CONFORMITY TEST OF HUMAN CHORIONICGONADOTROPIN (HCG) TEST RESULTS USING IMMUNOCHROMATOGRAPHIC METHOD BETWEEN VARIOUS BRANDS

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ABSTRACT

Human Chorionic Gonadotropin (HCG) is a hormone produced by the placental tissue in early pregnancy. This hormone is excreted in the urine or when there is an abnormal proliferation of the chorionic epithelial tissue, such as moles or choriocarcinoma. The problem formulation in this study is that there is a match between the results of the HCG examination using the immunochromatographic method on three different brands at the Kabila Health Center, Bone Bolango District. This study aims to determine the suitability of the results of the HCG examination with the Immunochromatographic Method on three different brands.

The method in this study used a quantitative approach. The type of data used was primary data in the form of research results and secondary data in the form of data from literature, books and documents. The sampling technique in this study used an accidental sampling technique with a sample of 30 people.

From the research that has been conducted on 30 urine samples of pregnant women using three brands of Human Chorionic Gonadotropin (HCG) kits, namely: 1) one med test. 2) medical sterile test. 3) the accurate strip; shows the results that there was no significant difference to the results of the suitability test of HCG using these three brands.

Keywords: HCG, pregnant women, immunochromatography

PENDAHULUAN

Pregnancy is a natural process in women that starts from conception, continues with the growth and development of the fetus, until it ends in childbirth. Pregnancy causes changes in the mechanism, regulation, and function of organs in the body in the form of physiological, metabolic, and anatomical changes [2].

Pregnancy is characterized by an increase in Human Chorionic Gonadotropin (HCG) in the urine of pregnant women in the first trimester. Generally, these pregnancies develop normally and give birth to healthy babies. HCG hormone can be found when there is an abnormal proliferation of chorionic epithelial tissue such as a mola hydatidosa or a choriocarcinoma. HCG can be used to synchronize ovulation and mating so that conception occurs [12].

Pregnancy is a condition in which there is an embryo or fetus in a woman's

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body. The initial phase of pregnancy is when the egg is released and enters the ampulla of the fallopian tube. The formation of the fetus is the result of fertilization of the egg and sperm. The fetus makes a woman's body undergo physical and psychological changes. Physical changes that are very prominent are the enlargement of the uterus, breasts, and blackening of the skin in certain areas and also softening of the genitals. This change aims to provide an opportunity for the fetus to grow and develop until delivery [17].

From 20 to 40 million sperm cells, only a few sperm cells can successfully penetrate and reach the place where the egg is located. Of the few sperm cells that managed to enter, only one sperm cell can fertilize the egg [1].

The beginning of the first trimester occurs in a weekly period of 0 to 13 weeks. In the first trimester, the growth and development of the fertilized egg occurs in three phases, namely the ovum phase, the embryonic phase, and the fetal phase [16].

Pregnancy in the second trimester occurs at gestational age entering weeks 14-26 where fetal growth is very fast due to an increase in renal venous pressure. In the second trimester, it is recommended for pregnant women to carry out laboratory examinations to determine the possibility of the emergence of diseases that are harmful to the process of fetal growth [16].

Pregnancy in the third trimester occurs at gestational age entering weeks 27-40 where there has been an improvement in the organs and body shape of the fetus so that it is ready to be born. In the third trimester there are various changes both anatomically and physiologically in the mother. The third trimester is often referred to as the waiting and alert period because at that time, the mother can't wait for the birth of her baby [16].

HCG is a hormone produced by the placental tissue in early pregnancy. This hormone will be excreted in the urine and can be produced if there is an abnormal proliferation of the chorionic epithelial tissue such as mola hydatidosa or choriocarcinoma [7].

HCG levels can change during the first trimester. This hormone begins to be produced from 3 to 4 weeks of gestation by the trophoblast tissue (placenta). To detect pregnancy using beta HCG urine, it can be reached using the agglutination method and Immunochromatography (strip) methods [15].

HCG hormone occurs when there is an abnormal proliferation of the chorionic epithelial tissue such as mola hydatidosa or choriocarcinoma and in pregnant women, the HCG levels in urine increase in the first trimester within 7 days after ovulation [5].

HCG hormone can fluctuate during the first trimester. This hormone is initiated from 3 to 4 weeks of gestation by the trophoblast tissue (placenta). The levels will increase until 10 to 12 weeks of pregnancy, then decrease in the second trimester, and increase again until the end of the third trimester hence the presence of HCG in the urine can be used as a sign of pregnancy [15].

