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Effect of Gestational *Diabetes mellitus* Health Education Module on Pregnancy Outcomes

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Abstract: Women with Gestational *Diabetes mellitus* (GDM) are at high risk for maternal and neonatal complications including increased rate of preeclampsia, cesarean section delivery, neonatal Macrosomia, hypoglycemia, shoulder dystocia, premature birth, increased rate perinatal mortality and increased rates of admission to neonatal intensive care unit (NICU). The aim of this quasi-experimental research was to investigate the effect of health education module on maternal and neonatal outcomes among gestational diabetes women. Purposive sample with a total of 150 pregnant women diagnosed with gestational diabetes were recruited. The pregnant women were divided randomly to the line of management into study and control groups (75 each). Study group, received the routine care plus the health education module and control group received the routine care only. The research was carried out in two health settings: a) Antenatal outpatient clinic; and b) postpartum unit, both were located at El-Manial Educational University Hospital. Tools of data collection were: A Structured Interviewing schedule; Maternal Blood Glucose Levels & Anthropometric Measurements Follow-up record; Postpartum Maternal Assessment record; and Neonatal Assessment record. Results indicated a decrease in the Mean random blood glucose levels after 2 weeks & at 37 weeks' gestation after intervention in the study than in control groups ($p < 0.001$). Also, results revealed a statistically significant difference was found between both groups in relation to the effect of the health education module on Mean body weight and Mean Body Mass Index (MBI) at 37 weeks' gestation which was significantly decreased in the study group than in control group ($p=0.004$ & 0.001 respectively). The results indicated that polyhydramnios, preterm labor, pregnancy induced hypertension, premature rupture of membranes and vaginal infection were the most common pregnancy complications with higher percentages in the control group than in study group. The results revealed a highly statistically significant difference between study and control groups in relation to mode of delivery that more than two-thirds of women in the control group had cesarean section deliveries. Statistically significant differences were found between two groups regarded to Neonatal Mean Apgar score at 1st & 5th minutes ($p=0.001$, & 0.011 respectively). Statistically significant difference was found between two groups regarded to Neonatal maturational assessment using the 10^{th} & 90^{th} percentile assessment chart ($p=0.001$). Statistically significant difference was found between two groups as regarded to neonatal complications ($p=0.001$) Also statistically significant differences were found between two groups regarded to the insulin & the c-peptide levels ($p=0.001$). This research concluded that pregnant women with GDM who received the gestational diabetes health education module had better maternal & neonatal outcomes than those who did not. This research recommended that, Antenatal screening of GDM is very important as it is a risk factor for the development of type 2 diabetes mellitus later in life and its related maternal and fetal/neonatal complications.

Key words: Gestational *Diabetes mellitus* · Maternal Outcome · Neonatal Outcome

INTRODUCTION

Gestational *diabetes mellitus* (GDM) is defined as glucose intolerance that begins or first recognized during pregnancy [1]. Depending on the population sample and diagnostic criteria, the prevalence may range from 1 to 14% [2]. Of all pregnancies complicated by diabetes, GDM accounts for 90%. GDM affects 3-9% of all pregnancies, resulting in > 200,000 cases per year [3]. GDM is especially common during the last third trimester of pregnancy, it affects 1% of those under the age of 20 and 13% of those over the age of 44 [4].

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Moreover, Pregnancy is a diabetogenic condition characterized by insulin resistance with a compensatory increase in â-cell response and hyperinsulinemia. Insulin resistance usually begins in the second trimester and progresses throughout the remainder of the pregnancy. Insulin sensitivity is reduced by as much as 80% [5]. Placental secretion of hormones, such as progesterone, cortisol, placental lactogen, prolactin and growth hormone, is a major contributor to the insulin-resistant state seen in pregnancy. The insulin resistance likely plays a role in ensuring that the fetus has an adequate supply of glucose by changing the maternal energy metabolism from carbohydrates to lipids [6].

