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Glycemic Control And Birth Weight With Glycated Albumin In Women With Gestational Diabetes Mellitus at Zagazig University Hospital

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Abstract

Background:*The current monitoring standards for diabetes involve a combination of a self-monitored blood glucose (SMBG) procedure, continuous glucose monitoring, and glycated hemoglobin A1c (HbA1c) measurement. Increasing attention has been focused on the use of glycated albumin (GA) as a parameter of the short-term glycemic status. W aimed to evaluate GA as a potential glycemic marker in managing of gestational diabetes mellitus, and evaluating the association between glycemic control and birth weight with glycated albumin in women with GDM.* ***Methods:****Prospective study was carried out at Zagazig University Hospitals, Thirty women was control group and Thirty as the GDM (study) group. Maternal serum GA level was measured.* ***Results:****The result of this study showed that GA (24_28 weeks) more than 14.15 had sensitivity of 83.7% and specificity of 88% for prediction of fetal complication and GA (36_38 weeks) more than 14.45 had sensitivity of 85% and specificity of 88% for prediction of fetal complication.****Conclusion:****Strong support for the use of GA measurements, as a complement to finger stick glucose, for assessing short-term glycemic control and predicting large birth weight in the GDM women.*

Key words: *Diagnosis- Birth Weight- GA. GDM. Glycemic Control*

I. Introduction:

The current monitoring standards for diabetes involve a combination of a self-monitored blood glucose (SMBG) procedure, continuous glucose monitoring, and glycated hemoglobin A1c (HbA1c) measurement. The values of the SMBG only reflect instantaneous blood glucose, which is susceptible to factors such as diet and emotion. Several studies have reported that neither SMBG testing nor the frequency of testing was associated with a glycemic benefit in diabetic patients regardless of treatment. Furthermore, the pain and inconvenience of

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collecting blood from a finger results in poor compliance with the SMBG. Continuous glucose monitoring, while reflecting the glycemic level in the preceding 3 days, is limited in application because of the complicated set-up and high cost **(1).**

Although HbA1c provides a reliable assessment of chronic glycemic levels that are intimately related to the risk of diabetic complications, it could be a flawed indicator of blood glucose control in a short-term period, and be not appropriate during pregnancy **(2).**

Increasing attention has been focused on the use of glycated albumin (GA) as a parameter of the short-term glycemic status. GA is the product of non-enzymatic glycosylation of plasma albumin. Because albumin has a relatively short half-life time (approximately 12–19 days) in the human body, GA measurement reflects the blood glucose levels of diabetic patients in the preceding 2–3 weeks ***(3).***

Previous studies have shown that this measurement has a higher sensitivity to glycemic fluctuations than HbAlc, and provides useful information in evaluating blood glucose control in diabetic patients ***(4).***

In the present study, we aimed to evaluate GA as a potential glycemic marker in managing of gestational diabetes mellitus, and evaluating the association between glycemic control and birthweight with glycated albumin in women with GDM.

II. Patients and Methods

(1) Technical design:

a) Setting of the Study:

This prospective study was carried out in Department of Obstetrics and Gynecology at Zagazig University Hospitals, Zagazig, Sharkia, Egyptfrom December 2018 till October 2019.

b) Sample size:

As the attendance rate of pregnant women at 12-16 wks presenting to Zagazig university hospitals about 5 patients\week. So, the all number of patients in 11 months (230 cases) were included in the study.

According to the OGTT results at 24-28 weeks, of the 230 women enrolled in the study, 30 women were assigned as the normal (control) group and 30 as the GDM (study) group. The rest of women were excluded from the study because of their irregular follow up.

c) Target population: pregnant women at 12-16 weeks.

Inclusion criteria:

Pregnant woman at 12w+0 to 16w+0 of gestation with single living fetus presented for antenatal care in zagazig university hospital.