The HCG hormone can be detected for the first time about 11 days after conception if through a blood test. On examination through urine, this hormone can be detected as early as 12 to 14 days after conception. The HCG hormone will double every 72 hours, starting from the first week to the 12th week of

pregnancy, then will tend to decrease after that.

The HCG hormone can be produced by cells formed in the placenta which have a function to maintain the egg cell fertilized by sperm attached to the uterine wall. Every woman usually has an HCG level of less than 5 IU/mL. However, HCG levels will increase even more once the placenta begins to excrete high amounts of HCG rising to greater heights of up to 25 IU/mL. This level is considered higher than the normal state of a woman.

Urine consists of several parts, namely water (96%) and a small amount of dissolved substances (4%) which are produced by the kidneys and temporarily stored in the bladder and then excreted from the body through the lower urinary tract. Solutes from urine consist of organic materials urea, uric acid, creatinine, and organic materials such as NaCl, ammonia, sulfate, and phosphate. Human organs generally perform excretion within 24 hours with an amount of approximately 1500 cc. This depends on fluid intake and other factors. Urine is generally clear yellow, but it can be cloudy if there are factors that influence it. The yellow color of urine is influenced by the concentration of urine, food consumed, diet, and drugs [4].

Good urine used during the test is the urine that is issued the first time after waking up or commonly called morning urine. In the morning, urine contains a higher concentration of HCG than other times. Drinking water in the morning before taking urine should be avoided because it can cause the urine to become dilute, making this hormone difficult to detect [15].

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HCG hormone examination using the immunochromatographic method is the reaction of pregnant women's urine containing alpha and beta HCG (complete monoclonal Human Chorionic Gonadotropin) in the form of anti a and b Human Chorionic Gonadotropin HCG on the T line test and C line control. If the test stick is inserted into the urine that has been prepared, the urine will seep quickly so that there can be a bond between urine anti a and urine anti b on the T line test and the C line control which will cause a red line [7].

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Interpretation of the results using immunochromatography method as follows: (1) Negative - only one red mark appears on the control line (C) and no red line appears on the test line (T) (Sensitivity 0 IU/mL). (2) Positive - there are two red marks, one on the test line (T) and one on the control line (C) (Sensitivity 25 IU/mL).

Although there are many advantages in checking HCG levels, there are also disadvantages, namely, the exact amount or levels of HCG is not known. Pregnancy tests using this method aim to detect pregnancy early after ovulation. HCG hormone can be detected in the urine of pregnant women about 14 days after fertilization of the egg. With the presence of HCG levels, it will be very helpful in determining the diagnosis of early pregnancy [7].

Agglutination is a technique to determine antigen or antibody semiquantitatively. Agglutination can be seen with the naked eye or with a microscope. The agglutination method that is often used is agglutination using latex particles. This type of agglutination is widely used to determine the presence of rheumatoid factor (RFi) or CRP in serum and HCG hormone in urine [15].

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In this study, three HCG test kits with different brands were used, namely: (1). HCG brand A, which is a pregnancy test that is very easy to use and has an accuracy of 99.9%. This pregnancy test is very practical and fast in knowing the results of the pregnancy test. (2). HCG brand B, which is an instant, fast, accurate, and very easy pregnancy test. (3). HCG brand C, which is a tool to detect pregnancy with a sensitivity level of 10 mIU HCG in urine and can provide results with an accuracy rate of 99%.

Based on the Basic Health Research (RISKESDAS) report, it was found that the prevalence of pregnant women in Indonesia in 2018 was in the age range of 10-54 years where the highest number of pregnancies occurred in Southeast Sulawesi at 6.2% while the lowest occurred in Papua at 3.0%. The prevalence of pregnant women in Indonesia is quite high, so the risk of maternal death is also high. In addition, there are labor disorders in women aged 10 to 54 years. The prevalence of pregnancy that occurs in the age range 10-14 years is 38.6%, the age range 15-19 years is 25.1%, the age range 20-24 is 14.3%, and in the age range 45-49 years is 0.1% [6].