In addition, women with GDM have a greater severity of insulin resistance compared to the insulin resistance seen in normal pregnancies. They also, have an impairment of the compensatory increase in insulin secretion, particularly first-phase insulin secretion, this decrease in first-phase insulin release may be a marker for deterioration of â-cell function [6].

There have been controversies on the screening and treatment of GDM; however, recent reports have shown the importance of universal screening and treatment in communities with a high prevalence of GDM [7]. Following the results of the study of hyperglycemia and adverse pregnancy outcome, a consensus on the diagnosis and screening of hyperglycemia in pregnancy was reached by representatives of 10 international organizations; the International Association of Diabetes and Pregnancy Study Group (IADPSG) and the recommendations included the use of a 2-h 75 g oral glucose tolerance test for all pregnant women between 24 and 28 weeks of pregnancy to screen and diagnose GDM [8].

The advantage of the recommendations of the IADPSG over previously suggested criteria for the diagnosis of GDM is that they are linked to the risk of adverse pregnancy outcome rather than the diagnosis of diabetes outside pregnancy. However, with the new criteria for diagnosis, the number of women diagnosed with GDM will increase considerably [9]. Following the diagnosis of GDM, normalization of maternal blood glucose by nutritional regiments and insulin if needed, is of paramount importance to prevent the complications of GDM [10].

The factors that have been postulated to influence the risk of GDM among mothers include higher parity, advanced maternal age, obesity, family history of diabetes, treatment for infertility, recurrent urinary tract infections, macrosomic infant, unexplained neonatal death, prematurity, pre-eclampsia and diabetes in previous pregnancy [11]. In addition, the adverse effect of GDM on pregnancy is caused by maternal hyperglycemia, which stimulates fetal hyperinsulinemia, with subsequent increased and abnormal fat distribution in the fetus [8].

Moreover, women with GDM are at high risk for maternal and neonatal complications including increased rate of preeclampsia, cesarean section delivery, neonatal macrosomia, hypoglycemia, shoulder dystocia, premature birth, & increased rate perinatal mortality [12,13] and increased rates of neonatal intensive care unit (NICU) admissions due to hypoglycemia, macrosomia, respiratory distress syndrome (RDS), jaundice, polycythemia, electrolyte imbalance & birth trauma [14]. Additionally, women who are affected by GDM have more than a 7 times increased risk of developing type 2 diabetes 5 to 10 years later [15].

The association between GDM and perinatal mortality has been more controversial. Several studies have concluded that the rate of perinatal mortality (Including stillbirths and neonatal deaths) was increased in women with GDM in the past [16]. However, recent studies have shown that, with the combination of increased antepartum monitoring, medical nutrition therapy (MNT) and insulin therapy if needed, this difference in perinatal mortality rates is potentially avoidable [9].

Counseling before and during pregnancy and multidisciplinary management are important for good pregnancy outcomes [17]. Most women can manage their GDM with dietary changes and exercise. Self-monitoring of blood glucose levels can guide therapy. Some women will need antidiabetic drugs, most commonly insulin therapy. In addition, any diet needs to provide sufficient calories for pregnancy, typically 2,000 – 2,500 kcal with the exclusion of simple carbohydrates [18]. The main goal of dietary modifications is to avoid peaks in blood sugar levels; this can be done by spreading carbohydrate intake over meals and snacks throughout the day and using slow-release carbohydrate sources. Since insulin resistance is highest in mornings, breakfast carbohydrates need to be more restricted, ingesting more fiber in foods with whole grains, or fruit and vegetables can also reduce the risk of gestational diabetes [19].

The role of the maternity nurses are focusing on the prevention as well as reduction of the complications that may have direct influence on women during antenatal, perinatal & postnatal periods and their infants by providing the health information to help them to comply with the diet regimen and with the treatment throughout

their pregnancy period. In addition, health care professionals' especially maternity nurses should empower women at risk for developing diabetes during pregnancy to make this experience a positive one by providing information, advice and support that will help to reduce the risks of adverse pregnancy outcomes for mother and baby. Women are at risk of developing diabetes and planning to become pregnant should be informed to establish good glycemic control before conception and throughout pregnancy to reduce the future risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated [20].Therefore this research was carried out to investigate the effect of health education module on maternal and neonatal outcomes among gestational diabetes women.

