The Comparison of Gestational Diabetes Mellitus Screening between the One Step Method and the Two Step Method

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Abstract

This research aimed to compare the results of gestational diabetes mellitus (DMG) screening based on the One Step and Two Step method. This research was a cross-sectional study conducted in pregnant women 24-28 weeks of gestation who meet the research criteria. The diagnosis of gestational diabetes using the One Step and Two Step method was each carried out on 53 pregnant women so that the total sample of the research was 106 pregnant women. The results showed that 28.3% of pregnant women (15/53) were diagnosed with DMG with the One Step method compared with 3.8% (2/53) of pregnant women diagnosed by the Two Step method. There was a significant difference ($p < 0.05$) between the diagnosis results of the two DMG diagnosis method. Further analysis of DMG risk factors showed that the highest positive likelihood ratio (LR +) was found in the history of macrosomia with LR + = 4.45 with the One Step method while the highest LR + for the Two Step method was found in obesity factors for pregnant women with LR + = 6.57. The highest positive predictive value (PPV) for the One Step method of 46.70% was found in pregnant women with risk factors for obesity while the Two Step method was found in pregnant women with a history of DM (PPV = 100%). Pregnant women diagnosed with DMG were significantly greater in the One Step method than the Two Step method. History of macrosomia (is found) as a risk factor for pregnant women diagnosed with DMG with the One Step method, while a history of DM for the Two Step method.

Keywords: *Diabetes mellitus, pregnancy, screening, risk factors.*

Introduction

Gestational diabetes mellitus (DMG) is a carbohydrate intolerance of varying degrees that occurs or is first known during pregnancy. Diabetes mellitus is a medical complication that often occurs during pregnancy. According to the American Diabetes Association (ADA) in 2004 gestational diabetes mellitus occurred in about 4% of all pregnancies in the United States, and 3-5% in the United Kingdom. The prevalence of gestational diabetes mellitus in Europe is 2-6%[1].

Increased perinatal morbidity and mortality in pregnancy with DMG is directly correlated with maternal hyperglycemia. The effect shown by mothers with gestational diabetes mellitus is that they have high risk of excess weight gain, the occurrence of preeclampsia, eclampsia, cesarean section, and cardiovascular complications to maternal death. After delivery occurs, the mothers are at risk of developing type 2 diabetes mellitus or recurring gestational diabetes in subsequent pregnancies while babies born to mothers who have gestational diabetes are at high risk of experiencing macrosomia and birth trauma. In addition, babies are also at risk of developing hypoglycemia, hypocalcemia, hyperbilirubinemia, respiratory distress syndrome, polycythaemia, obesity and type 2 diabetes mellitus[2].

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Screening is done to identify asymptomatic individuals who are at high risk for having or are in the development of certain diseases. Screening can be done as a two-step or one-step process. In the two-step technique, the first step is carried out to identify individuals who are at risk of disease, so that the second step (a more definitive diagnostic test, but usually more expensive and complex than screening) is only done in groups that are truly at risk and not carried out in groups low risk. While the One Step technique is done by filtering all individuals. Over the past three decades, the procedure and criteria which are most widely used to detect early DMGs is the two-step procedure (wherein): oral glucose tolerance test 1 hour 50 g and is followed by 3 hours 100 g for positive cases at initial screening. The One Step procedure is carried out with a simple step of performing an oral glucose tolerance test of 2 hours 75 g but (it) requires fasting for 8-14 hours before the glucose check[3].

Until now, there is still no agreement on the most appropriate screening method or DMG screening for pregnant women in Indonesia. For this reason, an approach is needed about screening for DMG so that it can improve pregnancy outcomes for both mother and baby.

This research aimed to compare the results of gestational diabetes mellitus (DMG) screening based on the One Step and Two Step method.

Methodology

This research was an analytic study with cross-sectional approach. Sampling was done by simple random sampling with the ordinal method until the required number of samples was met. The minimum sample required for this research is 53 samples for each of the One Step and Two Step method so that the total sample of this study was 106 samples.

Sample: The sample in this research were pregnant women who came to the Obstetrics and Gynecology clinic in Wahidin Sudirohusodo Hospital, Jumpandang Public Health Center, Tamalanrea Jaya Public Health Center, to undergo a pregnancy check during the research period that met the inclusion and exclusion criteria. Inclusion criteria in this research were pregnant women — who are 18 years old or older, gestational age are between 24 and 28 weeks, who have single pregnancies, and who are willing to be involved in the research. The exclusion criteria in this research were pregnant women who are having medical or obstetric complications during pregnancy, being treated for diabetes mellitus, and not being able to undergo an Oral Glucose Tolerance Test (TTGO) due to nausea or vomiting.