Exclusion criteria:

- Pregnant women who had a gestational age less than 12 weeks or more than 16w.
- If they had pre-existing diabetes and other endocrine diseases (e.g., hyperthyroidism,

hypothyroidism and Cushing's syndrome),

- Prior gestational diabetes,
- Multiple pregnancy,
- History of chronic hypertension, heart disease, hematological disease or renal disease.
- If they were taking corticosteroids.
- If there was a history of known fetal anomaly.

(2) Operational design:

Type of the study: Prospective Cohort study.

Steps of performance:

All cases who met inclusion criteria had been subjected to the following:

Full history

Maternal serum GA level was measured at 12-16 wks, not need fasting, to all cases who met our inclusion criteria in the second and third trimesters at our hospital.

Maternal screening for all cases at 24-28 wks using 75gm oral glucose tolerance test (OGTT)

A fasting blood glucose sample had been obtained.

Values that indicate diabetes:

- Fasting: More than or equal to 92 mg/dL or 5.1 mmol/L
- 1-hour: More than or equal to 180 mg/dL or 10.0 mmol/L
- 2-hour: More than or equal to 153 mg/dL or 8.5 mmol/L.

Pregnant diabetics were diagnosed with at least two values of plasma glucose levels exceeding the carpenter and coustan criteria dorsed by the American Diabetes Association.

Follow up of our patients in antenatal outpatient clinic:

Every 2 weeks till 36 weeks, then every week till delivery, in the 1st visit:

General examination: vital signs (pulse, Blood Pressure & Temperature).

- Maternal BMI had been measured by dividing the weight in kilograms by square of the height in meters.
- Normal (18.5 – 25) kg/m^2
- Over weight (25-30) kg/m^2
- Obese > 30 kg/m^2

Abdominal examination:

It was performed at each antenatal visit from 24 weeks to estimate fetal size and from 36 weeks gestation to assess fundal height, presentation, position and station/ engagement of the presenting part.

Investigations:

- Maternal investigations: (HB, AST, ALT, Urea, Creatinine and Urine analysis).
- Fetal investigations:

1. Trans-abdominal ultrasound examination for fetal viability, gestational age confirmation, measurement of fetal abdominal circumference (AC), and calculation of expected fetal birth weight (EFBW) before delivery.

2. CTG was performed in the third trimester of pregnancy (after 28 weeks) as an indicator of fetal well-being.

- At 24-28 weeks of gestation, a 75-g oral glucose-tolerance test had been carried out, and the GA levels had been determined.
- The participants had been divided into two groups (the normal group as the control group and the GDM group as the study group), according to the OGTT results.
- GDM women had been referred to internal medicine clinic for management of case either by diet control, oral therapy or insulin therapy.
- At 36-38 weeks of gestation, the GA levels had been measured.

GA and Plasma Glucose Measurements:

GA was measured using fructosamine level, as GA kits not available in Egypt.

Measurement of Fructosamine and Glycated Albumin:

Fructosamine was measured in serum spectrophotometrically using the Roche fructosamine kit and th e Roche Cobas BIO Centrifugal Analyzer. The method is based on the ability of fructosamines to reduce nitrobluetetrazolium (NBT) at an alkaline pH. The kit manufacturer's protocols were used and the assay was calibrated using the 1 -deoxy-l-morpholino- D - f ructose standard (3 .2 mmol/L) supplied by Roche.

GA was measured by this equation:

1186 µmol/l fructosamine = 30 mg/ml GA

The amount of glycated albumin had been expressed as absolute concentration (mg/ml) or as a relative %, determined by the equation below;

GA (%) in the sample was then calculated as follows:

% Glycated Albumin (GA) =Glycated Albumin sample divided by

Total albumin sample× 100

Where;

a) Glycated Albumin is in mg /Ml

b) Total Albumin is in mg /mL

Mode of delivery was according to hospital protocol.

statistical analysis

Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) **(Statistical Package for the Social Sciences)** software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD, the following tests were used to test differences for significance; difference and association of qualitative variable by Chi square test (X^2). Differences between quantitative independent groups by t test, correlation by Pearson's correlation or Spearman's. P value was set at <0.05 for significant results &<0.001 for high significant result.

