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ASSESSING THE EFFECTIVENESS OF A NEW DEVELOPMENT INSTRUMENT OF DETECTING BLOOD GLUCOSE AMONG DIABETIC PATIENT: NON-INVASIVE BLOOD GLUCOSE MEASUREMENT TOOL

Yani Sofiani

Universitas Muhammadiyah Jakarta

Abstract

Diabetes mellitus is a major cause of mortality and morbidity in every country including Indonesia. The disease has serious impact to health, socioeconomic and quality of life. The patient can control their blood glucose with correct diet plan, routine activity, obey the treatment, proper skin and foot care, and blood glucose monitoring. The purpose of this study was to determine the accuracy of a new development of non-invasive blood glucose measurement tool. This cross sectional study was used a descriptive correlation design. This research included 188 respondents. The analysis of this study was used Bland Altman test. The result has been shown that a new development of non-invasive blood glucose measurement tool had a similarity with the gold standard blood glucose measurement with R2 repeatability value was 0.163, and the average of discrepancy was 0.00088. This new development of non-invasive blood glucose measurement tool is reliable to be used as blood glucose measurement with blood sugar levels ranging from 72-408. Further test need to conduct to ensure whether this measurement tool can accurately diagnose Diabetes Mellitus (DM).

Keywords: *Diabetes Mellitus, Blood Glucose Monitoring, Near Infrared.*

INTRODUCTION

Diabetes Mellitus (DM) is a chronic disease that is rapidlygrowing nowadays. In 2013, International Diabetes Federation (IDF) data showed that there was more than 382 million of world population ranging from 20 – 79 years old suffering from diabetes, with 83% or 316 million experiencing tolerance disorder toward glucose that was viewed as the beginning stage of diabetes, and there were more than 72 million people were from Asia (19%).

Indonesia is one is a developing country in Southeast Asia nation where there is a changing disease pattern epidemiologically from high infectious diseases to non-communicable diseases, including DM, from 382 million of world population; 8,5 million come from Indonesia. It is the 7th number out of 10 countries which have diabetic patients after China, India, USA, Brazil, Russia and Mexico. IDF, in 2013, estimated that in 2035 Indonesia will on the sixth level of diabetic patient with the number of 14.1 million people. The high number of diabetic patient can increase earlier mortality as well as shorten the life chance of about 7 – 15 years (Franco et al, 2007), improve disability, decrease hope and quality life, lack of human resource, social disorder and loss of national revenue (King, Aubert& Herman, 1998).

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Holt et al (2010) explained that to achieve the glucose level in a normal range, then , the people need lifestyle changing that include consuming nutritious food, doing physical activities (150 minutes/week); applying suggested therapy (Parker, 2008), caring the skin and feet, checking up to a GP regularly (Milchovich and Dunn-long, 2011), minimizing the psychology stress, and controlling the glucose.

The technique of checking the glucose level by Food and Drug Administration (FDA) nowadays is using invasive or minimal invasive method which is using glucometer through injecting the finger to take the blood sample that *in fact* has some weaknesses. Many people do not like to use sharp tool and see the blood, as there is an infectious risk, and can cause the tissue destruction when it is used in a period of time. Besides, the glucometer tool sometimes cannot give a clear description when hypoglycemia or hyperglycemia takes place because of unrecorded measurement (So et al, 2012).