Procedure: The way this research worked was by explaining the purpose and objectives of the research to pregnant women, if they are willing to take part in the research, pregnant women sign an agreement. Anamnesis was conducted on the research participants and other data were recorded in the research sheet, then DMG diagnosis test with the One Step method and Two Step method were carried out.

GDM diagnosis using the One Step method: Patients were asked to fast for at least 8 hours before the test. OGTT was performed in the morning after fasting — with 75 grams of glucose in 250 mL of water. Glucose level examination was done when the patient was fasting, 1 hour and 2 hours after OGTT. Analysis of blood glucose levels was carried out using the GOD-PAP method in serum at Prodia Laboratory Makassar. The diagnosis of GDM is positive if one or more of the following criteria has an abnormal (greater) value:

Glucose Examination	Glucose level	
	mg/dL	mmol/L
Fasting blood sugar	92	5.1
Glucose at 1 hour	180	10
Glucose at 2 hour	153	8.5

GDM diagnosis using the Two Step method:

Step 1. 50 gram glucose loading test (without fasting) was carried out, plasma glucose levels were measured 1 hour after glucose loading. If the plasma glucose level on 1 hour after glucose loading> 140 mg/dL (7.8 mmol/L) then (the test)would be followed by OGTT 100 grams of glucose.

Step 2. OGTT 100 grams of glucose was performed on patients in a state of fasting. Glucose level examination was performed when the patient was fasting, 1 hour, 2 hours and 3 hours after OGTT. Analysis of blood glucose levels was carried out using the GOD-PAP method in serum at Prodia Laboratory Makassar. The diagnosis of GDM is positive if two of the four plasma glucose measurements exceed the following values:

Glucose Examination	Glucose level	
	mg/dL	mmol/L
Glucose 50 mg/dL	105	5.8
Glucose 100 mg/dL at 1 hour	190	10.6
Glucose 100 mg/dL at 2 hour	165	9.2
Glucose 100 mg/dL at 3hour	145	7,9

Data analysis: Differences in the characteristics of the research sample between the two groups were tested by the independent t test, the Mann Whitney test and the Chi square test. Differences in diagnosis results between the One Step and Two Step method and differences in the characteristics of the research sample based on the diagnosis of DMG were tested by Fischer's exact test. Data were analyzed with SPSS with significance level (p) <0.05.

Results

This research involved 106 pregnant women consisting of 53 pregnant women getting DMG diagnosis test with the One Step method and 53 pregnant women with the Two Step method. This research was carried out on pregnant women with 24-28 weeks gestation and had passed the screening process for DMG as a research sample.

Table 1. The characteristics of research samples

Characteristics	One Step Method (n = 53)	The Two Step Method (n = 53)	
Mother's age (mean ± SD year)	27.3 ± 5.1	29.4 ± 6.1	0.056 *
Parity			
Primipara	26 (49.1%)	22 (41.5%)	0.558 ***
Multipara	27 (50.9%)	31 (58.5%)	
Gestational age (mean ± SD week)	25.8 ± 1.2	25.9 ± 1.3	0.487 **
Family history of DM			
Yes	5 (9.4%)	4 (7.5%)	1,000 ***
Not	48 (90.6%)	49 (92.5%)	
Macrosomia History			
Yes	4 (7.5%)	2 (3.8%)	0.678 ***
Not	49 (92.5%)	51 (96.2%)	
BMI (kg/m^2)			
≥ 30	44 (83%)	46 (86.8%)	0.786 ***
<30	9 (17%)	7 (13.2%)	

*Independent t test, **Mann Whitney Test, ***Chi Square Test

Table 1 shows (that) the proportions for the age of pregnant women, parity, gestational age, risk factors for family history of DM, history of childbirth, macrosomia and BMI ≥30 kg/m^2 for both DMG diagnosis method is almost the same. The results of further statistical tests on the research sample in the two diagnosis groups showed no significant difference in characteristics (p> 0.05) between the two research groups so that the two groups were comparable.

Table 2. The diagnosis of DMG based on the One Step and Two Step method

DGM diagnosis	One Step Method (n = 53)	Two Steps Method (n = 53)	p*
Positive	15 (28.3%)	2 (3.8%)	.001
Negative	38 (71.7)	51 (96.2%)	

* Fischer Test

Table 2 shows (that) the general prevalence of DMG in this research was 16.04% (17/106). DMG was diagnosed more in the One Step method than the Two Step method. DMG diagnosis results of this research consisted of 15 pregnant women (28.3%) diagnosed by the One Step method and 2 pregnant women (3.8%) diagnosed by the Two Step method and there were significant differences ($p < 0.05$) between the diagnosis results from both method of diagnosis of DMG.