Data were collected and submitted to statistical analysis. The following statistical tests and parameters were used

- **Sensitivity specificity predictive value**

	Condition (as determined by "Gold standard")			
	Negative	***Positive***		
→ **Positive predictive value** $= \frac{\Sigma \text{ True Positive}}{\Sigma \text{ Test outcome Positive}}$	**False Positive** (Type I error)	**True Positive**	***Positive***	**Test outcome**
→ Negative predictive value $= \frac{\Sigma \text{ True Negative}}{\Sigma \text{ Test outcome Negative}}$	**True Negative**	**False Negative** (Type II error)	***Negative***	
	↓ Specificity $= \frac{\Sigma \text{ True Negative}}{\Sigma \text{ Condition Negative}}$	↓ Sensitivity $= \frac{\Sigma \text{ True Positive}}{\Sigma \text{ Condition Positive}}$		

ROC curve was done

III. Results:

This prospective cohort study included 60 women who completed the study. The participants were divided into two groups (30 normal pregnant women as the control group and another 30 women with GDM as the study group), according to the OGTT results.

Table 1: Basic demographic data distribution between groups at time of beginning of the study

			Study (N=30)	**Control** (N=30)	t/X^2	P
Age			32.25±9.91	29.1±8.78	1.352	0.113[1]
Weight			75.96±10.4	65.16±9.19	4.256	**<0.001****[1]
Height			160.8±4.16	160.53±2.9	0.287	0.775[1]
Gestational Age			13.46±1.35	13.4±1.32	0.192	0.848[1]
BMI group	**Average**	**N**	4	20		
		%	13.3%	66.7%		
	Overweight	**N**	12	8	20.46	**<0.001****[2]
		%	40.0%	26.7%		
	Obese	**N**	14	2		
		%	46.7%	6.7%		
	Mean ±SD		29.56±4.33	25.23±3.28	3.121	**0.001****[1]
Parity	**1**	**N**	6	17		
		%	20.0%	56.7%		
	2	**N**	12	13		
		%	40.0%	43.3%		
	≥3	**N**	12	0	17.3	**0.001****[2]
		%	40.0%	0.0%		

*Abbreviations: **BMI,** body mass index (calculated as weight in kilograms divided by the square of height in meters); **GDM,** gestational diabetes mellitus; **SD**, standard deviation.*

There was no significant difference regard age or height or GA. Study group had significantly higher mean of weight (75.96±10.4) than control group (65.16±9.19) (p<0.001). Mean BMI was significantly higher among study group (29.56±4.33) than control (25.23±3.28) (p=0.001) with significant higher percentage of obese among study group (46.7%). 40% of study group had significantly higher parity ≥3.

Table 2: Clinical characters distribution between groups

			Group		X^2	P
			Study (N=30)	**Control (N=30)**		
Abortion	**-VE**	**N**	24	24		
		%	80.0%	80.0%		
	+VE	**N**	6	6	0.0	1.0
		%	10.0%	16.7%		
Contraception	**-VE**	**N**	5	16		
		%	16.7%	53.3%		
	+VE	**N**	25	14	8.86	**0.003***
		%	83.3%	46.7%		
Medical past history	**-VE**	**N**	28	26		
		%	93.3%	86.7%		
	+VE	**N**	2	4	0.74	0.38
		%	6.7%	13.3%		
Surgical past history	**-VE**	**N**	24	22		
		%	80.0%	73.3%		
	+VE	**N**	6	8	0.37	0.54
		%	20.0%	26.7%		
Family history diabetes	**-VE**	**N**	7	22		

		%	23.3%	73.3%		
	1ST degree	**N**	17	5	15.3	**<0.001****
		%	56.7%	16.7%		
	Relative	**N**	6	3		
		%	20.0%	10.0%		

In this table study group had significantly higher contraception percentage (83.3%) than controls (46.7%) (p=0.003). Also study group had higher family history of diabetes than controls (p<0.001).