Significance of the Research: Gestational *diabetes mellitus* (GDM) affects a significant number of women each year and is associated with a wide range of adverse outcomes for women and their babies [18]. Dietary counseling is the main strategy in managing GDM, but it remains unclear and controversy which dietary therapy is the best. Also, the mainstay of treatment of GDM remains nutritional counseling and dietary intervention. The optimal diet should provide caloric and nutrient needs to sustain pregnancy without resulting in significant postprandial hyperglycemia. Women with GDM in most cases can receive dietary instruction and selfblood glucose management teaching in an outpatient setting [19]. Numerous research studies in the general population have shown that adoption of healthy lifestyles (e.g. healthy diet, exercise, weight loss) can prevent Diabetes Mellitus (DM); however, there are limited researches which focus on healthy lifestyle behavior in women with GDM [21].

There is paucity of information on the standard of health services provided to diabetic pregnant women in Egypt in addition to lack of national guidelines for the screening and treatment of diabetes during pregnancy. It is unfortunate that nutritional management, the cornerstone of treatment of GDM, is understudied. There are scarce studies that evaluate the effect of GDM health education module on the pregnancy outcome, Nankervis and Conn [22] that encouraged lifestyle changes which include optimal nutrition and controlling weight gain. The effectiveness of diet can be monitored by measuring weight and self-monitoring of blood glucose levels. Also, exercise can be helpful in lowering blood glucose levels. The most acceptable form of exercise for most women is walking in their normal daily routine.

Aim of the Research Study: This study aimed to investigate the effect of health education module on maternal and neonatal outcomes among gestational diabetes women

Research Hypotheses:

- Gestational diabetes women who receive health education module will have better maternal outcomes than those who will not.
- Gestational diabetes women who receive health education module will have better neonatal outcomes than those who will not.

MATERIAL AND METHODS

Research Design:

- Non-equivalent two groups' quasi-experimental design was adopted to evaluate the effect of GDM health education module among women with gestational diabetes mellitus on pregnancy outcomes.

Setting: The study was carried out in two health settings: A) Antenatal outpatient clinic; and B) postpartum unit. Both settings were located at El-Manial Educational University Hospital, which provides free healthcare services to obstetrics & gynecologic clients.

Sample: Purposive sample with a total 150 pregnant women diagnosed with gestational diabetes were recruited according to the following inclusion criteria; gestational age between 28-32 weeks, having singular pregnancy and aged between 25-35 years old. The exclusion criteria included women with type 1 and type II diabetes mellitus, history of chronic diseases such as chronic hypertension, using medications that increase blood glucose such as corticosteroids. The pregnant women were divided randomly to the line of management into study and control groups (75 each). Study group, received the routine care plus the health education module and control group received the routine care only. The sample size was determined by using the rule of sum (sum of the study variables and multiply by constant).

Data Collection Tools: Four tools were designed and filled by researchers to collect the required data for this research:

Structured Interviewing Schedule: it elicited data related to personal characteristics and obstetric profile of the women in both groups as; age, education, gestational age

and current pregnancy complications as pregnancy induced hypertension, vaginal infection, antepartum hemorrhage, etc.

Maternal Blood Glucose Levels & Anthropometric Measurements Follow-up Record: random blood glucose levels for both groups were examined. The first blood sample was taken at 28 -32 weeks' gestation, the second blood sample was taken after two weeks from the first one and the third sample was taken at 37 weeks' gestation. The blood samples were taken by the researchers and transferred to lab by woman' code number. Also, anthropometric measurements as weight, height and body mass index (BMI) for both groups were assessed during the first interview (Baseline) and at 37 weeks' gestation.

