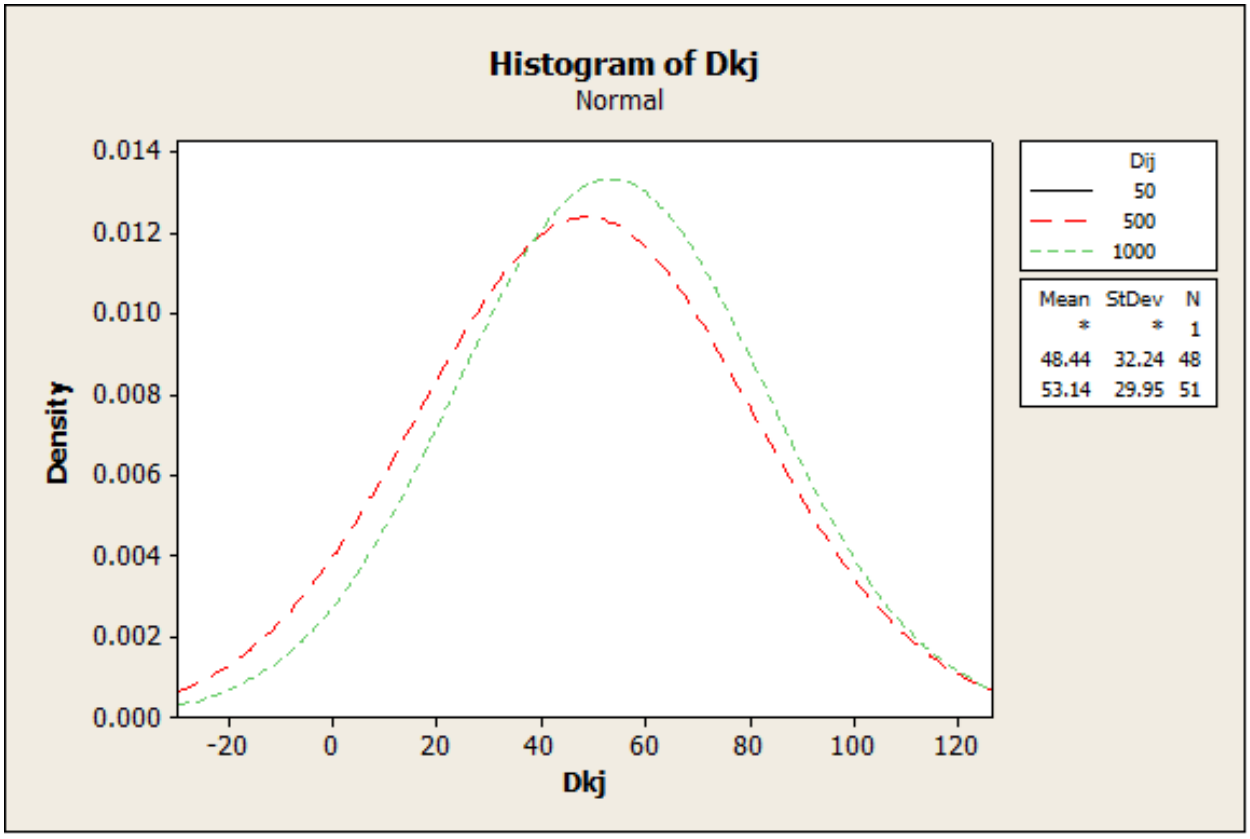

Figure 2. The graph of the test preparation

that it is bell shaped.

3.2. *Relative potency = 1.62*

Decision: since the relative is > 1, it means that the test preparation is less potent.

3.3. *T test calculation*

Using equations 2 and 3 to calculate for the variance R, we have

R = 0.618

$Var(Z_s^2)$ = 2025

$Var(Z_t^2)$ = 96.47

Pooled variance ($S_p{}^2$) = 58.364

Variance (S^2) = 1.167

Then the variance of R

Var (R) = 0.0269

The 95% CI of $R^{\pm} t_{1-\frac{\alpha}{2},198}\sqrt{VarR}$

Tabulated t = $t_{0.975,198}$ = 1.96

T calculated=1.93

Decision rule

Since t_{cal}= 1.93 <t_{tab}=1.96 we accept H_0, and conclude that there is no significant difference between Dji and Djk drugs.

Confidence interval= (-12.88. 17.05)

4. Conclusion

Diabetes is a metabolic disorder that requires attention because, if lest unnoticed, can cause havoc to the life of any human that is affected by the disease. This prompted the researchers to carry out this research. From the analysis and all indices, it can be concluded that there is a significant difference between the standard preparation and the test preparation Also, the result of the relative potency shows that the test preparation is less potent and so such drugs' needs to be improved. In that case diabetic patients should be sensitive to any drug that brings improvement to their health status. By so doing, they will not experience complication as a result of diabetes.

Acknowledgement

We wish to appreciate the referees for the great and wonderful comments which have helped us in improving the work.

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