Table 3: Obstetric characters distribution between groups

			Group		X^2	P
			Study (N=30)	**Control (N=30)**		
Mode of delivery	**CS**	**N**	21	16		
		%	70.0%	53.3%		
	Vaginal	**N**	9	14	1.76	0.18
		%	30.0%	46.7%		
		%	80.0%	100.0%		
Intra operative blood transfusion	**+VE**	**N**	1	2		
		%	3.3%	6.7%		
	-VE	**N**	29	28	0.35	0.55
		%	96.7%	93.3%		
Intraoperative complication	**+VE**	**N**	2	1		
		%	6.7%	3.3%		
	-VE	**N**	28	29	0.35	0.55
		%	93.3%	96.7%		

In this table there was no significant difference or association between groups

Table 4: Fetal outcome distribution between groups

			Group		t/X^2	P
			Study (N=30)	**Control (N=30)**		
Fetal weight	Mean ±SD		3850.0±513.7	3396.6±334.7	4.049	**<0.001***
Fetal sex	**Male**	**N**	13	14		
		%	43.3%	46.7%		
	Female	**N**	17	16	0.067	0.79
		%	56.7%	53.3%		
Fetal complication	**No**	**N**	17	29		
		%	56.7%	96.7%		
	LGA	**N**	10	0		
		%	33.3%	0.0%	31.32	**0.00****
	Premature	**N**	1	0	17.13	**0.002***
		%	3.3%	0.0%	1.66	**0.21**
	Neonatal death	**N**	0	1		
		%	0.0%	3.3%	1.66	**0.21**
	Shoulder dystocia	**N**	2	0		
		%	6.7%	0.0%	4.88	**0.02***
NICU admission	**Yes**	**N**	13	1		
		%	43.3%	3.0%		
	No	**N**	17	27	8.52	**0.004***
		%	56.7%	90.0%		

*Abbreviations: **LGA**, large for gestational age; **NICU**, neonatal intensive care unit.*

Table 4 showed that fetal weight was significantly higher among study group (3850.0±513.7) than controls (3396.6±334) (p<0.001). Fetal complications LGA, premature and shoulder dystocia were significantly higher among study group than controls. NICU admission was significantly higher among study group (43.3%) than controls (10%) (p=0.004).

Table 5: Marker distribution between groups

	Study (N=30)	**Control** (N=30)	t	P
FBG (12-16 weeks) 75g oral glucose load	82.63±6.27	79.62±6.83	1.765	**0.083**
FBG (12-16 weeks) 75g oral glucose load 1H	163.2±8.33	147.5±11.58	6.027	**0.00****
FBG (12-16 weeks) 75g oral glucose load 2H	134.06±8.9	138.56±8.08	-2.049	**0.045***
FBG (24-28 weeks) 75g oral glucose load	105.83±6.7	75.66±6.64	17.394	**0.00****
FBG (24-28weeks) 75g oral glucose load 1H	195.56±9.75	140.76±10.74	20.691	**0.00****
FBG (24-28) weeks 75g oral glucose load 2H	166.66±7.39	132.06±8.77	16.520	**0.00****
HbA1c	7.19±0.48	5.76±0.35	13.052	**0.00****
GA (12-16 weeks)	12.99±0.7	13.08±1.02	-0.432	**0.667**
GA (24-28 weeks)	13.84±0.89	13.2±1.01	2.587	**0.012***
GA (36-38 weeks)	14.88±0.82	12.63±0.97	9.634	**0.00****

*Abbreviations: **FBG**, fasting blood glucose; **GA,**glycated albumin.*

In this table, FBG (12-16 weeks) 75g oral glucose load 1H,

FBG (12-16 weeks) 75g oral glucose load 2H,

FBG (24-28 weeks) 75g oral glucose load,

FBG (24-28 weeks) 75g oral glucose load 1H,

FBG (24-28 weeks) 75g oral glucose load 2H,

HbA1c, GA (24-28 weeks) and GA (36-38 weeks) were significantly higher among study group than control group.