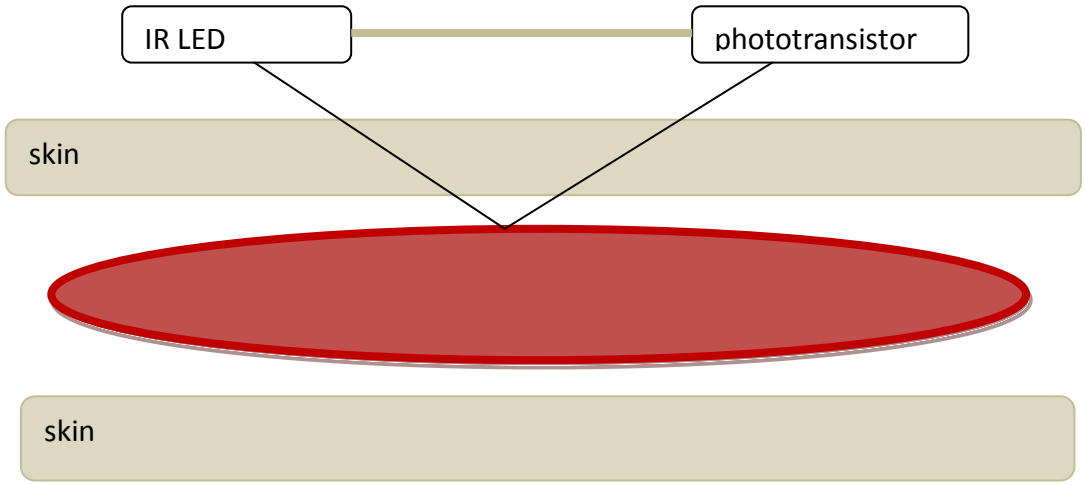
However, since thirty years ago, there has been an effort to overcome the condition to develop blood glucose by using non- invasive methods that one of them is the use of infrared rays which have 700 nm up to 1 mm wave. These infrared rays is invisible light with spectroscope rays, the radiation will come up on the electromagnetic spectrum and the rays will be felt and detected by infrared rays. Infrared rays is divided into three parts; *Near Infrared (NIR) (750 – 1500 nm), Mid Infrared (1500 – 1000 nm), and Far Infrared (10 – 100 nm).* NIR is one of the most usage of optical technic explored as the high penetration to the skin (Carlos and Benhard 2008) and it can be applied around the other parts of body such as finger, palm hand, lower and upper arm, earlobe and neck (Maruo et al, 2003). The result conducted by Yaday, 2014, used NIR LED 940 nm to seven persons showed that the lower voltage the more increase the blood glucose. Meanwhile, the research conducted by Taufiq in 2013 that used LED with 900 – 1000 nm wave, resulted the voltage in the sample of fasting blood glucose was lower than those who took blood glucose after fasting. The other research that was conducted by Sia, 2010, that used LED 1450 E and 2050 P resulted infrared rays with 2050 nm wave in length that is lack sensitive to analyze blood glucose and the length of the wave used have not determined the level of blood glucose certainly. Based on the research finding, the researcher developed the non-invasive detector of blood sugar level tool of near infrared rays with the length of wave of 940 nm.

METHODOLOGY

The research compared two kinds of measurements towards blood glucose level using two methods. The first one is using minimal invasive method and the second one is using non- invasive detector of blood sugar level that the researcher developed. The result of the minimal non-invasive tool is the voltage of readable information on the LCD monitor (conducted the blinding).

The research used *cross sectional design*. It involved 188 respondents who checked blood sugar level at Jakarta Islamic Hospital CempakaPutih. The research was conducted from November 2015 up to March 2016. All of the respondents have signed the informed consent, and the researcherhas got permission to conduct the research at the hospital.

The way how to work the tool. General Description



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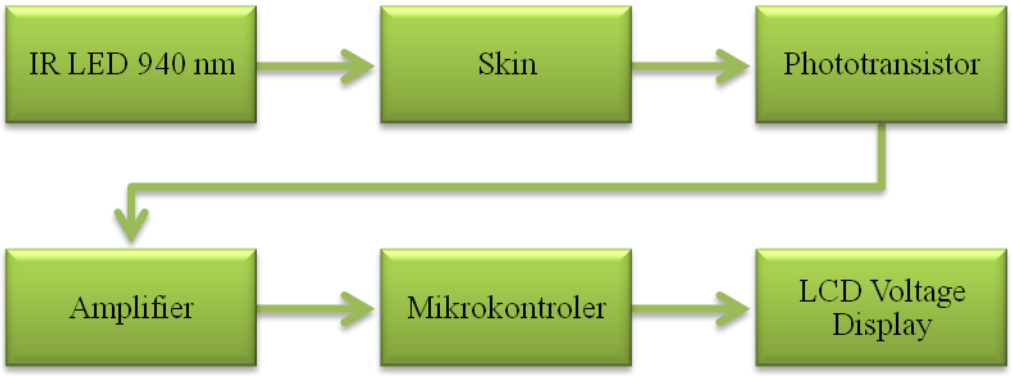
The infra red rays with the length of 940 nm will be transmitted through the skin, that will be reflected by the blood glucose (the length of the blood glucose is between 939 – 236 nm), then, the reflected rays will be received by the detector.

Flowchart of the suite of tool



THE RESEARCH RESULT AND DISCUSSION

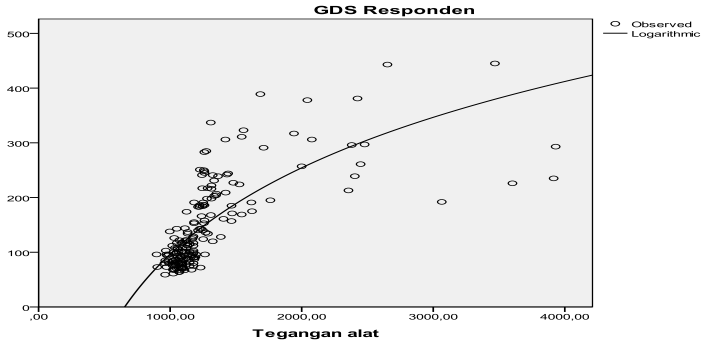
The result of the data processing is taken from the level of blood glucose level and the voltage value of the tool, meanwhile to conduct the test of bland altman is the test of two measurement, therefore the voltage value resulted from the tool analysis to make the blood glucose value is based on the tool. The following is the result of the analysis:

