Accuracy of Hemoglobin Measurement Using Noninvasive Oxyhemoglobinometer in Pregnant Women at Health Center of Bantul District

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Abstrak
Anemia defisiensi besi merupakan masalah kesehatan yang utama pada wanita hamil dan mempunyai efek yang merugikan pada ibu dan bayi baru lahir. Mengingat konsekuensi anemia selama kehamilan, diagnosis yang mudah dan akurat merupakan hal penting. Selama ini pengukuran kadar hemoglobin dengan cara melibatkan pengambilan darah secara invasif, sehingga menimbulkan ketidaknyamanan dan trauma tersendiri bagi pasien. Oleh karena itu, diperlukan alat ukur kadar hemoglobin dengan menggunakan sistem oksimeter secara noninvasif, di mana pasien akan terbebas dari rasa nyeri dengan risiko minimal mengalami infeksi dan memungkinkan untuk pemantauan pasien dalam keadaan kritis. Tujuan penelitian ini untuk membandingkan hasil kadar hemoglobin menggunakan alat oksihemoglobinometer dengan automated hematology analyzer sehingga diketahui perbedaan hasil, diperoleh nilai sensitivitas, spesifisitas, nilai duga positif, nilai duga negatif, rasio kemungkinan positif, rasio kemungkinan negatif, dan akurasi.

Penelitian ini merupakan uji diagnostik dengan desain cross sectional. Tujuh puluh delapan ibu hamil normal yang memeriksakan kehamilannya di Puskesmas wilayah Kabupaten Bantul, masing-masing dilakukan pemeriksaan kadar hemoglobin dengan menggunakan alat oksihemoglobinometer dan automated hematology analyzer sebagai pembanding. Untuk perbedaan hasilnya digunakan Uji t berpasangan, dan dengan rumus uji diagnostik diperoleh nilai sensitivitas dan spesifisitas.

Terdapat perbedaan antara alat oksihemoglobinometer dengan hasil rata-rata 12,2±1,7 dan pada automated hematology analyzer diperoleh rata-rata 11,6±1,2. Dengan nilai p 0,001 yang artinya terdapat perbedaan yang signifikan terhadap kedua alat. Hasil analisis uji diagnostik didapatkan akurasi 69,2%. Alat oksihemoglobinometer belum bisa digunakan sebagai alat ukur kadar hemoglobin secara akurat karena hasil akurasi dari alat yang masih rendah yaitu 69,2%.

Kata kunci: oksihemoglobinometer noninvasif, diagnosis anemia, akurasi

Abstract
Iron deficiency anemia is a major health problem in pregnant women and has a detrimental effect on mothers and newborns. Given the consequences of anemia during pregnancy, an easy and accurate diagnosis is important. During this measurement of hemoglobin levels by involves taking the blood invasively, causing discomfort and trauma for the patient. Therefore, a hemoglobin level gauge is required using a non-invasive oxymeter system, in which the patient will be free of pain with minimal risk of infection and allow for the monitoring of the patient in critical condition. The purpose of this study was to compare the results of hemoglobin concentration using an oxyhemoglobinometer with automated hematology analyzer as gold standard to know the difference of result of accuracy. This
Introduction

Pregnancy influences a variety of physiological changes. One of the most significant changes is improvement volume so that hematocrit normally declines. This often results in the state of pregnant women experiences iron deficiency anemia.(1) Iron deficiency anemia is a major health problem in pregnant women and it has adverse effects on mothers and newborns. This affects about 1.62 billion people from the global population(2). The prevalence of anemia in India is 82% (3), Ethiopia is 56.8% (4). In Indonesia, the prevalence of anemia in pregnant women is 37.1% according to the data of Basic Health Research in 2013(5). In Yogyakarta the prevalence of maternal anemia increases in 2012 to 2013, which is 17.35% to 17.60%. The prevalence of pregnant woman’s anemia in Bantul Regency is 27, 76%(6). Iron deficiency anemia in pregnancy can result in harmful effects for the mother and fetus(7). Given the consequences of anemia during pregnancy, an easy and accurate diagnosis is important. Several methods are available for HB estimation in field settings, such as heavy copper sulphate type method, Lovibond comparator, HemoCue, Rapid test, Hemoglobin Color Scale, Cyanmethemoglobin, and Automated Hematology Analyzer(2).