Postpartum Maternal Assessment Record: (Filled within two hours after delivery): it included data related to mode of delivery, labor complications such as preterm labor, premature rupture of membranes, prolonged second stage of labor, birth canal injury and bleeding during third stage of labor and postpartum complications.

Neonatal Assessment Record: it included four parts: a) Apgar score (In 1st &5th mint.); b) Neonatal gestational age Assessment Chart (Tenth and ninetieth percentile); c) Neonatal complications and d) Assessment of insulin and cord C-peptide levels.

Apgar score was designed in (1966) by Apgar [23]. It was used at first and fifth minutes after delivery. It included heart rate, respiratory effort, muscle tone, reflex irritability and color of the newborn skin. The results were utilized to evaluate the newborn's Cardio-respiratory adaptation after birth. The total score ranged from 0 to 10 and each sign was given a score of 0, 1 and 2. Apgar score of 8 to 10 indicated that the neonate in a good condition. Apgar score of 4 to 7 indicated mild asphyxia that required more vigorous stimulation of breathing. A score of 0 to 3 indicated severe depression that required immediate intubation and bag ventilation.

Neonatal gestational age Assessment Chart (Tenth and ninetieth percentiles) developed by WHO [24]: it included assessment of the neonatal Anthropometric measurements as weight, height, head & chest circumference and plotted their results on the chart and compared them by using of curve at tenth and ninetieth percentile on the growth chart to determine if the neonate appropriate for gestational age (AGA), small for gestational age (SGA) or large for gestational age (LGA) macrocosmic baby

Neonatal complications as stillbirth, respiratory distress, preterm baby, congenital anomalies and admission to neonatal intensive care unit (NICU).

Assessment of insulin and C-peptide levels through cord blood specimen, collected by the researchers immediately after delivery from the umbilical cord.

Ethical Consideration: An official permission was granted from the administrative personnel in the two selected health settings for data collection. The researchers explained the aim of the study to the women and informed them that the information obtained will be confidential and their participation was in a voluntary base. A written Informed consent was taken from women to obtain their acceptance to participate in the research.

Tool Validity: Validation of the tool was done through submission to the panel of 5 experts in the field. Modifications were carried out according to the experts' judgments on the clarity of sentences and the appropriateness of content.

Pilot Study: It was conducted on 10% of the sample to ensure clarity of the questions and to detect ambiguity and estimate the time required to fill the questions in each tool. Subjects who participated in the pilot study were excluded from the actual study.

Procedure: Data were collected through a period of six months (March-August, 2015). Data were collected through five phases: interviewing, assessment, implementation, follow-up phase and evaluation phase.

Interviewing Phase: Interviewing was carried out using interviewing questionnaire schedule for both study and control groups at antenatal outpatient clinic. The researchers identified themselves to the women and explained the study, its importance, aim, benefits and the procedures to be performed. Women who were willing to participate in the study and met the inclusion criteria were approached by the researchers. The time needed for completing the questionnaire was 10 minutes for each woman.

Assessment Phase: After interviewing data was obtained, Random Blood Glucose (RBG) samples were collected from women in both groups and transferred to the lab, & results were documented as baseline assessment and anthropometric assessment was carried out to women in both groups, that the researchers assessed height & weight and calculated BMI through the formula "woman's

weight in Kilogram divided by height squared in meter (BMI= Kg/m^2)" [25] and the researchers categorized women's body mass index values as, BMI<18.5 kg/m2 (Underweight); BMI of 18.5-24.9 kg/m2 (Normal weight); BMI of 25-29.9 kg/m2 (Overweight); BMI of 30-34.9 kg/m2 (Obesity- class- I); BMI of 34.9-39.9 kg/m2 (Obesity-class- II); and BMI greater than or equal to 40 kg/m2 (Severe or morbid obesity).