Table 6: Correlations between GA at each time and birth weight

		GA at 12-16	GA at 24-28	GA at 36-38
Birth weight	r	0.143	0.362	0.571
	P	0.274	0.004**	0.000**

Abbreviations: ***GA,****glycated albumin.*

This table found significant positive correlation between GA from 24-28 weeks till 36-38 weeks and birth weight.

Table 7: Relation between fetal complication and GA at each time

	Study Group	Study Group		
	No complication	Fetal complication	T	P
GA 12-16	**12.96±0.88**	**13.28±0.83**	**-1.182**	**0.242**
GA 24-28	**13.27±0.89**	**14.33±0.93**	**-3.809**	**0.00****
GA 36-38	**13.32±1.25**	**15.21±1.02**	**-5.120**	**0.00****

Table 6 showed that GA was significantly higher among complicated cases in the study group at 24-28 weeks and 36-38 weeks.

Table 8: Validity of marker cutoffs regards study group

Test Result Variable(s)	Area	Cutoff	P	95% Confidence Interval		Sensitivity	Specificity
				Lower Bound	**Upper Bound**		
FBG (12-16 weeks) 75g oral glucose load 1H	**0.849**	**155.500**	**0.00****	**0.754**	**0.944**	**78.5%**	**77.6%**
FBG (24-28 weeks) 75g oral glucose load 1H	**1.000**	**172.500**	**0.00****	**1.000**	**1.000**	**100.0%**	**100.0%**
GA (24-28 weeks)	**0.683**	**13.400**	**0.015***	**0.548**	**0.819**	**82.0%**	**72.0%**
GA (36-38 weeks)	**0.959**	**13.900**	**0.00****	**0.915**	**1.000**	**97.5%**	**87.7%**

Abbreviations: ***FBG****, fasting blood glucose;* ***GA,****glycated albumin.*

*Significant area under curves with good validity of all markers

In this table FBG 12-16 weeks 75g oral glucose load 1H more than 155.5 had sensitivity of 78.5% and specificity of 77.6% for GDM. FBG 24-28 weeks 75g oral glucose load 1H more than 172.5 had sensitivity of 100% and specificity of 100% for GDM. GA 24-28 weeks more than 13.4 had sensitivity of 82% and specificity of 72% for GDM. G A36-38 weeks more than 13.9 had sensitivity of 97.5% and specificity of 87.7% for GDM.

Table 9: Validity of GA cutoffs regards fetal complication

Test Result Variable(s)	Area	Cutoff	P	95% Confidence Interval		Sensitivity	Specificity
				Lower Bound	Upper Bound		
GA 24-28 weeks	0.872	14.150	**0.00****	0.735	1.000	83.7%	88.0%
GA 36-38 weeks	0.878	14.450	**0.00****	0.778	0.979	85.0%	88.0%

Abbreviations: ***GA,****glycated albumin.*

*Significant area under curves with high validity

In this table GA 24-28 weeks more than 14.15 had sensitivity of 83.7% and specificity of 88% for prediction of fetal complication. GA 36-38 weeks more than 14.45 had sensitivity of 85% and specificity of 88% for prediction of fetal complication.

IV. Discussion

This prospective cohort study included 230 pregnant women at 12-16 wks of gestation. Only 60 of the participants completed the study, they were divided into two groups (the normal group as a control group and the GDM group as a study group), according to the OGTT results.

The present retrospective analysis of prospectively collected data has shown that the GA levels were significantly higher after 24 weeks of gestation in the GDM group compared with controls. We also observed that elevated GA levels had a positive correlation with birth weight.

This is in agreement with **Li et al., [(5)]** study which found significant positive correlation between GA levels and the incidence of babies with birthweights ≥3,500 g, and macrosomia in GDM women with poor glycemic control.

Additionally, we found that the GA levels decreased as pregnancy progressed without GDM and increase with GDM with significant difference at 24-38 week. These results show that the GA levels could directly reflect the severity of glucose tolerance impairment for GDM women, and could be a useful marker for monitoring short-term glycemic status. However, these suggest that BMI and gestational age should be considered as the complicating factors when we assessed the validity of GA in controlling for GDM.