The key for detecting anemia is proper diagnosis and monitoring of hemoglobin levels. However, measurement of hemoglobin levels by involving invasive blood sampling may potentially pose a risk of infection in both health care and patients. This is a major challenge in areas where there is a lack of water, electricity, necessary hygiene infrastructure and skilled healthcare providers. Thus, noninvasive hemoglobin screening is expressed by the World Health Organization (WHO) as one of the key medical technologies for improving health globally(8).

From the above problems, both in terms of technology, patient comfort and other factors, a hemoglobin level gauge is required using a noninvasive oxymeter system. Where the patient will be free from pain with minimal risk of infection and allow for patient monitoring in critical condition(9). The results of a study from Jung YH et al. entitled The efficacy of noninvasive hemoglobin measurements by CO-oximetry in neonates, Noninvasive Hb values measured by CO-oximeter oximeter significantly correlated with venous Hb levels (correlation coefficient, $r = 0.758$; $p < 0.001$). The Hb value measured by the CO-
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oximeter was higher than that measured by the laboratory hematological analyzer (13.3 ± 2.6 g / dL vs. 12.5 ± 3.1 g / dL). The conclusion is noninvasive Hb measurements with Pulse CO-Oximetry provide clinically acceptable accuracy, and they significantly correlate with laboratory Hb measurements in neonates. In the case of clinical application, noninvasive Hb monitoring with CO-oximeter pulses can be useful in the early detection of Hb changes in neonates. Accuracy is one of the parameters to measure the effectiveness of oxyhemoglobinometer compared to the automated hematology analyzer as the gold standard(20).

MATERIALS AND METHOD

This research is a diagnostic test with cross sectional design, which is the data retrieval for each subject is done in one unit of time(10). This research is to compare the result of hemoglobin content using new tool with gold standard so that the difference of the result is obtained the accuracy.

The subjects of this study are pregnant women at Health Center of Bantul District who fulfilled inclusion criteria, pregnant women who came to check their pregnancy at Health Center of Bantul Regency and pregnant mother who was willing to take blood for hemoglobin examination, and pregnant mother who do not use nail polish. The exclusion criteria of pregnant women who experience an emergency.

The primary data were collected from hemoglobin concentration from oxyhemoglobinometer and automated hematology analyzer. The data collection instrument in this study used a hemoglobin diagnostic tool consisting of an oxyhemoglobinometer and an automated hematology analyzer.

The data obtained from the two examination tools in the form of interval data will be known whether there is a significant difference between the results of the tool oxyhemoglobinometer with automated hematology analyzer. Before the bivariable analysis is done normality test, if normal test used is paired P test T, if the data is not normal test used Wilcoxon. The validity of the oxymeter device is calculated based on the degree of accuracy. This research seeks to uphold the scientific attitude and is very concerned about ethics considering the subject of research is human. This research has applied 3 basic principles of research ethics, namely: Respect for persons, Beneficent and non-efficiency, Justice(11)(12).

The research was conducted in the area of Health Center of Bantul Regency which purposively random sampling was taken that is determining the Health Center in Bantul district as the location of respondent taking with consideration of Health Center using hemoglobin level measurement with automated hematology analyzer. Among other things, Health Center of Kasihan I, Kasihan II health center, Sedayu II health center, Sewon I community health center, Banguntapan I community health center.

RESULT AND DISCUSSION

Result

The characteristics of research subjects presented to determine the frequency distribution of respondent characteristics, can be seen in the following table 1.