Implementation Phase: The researchers introduced health education module for the study group only, while, the control group received the routine care. The health education module was developed and prepared by the researchers after extensive review of updated literature and guided by the NICE [20]. It included all items related to Gestational Diabetes as the definition, risk factors, sings & symptoms, maternal risks, fetal-neonatal risks; antepartum care, included instruction related to eating a high-fiber, low-sugar diet, reduced the total intake of sugars and starches and replaced them with Fruits and vegetables. Also, ate whole grains, enough protein, however, foods high in polyunsaturated fatty acids and fatty foods were avoided. Women should practice exercise as walking half an hour daily, trained about self blood glucose measure and how to apply insulin. The module was carried out in the form of individualized health education sessions and each woman was given a chance to share her opinion and asked questions. Handout booklet in Arabic version was used to facilitate the process of education.

Follow-up Phase: Each woman was informed to come after two weeks to the clinic to re-measure the random blood glucose level (BGL) and asked to come again at 37 weeks' gestation to re-measure BGL as an indicator to assess the effect of the module on normalizing BGL. At the same time women's weight was reassessed to calculate the BMI to follow-up the pattern of weight gain and the effectiveness of the module on decreasing body weight. Also, women were followed up for the pregnancy progression and the development of any complications, utilizing maternal blood glucose Levels and anthropometric measurements Follow-up record.

Evaluation Phase: Evaluation of maternal condition was performed within 2 hours after delivery related to the development of any complications as prolonged second stage of labor, birth canal injury and bleeding during third stage of labor utilizing Postpartum Maternal Assessment record. Evaluation of neonatal condition was carried out through Neonatal Assessment record, which included (Apgar scoring, Neonatal Gestational Age Assessment Chart (Tenth and ninetieth percentile) and Neonatal complications were assessed.

Apgar score for 1st & 5th minutes was evaluated and its results were recorded. In case of low Apgar score at fifth minute (Less than 7) the researchers made a report for specialist. Resuscitative measures have been taken as suctioning; oxygen administration, endotracheal intubation and admission to NICU were recorded by researchers and the cause of admission. The anthropometric measurements as (Length, weight, head and chest circumference) were assessed within 2 hours after delivery, that the researchers measured neonates' weights when they quiet and unclothed. Also, they measured neonates' length from head to toe when the neonates in supine position and legs extended. Then, measured head circumference by applying measurement tape firmly around head above the eyebrow ridge. The researchers plotted neonate' weight, length and head circumference by gestational age on the chart, to determine if the growth below 10th percentile, the neonate was small for gestational age (SGA), if the growth above the 90th percentile, the neonates was large for gestational age (LGA) called macrosomic baby, if the growth in between 10th and 90th percentiles, the neonates was appropriate for gestational age (AGA).

Statistical Analysis: Data were entered and statistically analyzed by using statistical package for the social sciences (SPSS) software program version 20. Data were summarized and tabulated by using descriptive statistics. Parametric inferential statistics (independent sample t-test and Chi- square test) was used to examine the differences and similarities. The level of significance was set at $p < 0.05$.

RESULTS

Section 1: Description of the Sample:
it Included Five Parts
Demographic Characteristics:

The age range of the women was 25-35 years old. The mean age of women in the study and control groups was (28.4± 2.97 & 29.3±3.6 respectively). There was no statistically significant difference found between two groups (p=0.357). Regarding to the level of education, 33.4 % of women in the study group vs. 34.7% women in the control group cannot read and write; 29.3% in the study group vs. 34.7 % in the control group had secondary education. There was no statistically significant difference found between two groups (P= 0.431).

Base Line (RBGL) and Anthropometric Measurements Assessment: Mean random blood glucose levels at the baseline assessment was (114.3± 10.7; &128.7±14.8 respectively) for both study and control groups with no statistically significant difference found between them (p= 0.745). Women's height was ranged from 150 – 180 cm with the mean height of 161 ± 5.92 cm. in the study group, as compared with 161 ± 6.64 cm. in the control group. Women's Weight was ranged from 80-100 kg with the mean weight of (81.230 ±15.415) Kg. in the study group, as compared with (81.480±15.890) Kg. in the control group. There was no statistically significant difference found between two groups (P=0.612). Mean Body Mass Index (BMI) was (31.026±5.879 & 31.148 ±5. 471 kg/m^2 respectively) for both study and control group. There was no statistically significant difference found between two groups (p=0.571) (Table 1).