Based on data from the Gorontalo Provincial Health Office, the number of pregnant women in Gorontalo Province since 2017-2019 continues to increase. In 2017 the number of pregnant women was 26,110 people, in 2018 the number was 26,191 people, and in 2019 (data up to December 2019) the number increased by 26,242 people divided into several areas including Gorontalo City as many as 4,473 people, Gorontalo District as many as 8076 people, Boalemo District as many as 3,746 people, Pohuwato District as many as 743 people, Bone Bolango District as many as 3,489 people, and North Gorontalo District as many as 2,713 people [3].

Based on the results of data observations conducted at the Kabila Health Center, Bone Bolango District,

the number of pregnant women in the first trimester in 2021 in April, May and June is 56 people.

Detection of the HCG hormone in a woman's urine can be used as a sign of a possible pregnancy. This test can be done in early pregnancy (first trimester) because this hormone begins to be produced at 3 to 4 weeks of gestation by the trophoblast tissue. This hormone can be used in synchronizing ovulation and mating in order for a conception to occur. This system aims to carry out various excretions in the form of waste products originating from the body [5].

Sofiah (2016) conducted an initial survey in shops and pharmacies about the use of the cheapest immunochromatographic test on the market and is quite in demand by the public. Almost every pharmacy sold about 60 test sticks per month. The price of immunochromatographic tests circulating in the market today is very diverse, ranging from the cheapest price of Rp. 5,000, - to the most expensive of Rp. 65,000,- which is available in full at pharmacies [11].

These data indicate that in general the immunochromatographic method is more widely used in the field as well as in the community, but its sensitivity cannot be ascertained, so the researchers took the initiative to conduct research on the results of the HCG test on three kits with different brands to determine its sensitivity.

RESEARCH METHOD

This study used a quantitative approach, with data collection techniques through interviews and observations. This study aimed to get a complete picture of an object to be studied and describe how the results of the suitability test of Human Chorionic Gonadotropin (HCG) immunochromatography method on three different brands at the Kabila Health Center, Bone Bolango district.

This research was conducted with a cross sectional approach. Cross Sectional Research is research that studies the dynamics of the correlation between factors and effects of research with an observational approach and data collection. In cross sectional research, observations are made only once and measurements are made on subject variables at the time of the study [9].

The population is a generalization area consisting of objects or subjects that have certain quantities and characteristics determined by researchers to draw conclusions [16]. The population of this study were all first trimester pregnant women at the Kabila Health Center, Bone Bolango district as many as 56 people.

The sample is part of the population to be studied or part of the number of characteristics possessed by the population [10]. The sample from the study was some pregnant women who did urine health checks at the Kabila Health Center, Bone Bolango district. The sampling technique was carried out using the Accidental Sampling technique, namely sampling by chance at the place to be researched with a total sample of 30 samples..

The data obtained were processed using the Statistical Package for Social Science (SPSS) and statistical tests using the One Way Anova method.

RESULTS

Berdasarkan The research was carried out on June 14-July 5, 2021 at the Kabila Health Center, Bone Bolango Regency with the research title of

conformity test for Human Chorionic Gonadotropin (HCG) examination results with immunochromatographic method on three test kits with different brands. The population in this study was 56 samples, and the sample size was 30 samples of first trimester pregnant women. The results obtained are as follows: :

Table 1. Tests Results between three brands

No	Name	Brand A	Brand B	Brand C
1.	Mrs. D.S	Positive	Positive	Positive
2.	Mrs. D.A	Positive	Positive	Positive
3.	Mrs. M.R	Positive	Positive	Positive
4.	Mrs. F.L	Positive	Positive	Positive
5.	Mrs. C.S	Positive	Positive	Positive
6.	Mrs. R.D	Positive	Positive	Positive
7.	Mrs. S.P	Positive	Positive	Positive
8.	Mrs. N.M	Positive	Positive	Positive
9.	Mrs. H.F	Positive	Positive	Positive
10.	Mrs. E.W	Positive	Positive	Positive
11.	Mrs. M.L	Positive	Positive	Positive
12.	Mrs. F.I	Positive	Positive	Positive
13.	Mrs. W.D	Positive	Positive	Positive
14.	Mrs. M.H	Positive	Positive	Positive
15.	Mrs. E.M	Positive	Positive	Positive
16.	Mrs. H.P	Positive	Positive	Positive
17.	Mrs. M.R	Positive	Positive	Positive
18	Mrs. Y.G	Positive	Positive	Positive
19.	Mrs. V.L	Positive	Positive	Positive
20.	Mrs. C.M	Positive	Positive	Positive
21.	Mrs. L.L	Positive	Positive	Positive
22.	Mrs. W.D	Positive	Positive	Positive
23.	Mrs. R.A	Positive	Positive	Positive
24.	Mrs. E.P	Positive	Positive	Positive
25.	Mrs. D.S	Positive	Positive	Positive
26.	Mrs. A.K	Positive	Positive	Positive
27.	Ny. A.A	Positive	Positive	Positive
28.	Ny. M.A	Positive	Positive	Positive