From the table above, it can be seen that on gravida characteristic more multigravida (71.8%) than primigravida (28.2%). Characteristic age of pregnant mother dominant at healthy reproductive age that is 20-35 years equal to 79.5%. On the characteristics of trimester or pregnancy age in pregnant women more in trimseter II that is equal to 43.6%. While on the characteristics of education, the dominant respondents of the research are high school graduates of 43.6%.

The result of difference of result from oxyhemoglobinometer and Sysmex KN-21 can be seen in table below:
Table 1. Respondent characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravida</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Primi</td>
<td>22</td>
<td>28.2%</td>
</tr>
<tr>
<td>• Multi</td>
<td>56</td>
<td>71.8%</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• &lt;20th</td>
<td>2</td>
<td>2.6%</td>
</tr>
<tr>
<td>• 20-35th</td>
<td>62</td>
<td>79.5%</td>
</tr>
<tr>
<td>• &gt;35th</td>
<td>14</td>
<td>17.9%</td>
</tr>
<tr>
<td>Trimester</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• I</td>
<td>20</td>
<td>25.6%</td>
</tr>
<tr>
<td>• II</td>
<td>34</td>
<td>43.6%</td>
</tr>
<tr>
<td>• III</td>
<td>24</td>
<td>30.8%</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Elementary/Junior High School</td>
<td>19</td>
<td>24.4%</td>
</tr>
<tr>
<td>• Senior High School</td>
<td>34</td>
<td>43.6%</td>
</tr>
<tr>
<td>• University</td>
<td>25</td>
<td>32.1%</td>
</tr>
</tbody>
</table>

Table 2. The Difference result of Oxyhemoglobinometer and Sysmex KN-21

<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxyhemoglobinometer</td>
<td>12.2 ± 1.7</td>
<td>0.001</td>
</tr>
<tr>
<td>Sysmex KN-21</td>
<td>11.6 ± 1.2</td>
<td></td>
</tr>
</tbody>
</table>

Note: *) Paired t test

From the table above can be seen that the value of p obtained 0.001, which means there is a difference of Hb levels between the oxyhemoglobinometer tool compared to Gold Standard Sysmex KN-21.

The results of the diagnostic test of the oxyhemoglobinometer tool compared with the automated hematology analyzer can be seen in the following table 3.

From the table above, the researcher can analyze with the formula of accuracy (a+d)/N=(4+50)/78 is 69.2%.

Table 3. The Oxyhemoglobinometer Diagnostic Test compared to Sysmex KN-21

<table>
<thead>
<tr>
<th></th>
<th>Sysmex KN-21</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anemia</td>
<td>Not Anemia</td>
</tr>
<tr>
<td>Oxyhemoglobinometer</td>
<td>Anemia</td>
<td>4 (17.4%)</td>
</tr>
<tr>
<td></td>
<td>Not Anemia</td>
<td>5 (9.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>69</td>
</tr>
</tbody>
</table>

Note: *) Diagnostic Test

Discussion

The principle of observation of hemoglobin and noninvasive blood oxygen content in the oxymeter system is the change in the color of the oxidized hemoglobin measured by the difference in absorption, when light is of a certain wavelength and penetrates tissue and blood. Blood containing oxygen-bound hemoglobin (HbO2 / Oxyhemoglobin) with no (Hb) will show different absorption spectra of light emission.

In this study, hemoglobin levels were examined in a non-invasive way or not by injury, ie light with a certain wavelength was transmitted across the probe and reached the detector / photodiode, then processed with a pre-programmed microcontroller so that the resulting hemoglobin levels were displayed on the LCD.

On developing tools using red and infrared LEDs. The wavelength on the red LED is 620nm and the infrared LED is 940nm. Both LEDs act as transmitters and photodiodes as receivers. The LED transmits light through the blood vessels and the photodiode receives the output from both LEDs which can be used to calculate the percentage of oxygen concentration. Appropriate wavelengths are selected for the relative analysis of changes in hemoglobin levels. Both wavelengths are chosen because the oxygen-containing hemoglobin absorbs the wavelength of 910 nm light and the hemoglobin-induced hemoglobin that absorbs oxygen absorbs the 650 nm wavelength.