Obstetric Profile: Results revealed that 72% of women in the study group vs. 85.4 % in the control group were multiparous, there was a statistical significant difference found between two groups (P=0.027).

Pregnancy Complications: Results of this research revealed that 45.3 % of women in the study group vs. 81.3 % in the control group had complications such as premature rupture of membranes (PROM), pregnancy induced hypertension (PIH), antepartum hemorrhage, polyhydramnios and vaginal infection, (26.5, 14.7, 14.7, 26.5, &17.6% respectively) in the study group, as compared with (26.3, 16.3, 9.8, 24.6 & 23% respectively) in the control group. A statistically significant difference was found between two groups (P=0.001) (Table 2).

Section 2: Effect of the Health Education module on Blood Glucose Level & Anthropometric Measurements.

Results revealed that Mean random blood glucose levels at two weeks after intervention in the study group was (102.4± 13.4) compared to the control group (132.3± 15.4) and was (106.6±11.4 & 142.1± 12.6 respectively) at 37 weeks' gestation. There was a statistically significant difference found between study and control groups (p < 0.001). (Table 3).

Results showed that Mean body weight at 37 weeks' gestation in the study and control groups was) 81.560±15.155 & 85.90±14.105Kg, respectively), with statistically significant difference found between both groups in relation to the effect of the health education module on body weight (p=0.004). While, mean BMI at 37 weeks gestation in the study and control groups was (31.136± 5.565 & 34.215±4.210 Kg/m2 respectively), with a statistically significant difference found between them (p=0.001) (Table 4).

Section 3: Effect of Health Education Module on pregnancy outcomes:

Maternal Outcome in the Present Labor and Delivery: it included data related to Gestational age at the time of delivery, mode of delivery, labor and delivery complications. The range of gestational age at the time of delivery was 33-40 weeks' gestation in the study group and 29-41 weeks' gestation in the control group with mean of (38.920 ±1.8655 & 37.95 ± 2.382) respectively with statistically significant difference found between two groups (p=0.02). Thirty-four point seven percent of women in the study group vs. 5.3% of women in the control group had normal vaginal delivery, 41.3% of them in the study group as compared with 14.7% of the control group had vaginal delivery with episiotomy while, 24% in the study group vs. 80% in control group delivered by cesarean section. There was a statistically significant difference found between two groups (P= 0.001). Results revealed that 24% of women in the study group vs. 41.3% in the control group had complications during labor such as prolonged second stage, birth canal injury and preterm labor (33.3, 22.2, & 44.5% respectively) as compared with (35.5, 25.8, & 38.7% respectively). There was a statistical significant difference found between two groups (p=0.001) (Table 5).

Neonatal Outcome of the Current Delivery: It included four parts: 1) Apgar score (1st &5th mint.); 2) neonatal gestational age assessment; 3) neonatal complications and 4) Assessment of insulin and C-peptide levels.

The mean Apgar score of the neonates at the first minute after delivery was 8.10±1.04 & 6.67±0.83 in study and the control groups respectively. A statistically significant difference was found between two groups (p=0.001). While the mean Apgar score of the neonates at the fifth minute after delivery was 8.53±1.20 & 7.89 ±1.61 in the study and control groups respectively. A statistically significant difference was found between two groups (p=0.011) (Table 6). Results revealed that, 77.1 % of the neonates in the study group received routine immediate care including nasopharyngeal suction and oxygen near face (No need for resuscitation), as compared with 62.1% in the control group, while, 14.3 % of them in the study group needed close observation and received oxygen mask & endotracheal suctioning as compared with 22.7 % in the control group. However, 8.6% of the neonates in the study group required endotracheal