Table 1Correlation Analysis and Respondents' with the voltage value

Variable	r	R^2	Linear Line	p *Value*
Voltage value	0,75	0,56	BG = -1475,852 + (227,622* (Ln*Teganganalat)	0,0005

The statistical test result shows that there is a relationship between blood glucose and voltage value resulted from non-invasive tool.The relationship shows strongly (r=0,75) (Hastono, 2007) and has positive pattern which means that the higher the blood glucose, the higher resulted of voltage value. Determinantcoefficient value is 0,56, means that the resulted voltage by the non-invasive tool is able to predict the blood glucose as 56%.

The linear line resulted from the blood glucose based on the non-invasive tool



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Next reliability test was conducted by Bland Altman method, the result is as follow: The steps of Bland Altman test: Started by the test of One Sample T Test to find out whether thevariable is able to go on to theBland Altman test or not (as the requirement of further test that p *value*> 0,05.

Table 2 Distributionof the difference average of blood glucose and the voltage tool

Variable	Mean	SD	p value	n
difference average of blood glucose	0,0009	53,52	1,000	188

Based on the table 2, it can be seen that the p *value* is 1,000 that means there is no significant difference between blood glucose levels resulted from the tool. This result has fulfilled the requirement to have Bland Altman test. The test result of Bland Altman is as follow:

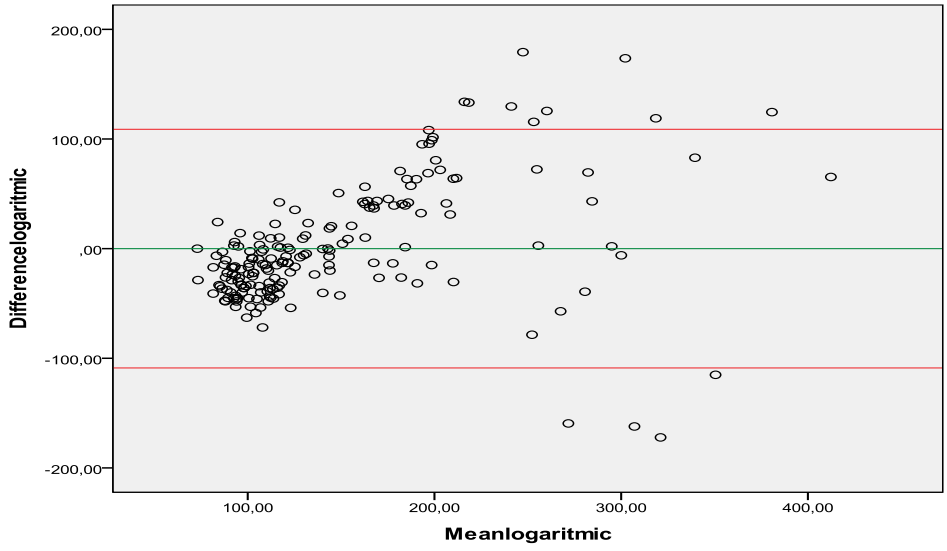
Table 3The regression analysis of difference of the blood glucose and the voltage tool

Variable	R	R2repetability	p value	Mean difference
the difference average	0,404	0,163	0,0005	0,00088

Table 3 shows that there is a relationship between the difference and the average of two measurements (p *value* 0,0005), the relationship is modest (r = 0,404), from the result of the analysis, it shows that the value of Repeatability is 0,163. It means that the two measurements have the same measurement result (the closer the value of 0the more similar the test are conducted),with the average difference of 0,00088.

Graph 1

Scatter diagram of the difference and the average of two measurements of blood glucose level



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The reliability test of non-invasive tool was conducted and the result was as follow:

Table 4 .Reliability test of non-invasive tool of blood glucose tool

Variable	r table	Alpha Cronbach's	GDS Prediction			
			Minimal	Maximal	Mean	SD
non invasive tool	0,169	0,837	72	408	147	61

Table 4 the reliability test result shows the value of Alpha Cronbach's is bigger than*r table*that can be concluded that non-invasive of glucose blood tool is reliable, with the prediction of blood between 72 – 408.

CONCLUSION

The detector of blood glucose tool that is being developed is trusted to detect the blood glucose level that is predicted between 72 – 408.

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