Table 3. The comparison of DMG screening diagnosis results based on risk factors

Risk Factors	One Step				Two Step			
	PPV (%)	NPV (%)	LR +	LR -	PPV (%)	NPV (%)	LR +	LR -
DM history	26.70	97.40	3.49	0.26	100.00	96.10	-	0.50
Macrosomia History	26.70	100.00	4.45	0.00	0.00	96.10	0.00	1.04
BMI	46.70	94.70	4.28	0.27	50.00	88.20	6.57	0.88

PPV = positive predictive value, NPV = negative predictive value, LR + = positive likelihood ratio, LR- = negative likelihood ratio

The data in table 3 shows (that) the highest positive likelihood ratio (LR +) was found in the history of macrosomia with LR + = 4.45 with the One Step method while the highest LR + for the Two Step method was found in the obesity factor of pregnant women with LR + = 6.57. The highest positive predictive value (PPV) for the One Step method of 46.70% was found in pregnant women with risk factors for obesity while the Two Step method was found in pregnant women with a history of DM (PPV = 100%).

Discussion

This research aimed to compare the results of gestational diabetes mellitus (DMG) screening based on the One Step and Two Step method. In this research, the prevalence of DMG was 16.04%. Research by Melchior et al (2017), reports that regardless of the screening method used, the prevalence of DMG has tended to increase in the past decade[4]. Another study by Ferrara (2007), reports that in the last 20 years there is an increase in the prevalence of DMG between 10-100% in the world[5]. This increase is in line with the increasing epidemic of type 2 diabetes mellitus and obesity. Globally, the prevalence of hyperglycemia in pregnancy (DMG and type 2 diabetes in pregnancy) is estimated to reach 15%. A retrospective cohort study of 567,191 pregnant women found a prevalence of 13.2% [4]. The prevalence of DMG varies between 1-28% depending on the characteristics of the population.

The true prevalence of DMG is difficult to estimate because of differences in risk factors in the study population, such as maternal age, BMI, diabetes and ethnic prevalence. In addition, the screening strategy, the testing method used, and the glycemic threshold used also differ. The use of data in reporting also greatly influences the prevalence of reported DMG.

The research also showed that pregnant women diagnosed with DMG were higher in the One Step method compared to the Two Step method. Some researches show the same results as this research. Research in Turkey in pregnant women with gestation of 24-28 weeks and using universal screening of 50 grams of TTGO reports a prevalence of DMG of 14.5% with the One Step method and 6% with the Two Step method[6]. Another research in Thailand also shows a greater diagnosis of DMG done by the One Step method (32%) compared to the Two Step method (10.3%)[7]. Research in Iran also shows the incidence of DMG is also higher with the One Step method (9.3%) compared to the Two Step method[8]. Conversely, a meta-analysis in 2. 333 pregnant women reports no significant difference in the incidence of DMG between the One Step and Two Step method [9]. However, this meta-analysis also shows that the One Step method is associated with better maternal and perinatal outcomes compared to the Two Steps method in terms of lower incidence of preterm labor, NICU care and neonatal hypoglycemia. The Two Step Method also deals with reducing the number of DMGs that cannot be followed up (lost to follow up) by about 5% thereby reducing the incidence of DMG [10]. lower NICU care and neonatal hypoglycemia. The Two Step Method also deals with reducing the number of DMGs

that cannot be followed up (lost to follow up) by about 5% thereby reducing the incidence of DMG [10]. The One Step Method increases the prevalence of DMG from 1.03 to 3.78 times compared to Two Step [11]. The results of this research are comparable to Brown's research that found a positive diagnosis of DMG with the One Step method increased about 2-fold from the positive diagnosis result by the Two Step method. Another research based on differences in the risk of DMG in pregnant women which are low risk and high risk shows DMG increased from 7% to 11.7% in high risk pregnant women using the One Step method [12]. Other researches have even reported a higher incidence of DMG (between 16% to 27%) with the One Step method compared to Two Step [13,14].

The difference in the prevalence of DMG between the One Step and Two Step method between researches can be caused by differences in population characteristics such as sample size, ethnicity/race, and DMG risk factors. Several studies have shown that ethnic/racial factors have implications for the prevalence of DMG worldwide. The prevalence of DMG increases significantly in European populations in the One Step method compared to Two Step.