29.	Ny. S.K	Positive	Positive	Positive
30.	Ny. S.P	Positive	Positive	Positive

Explanation: (Positive) contains HCG

(Negative) no HCG

Based on examination of 30 urine samples of pregnant women in the first trimester, it was found that there was no difference in results between brand A, brand B and brand C ..

Table 2. Normality Test on HCG Hormone Test Results

	Shapiro-Wilk			
Brands	Samples	Significant	Significant Rates	Explanation
A	30	.000	0,05	Abnormal
B	30	.000	0,05	Abnormal
C	30	.000	0,05	Abnormal

Source: Primary Data, 2021

The normality test was carried out to determine whether the data obtained had a normal data distribution or not, which became a reference in determining the Parametric or Non-Parametric comparative test. The results of the normality test in this study are presented in table 2.

According to Santoso (2014), in the Shapiro Wilk test, the data is said to be normally distributed if the significant value > significant level (5% or 0.05). Based on table 2, the results of the normality test on 30 urine samples using three different brands obtained the results of 000 <0.05. So it can be concluded that the data obtained are not normally distributed so that it is continued in the Non-Parametric comparative analysis test, namely the Kruskal-Wallis test [16].

Table 3. *Kruskal-Wallis* Test Results

Method	Significant	Significant Rates	Explanation
Qualitative	1.000	0,05	Not significant

Source: Primary Data, 2021

DISCUSSION

Human Chorionic Gonadotropin is a hormone produced by the placental tissue in early pregnancy. This hormone is excreted in the urine. In addition to pregnancy, this hormone can also be produced when there is an abnormal proliferation of chorionic epithelial tissue such as mola hidatidosa or choriocarcinoma. Increased levels of HCG in the urine of the first trimester indicate pregnancy because this hormone is secreted within 7 days after ovulation [7].

HCG levels can change dramatically during the first trimester. This hormone is initiated from 3 to 4 weeks of gestation by the trophoblast tissue (placenta). The hormone levels will increase when the pregnancy enters the 10-12th week, then decrease in the second trimester, and increase again until the end of the third trimester.

Detection of the HCG hormone in urine can be used as a sign of pregnancy [15].

HCG hormone can be detected in the urine of pregnant women about 14 days after fertilization of the egg. With the presence of HCG levels, it will be very helpful in determining the diagnosis of early pregnancy. However, checking HCG levels can be disadvantageous because the exact amount or levels of HCG is not known and the cost is very expensive [7].

The examination of HCG in pregnant women's urine can be performed using the immunochromatographic method. It contains alpha and beta HCG (complete monoclonal Human Chorionic Gonadotropin) in the form of anti a and b Human Chorionic Gonadotropin HCG on the T line test and C line control. A red line in the HCG test kit will appear if the test stick is inserted into the urine bonds between urine anti a and urine anti b in the T line test and the C line control [7].

From the results of research that has been carried out from 30 urine samples of pregnant women using three Human Chorionic Gonadotropin (HCG) test kits with different brands, the results show that there is no significant difference in the results of the conformity test between the three brands.

Furthermore, based on table 3, the results of the comparative analysis on the examination of conformity tests on the three brands indicate that there is no significant effect between brand A, Brand B and Brand C.

CONCLUSION

Based on the results of the research that has been done, it can be concluded that there is no significant difference in the results of the suitability test of the three Human Chorionic Gonadotropin (HCG) test kits with different brands, namely Brand A, Brand B and Brand C.

1. The results obtained from the Asymp value. Sig is 1000 < 0.05 indicating no difference or iH_a is rejected and iH_o is accepted. This indicates that there is no difference between Brand A, Brand B, and Brand C.
2. The results of the analysis obtained from the Kruskal-Wallis test are 1. 000 < 00,05 meaning that there is no significant effect between Brand A, Brand B, and Brand C

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