Hiramatsu et al., [6] showed similar changes of GA levels, which gradually decreased as pregnancy progressed toward the third trimester, in healthy pregnant women. One of the reasons, why GA decreases from early to late pregnancy is considered to be the decrease in plasma glucose levels.

In the present study, fetal weight was significantly higher among study group (3850.0±513.7) than controls (3396.6±334) (p<0.001). Fetal complications LGA, premature and shoulder dystocia were significantly higher among study group than controls. NICU admission was significantly higher among study group (43.3%) than controls (10%) (p=0.004).

In the present investigation, however, and contrary to what was found with glycated albumin, HbA1c only showed association with large-for-date status. ***Swierzewska et al.,*** [7] reported HbA1c concentration in late pregnancy (36–38 weeks) to be a good predictor of neonatal hypoglycemia in pregnant women with overt diabetes and GDM.

In our study GA24_28 more than 13.4 had sensitivity of 82% and specificity of 72% for GDM. GA 36_38 weeks more than 13.9 had sensitivity of 97.5% and specificity of 87.7% for GDM.

In agreement with ***Mendes et al.,*** [4] study in which the performance of glycated albumin and fructosamine as predictive factors of at least one neonatal complication and of respiratory disorders in infants of mothers with GDM was quite similar. They were also similar in their association with LGA newborns. Glycated albumin and fructosamine performed better than HbA1c for these purposes.

Li et al., [5]study further identified the value of a GA ≥11.60% level, which was derived from the ROC curve, as the cut-off point for identifying poor glycemic control in GDM women, and provided the optimal sensitivity (75.93%) and specificity (86.36%).

Meanwhile, the present study also found that in GDM women, GA 24_28 weeks more than 14.15 had sensitivity of 83.7% and specificity of 88% for prediction of fetal complication. GA 36_38 weeks more than 14.45 had sensitivity of 85% and specificity of 88% for prediction of fetal complication.

Similar to **Li et al.,** [5]study which found that the risks of birth weight ≥3,500 g and macrosomia increased significantly with GA levels ≥13.0 and ≥14.0%, respectively, during 24–28 weeks of gestation. Furthermore, the incidence of macrosomia in GDM women with GA levels ≥12.0% was increased at 36–38 weeks of gestation. It could also have an impact on screening and detecting birthweight ≥3,500 g and macrosomia.

In clinical practice, birthweight ≥3,500 g predicts an increased risk of a difficult vaginal delivery, and macrosomia is the strongest risk factor for maternal/fetal birth injuriesand increases the risk of obesity, and cardiovascular diseases in the offspring. No single measure was clearly superior in predicting macrosomia. When the GA measures were analyzed as continuous variables, GA levels ≥12.0% at 36–38 weeks of gestation were highly predictive of macrosomia***(8).***

In 2018, the GA Study Group of the Japanese Society of Diabetes and Pregnancy, that set the upper limit of normal HbA1c and GA in pregnant diabetic women in 5.7 and 15.7%, respectively, reported that the incidence of large-for-gestational-age infants was significantly higher in the group of women with GA >15.7%. However, there was no increase in the incidence of large-for date status when HbA1c >5.7% ***(3).***

V. Conclusion and Recommendations

In conclusion, GDM women had greater GA levels than normal pregnant women. There was a significant positive correlation between the GA levels and blood glucose, and the severity of GDM. GA can be used to assess glycemic control in GDM women during the second and third trimester of pregnancy.

We recommend GA level ≥13.9% as the cut-off point for poor glycemic control in GDM.

The regular monitoring of GA of these women (once/3–4 weeks) helps to reduce the frequency of SMBG, thereby to lower healthcare costs, and increase patient compliance.

In addition, in GDM women, the risk of macrosomia significantly increases when the GA levels are ≥14.45% in the third trimester.

The results reported in the present study provide strong support for the use of GA measurements, as a complement to finger stick glucose, for assessing short-term glycemic control and predicting large birth weight in the GDM women.

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