The DMG diagnosis approach is still being debated to this day. Based on the results of this research it was found that the diagnosis of DMG was significantly higher by the One Step method compared to Two Step method. There are several arguments related to the benefits and risks of using the One Step method as a DMG diagnostic approach. The One Step method is superior to the Two Step method because the women examined and showed positive results with the One Step method but negative with the Two Step method (meaning, having symptoms of lighter glucose intolerance) still have a higher risk for experiencing pregnancy complications such as gestational hypertension, preeclampsia and cesarean section, moreover, the babies born are also at risk of complications. Thus women who tested positive for the One Step method are eligible to be diagnosed with DMG and given treatment to reduce the risk of complications. Another advantage of the One Step method is that the level of patient compliance is higher compared to the Two Step method which is reported to be around 15% of patients not taking the second test. The use of the Two Step method can be a burden on patients. In addition to these two reasons, the One Step method is also more cost effective and results in maternal and neonatal outcomes have been proven to be better. A meta-analysis of 4 randomized controlled researches comparing these two approaches shows that the diagnosis and treatment of DMG with the One Step approach is associated with better maternal and neonatal outcomes. Compared to the One Step method, the second step with the Two Step approach will delay diagnosis and treatment. The One Step Method improves patient compliance and diagnosis can be established earlier. In high risk cases such as history of DMG, history of macrosomia, older maternal age, multiple pregnancy and others, screening with the One Step method can be done at the first antenatal visit.

Meanwhile, a counter argument was put forward by Hosseini et al (2018), who reports that the One Step approach tended to identify low-risk women as DMG positive[8]. This will increase anxiety and health costs because more antenatal visits and more ultrasound examinations will be needed, including an increase in the need for additional laboratory tests without clear benefits. ACOG does not recommend the use of the One Step method because there is not enough data available that the use of these criteria will increase maternal and neonatal outcomes and may even increase health costs.

Based on this research the DMG diagnosis results are higher when it is diagnosed with the One Step approach compared to Two Step. The One Step Method is recommended by IADPSG and ADA because it is more sensitive for identifying DMG. DMG diagnosis using the One Step method is used to uniform DMG diagnosis procedures for all pregnant women so as to increase the sensitivity of the screening method and the prevalence of DMG, pregnant women diagnosed with DMG earlier are expected to improve pregnancy outcomes for both mother and baby [15]. Increased sensitivity is associated with a low threshold for positive results (only one abnormal value is needed) and a cut-off value is also low.

Research conducted in Thailand states that the One Step method is not suitable for routine screening in clinics with as many ANC patients as in developing countries, because screening tends to be complicated for it requires prior fasting, with no real evidence of clinical improvement in pregnancy outcomes [7].

The One Step Method provides benefits for patients and health care providers because it can provide diagnostic results in just one ANC visit. But the increased prevalence of pregnant women with DMG also increases health costs, without any real evidence of the benefits of

treatment. Women diagnosed with DMG are also likely to face unintended consequences, such as increasing the risk of labor by cesarean section, requiring intensive newborn assessment, increasing the cost of care, and possibly experiencing psychosocial burdens.

This research also found that the possibility of pregnant women diagnosed with DMG was greater if they had a history of macrosomia and obesity in the One Step method while a history of DM and obesity for the Two Step method. This means that pregnant women who have a high risk of DMG will be more likely to experience DM during pregnancy compared to pregnant women without risk factors or low risk. Hosseini's research shows that pregnant women who are older than 35 years old and having a family history of DM significantly increased DMG development for both in the One Step and Two Step method. It further shows that a high BMI before pregnancy and lack of exercise during pregnancy and a history of previous cesarean section supports the development of DMG especially for the Two Step method [8]. Therefore, the presence of high risk factors for DMG supports the formation of DMG diagnoses for both DMG diagnosis method.

Some weaknesses of this study are (1) the sample used is different for the two diagnostic method so that diagnostic tests cannot be performed to see the sensitivity and specificity of both method; (2) it does not compare the results of pregnancy outcomes (from) both maternal and neonatal between the two examination method so that further research is needed with larger samples to conclude the most effective screening method.

Conclusions

Based on the results and discussions, it can be concluded that pregnant women diagnosed with diabetes mellitus by the One Step method were 28.3% and by the Two Step method were 3.8%. The prevalence of gestational diabetes mellitus is significantly greater with the One Step method compared to the Two Step method. History of macrosomia and obesity were found to be risk factors for pregnant women diagnosed with DMG by the One Step method while a history of DM and obesity (were found to be risk factors) for the Two Step method.

Ethical Clearance: No ethical approval is needed.

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Conflict of Interest: Nil

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