This research is in line with the research design entitled "Design of Measuring Tools of
Hemoglobin Level, Oxygen Content and Sugar Level in Human Blood Non-invasive Based on Microcontroller”. The realization of the design result of the tool can measure by 0-0.250 mg / dl for sugar content, 0-20 gr / dl for hemoglobin, and 0-100% for oxygen content in blood(17).

In the selection of red LED color is also in line with research conducted by Guruh and firends entitled "The Design of Building Microcontroller-Based Microcontroller ATMega16", the results of his research that red LEDs are better to break through the organ network of fingers.48

On examination of the tool researchers using the index finger, this is in line with the results of the research entitled "Design of Measure Measures Hemoglobin and Oxygen in Blood with the Sensor of Oxymeter Non-invasive", which concluded that the most accurate finger for measurement is the index finger because the index finger has the finger size corresponding to the oxymeter sensor.23

The results of the oxyhemoglobinometer showed that the accuracy were still low, its 69.2%. This could be due to several factors below: 1) Bright light (such as indoor lights or sunlight) directly on the probe can affect the reading. This is in line with the results of a study entitled 'Potential errors in pulse oxymetry', it is the external light source influences the reading, with the result decreasing from 97% to 93%. The researchers recommend the use of fabric or rubber-wrapped fabrics wrapped around the probe to reduce external light to reach the light detector.55,59 In this study the factor has been controlled by means of a probe protected by an opaque material; 2) Movement can make difficulty for probe in taking signal. In this study the factors were controlled by asking respondents not to talk and move during the test.59; 3) Pulse oxymeter works well when all light passes through arterial blood. However, if the probe is wrong or not properly applied, some light does not pass through the arteries or travel on the side of the artery (shunting). It will reduce the pulsed signal strength making the pulse oxymeter vulnerable to errors. Therefore it is important to select the probe of the correct size so that the finger placement is right for best results. In this study researchers used a probe that conforms to the standard for oxygen saturation checks.57; 4) Pulse oxymeter only detects pulsed flow. When blood pressure is low due to hypovolemic shock or low cardiac output or the patient has arrhythmias, the pulse may be very weak and the oxymeter may not be able to detect the signal.59; 5) Vasoconstriction can reduce blood flow to peripheral, this causes the oxymeter may fail to detect the signal if the patient is very cold (chills).59; 6) Poisoning can give high false saturation readings. Carbon monoxide binds hemoglobin and displaces oxygen to form a bright red compound called carboxyhaemoglobin. This can occur in patients who breathe smoke from fire.57,59; 7) Pulse oxymeter cannot distinguish between different forms of hemoglobin. Carboxyhaemoglobin (hemoglobin combined with carbon monoxide) is listed as 90% oxyhemoglobin and 10% deoxyhemoglobin. The presence of methaemoglobin will prevent the oxymeter from working accurately and the reading will tend toward 85%.58; 8) Nail polish can cause inaccurate readings. It based on the results of a study entitled "Effects of nail polish on oxygen saturation determined by pulse oxymetry in critically ill patients", suggesting researchers to remove nail polish to help reduce measurement errors.56 This factor is controlled by researchers by inserting into the criteria inclusion of respondents.

From the analysis of several factors causing inaccurate readings of the above pulse oxymeter, and only a few that can be controlled by the researchers, it is possible to be the cause of the low validity of the oxyhemoglobinometer tool in this study.
CONCLUSION AND RECOMMENDATION

There is difference result between tool of oxyhemoglobinometer and automated hematology analyzer (Sysmex KN-21) in checking hemoglobin level in pregnant woman at Health Center area of Bantul district of Yogyakarta with value $p = 0.001$. The oxyhemoglobinometer device cannot be used as a measure of hemoglobin levels accurately because of the low validity of the tool, it is accuracy 69.2%.

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