intubation and ambo-bagging (Need resuscitation) and needed more careful observation as compared with 15.2 % in the control group. A statistical significant difference was found between two groups (p=0.01) (Table 7). Regarding to admission to neonatal intensive care unit (NICU), 5% of neonates in the study group were admitted to NICU from 1 to 4 days as compared with 13.3 % in the control group. The cause of admission to NICU was respiratory distress syndrome. There was a statistical significant difference found between two groups (p= 0. 001). Regarding neonatal gestational age assessment, the mean neonatal length in the study group was 48.7±3.45 cm. as compared with 48.6±2.19 cm in the control group, with no statistically significant difference found between two groups (p= 0.43). The mean neonatal head circumference in the study group was 33.6 ±1.19 cm. as compared with 33.7±1.98cm in the control group, with no statistically significant difference found between two groups (p=0.25). While the mean weight in the study group was 2.96±0.42 kg as compared with 4.23±0.88 kg in the control group with statistically significant difference found between two groups (p=0.013) (Table 8). Neonatal maturational assessment using the 10^{th} & 90^{th} percentile assessment chart indicated that, 94.6% in the study group as compared with 34.9% of the women in the control group had babies who were appropriate for gestational age between (10^{th} & 90^{th} percentile), 4% in the study group vs. 4.5% in the control group had babies who were small for gestational age (Below 10^{th} percentile), while, 1.4% in the study group as compared with 60.6% in the control group had babies who were large for gestational age "Macrosomic baby" (Above 90^{th} percentile). There was a statistically significant difference between two groups (p=0.001) (Table 9).

Regarding Neonatal Complications at birth, 20% of women in the study group had neonatal complications as compared with 37.3% in the control group such as respiratory distress, stillbirth, congenital anomaly & intrauterine fetal death (IUFD) (53.3, 26.7, 13.3, & 6.7% respectively), as compared with (60.7, 21.4, 7.2, & 10.7% respectively) in control group (p=0.001) (Table 10).

Assessment of insulin and c-peptide levels, results revealed that 82.9% of neonates in the study group had insulin level within normal range as compared with 37.9 % of them in the control group, however, 7.1% of neonates in study group had hypoglycemia related to insulin level (>25 µU/mL), as compared with, 53 % in the control group. There was a statistically significant difference found between two groups (p=0.001). While, the c-peptide level, results revealed that 85.8 % of neonates in the study group had C-peptide level within normal range as compared with 42.4 % in the control, while 7.1 % of neonates in study group had hyperinsulinemia as compared with 53 % in the control group. There was a statistical significant difference found between two groups (p=0.001) (Table 11).

Table 1: Distribution of the Women in Both Groups by their Baseline Anthropometric Measurements Assessment

	Study group		Control group		
Baseline Anthropometric Measurements	X	SD ±	X	SD ±	P-value
Women's Weight by Kgm	81.230	15.415	81.480	15.890	0.612
Women's BMI by kgm/m^2	31.026	5.879	31.148	5. 471	0.571

Table 2: Distribution of the Women in Both Groups by their complications during current pregnancy

	Study Group N= 34		Control Group N=61		
Characteristics	Freq	%	Freq.	%	p-value
PROM	9	26.5	16	26.3	0.001
PIH	5	14.7	10	16.3	
Ante partum hemorrhage	5	14.7	6	9.8	
Polyhydramnios	9	26.5	15	24.6	
Vaginal infection	6	17.6	14	23	

Table 3: Distribution of the Women in Both Groups by their Blood Glucose Levels Follow-up

	Study group		Control Group		
Characteristics	X	SD ±	X	SD ±	p- value
Blood glucose level at baseline assessment (28-32 weeks) by mg/dl	114.3	± 10.7	128.7	±14.8	0.745
Blood glucose level after 2 weeks of intervention (by mg/dl)	102.4	± 13.4	132.3	± 15.4	< 0.001
Blood glucose level at 37 weeks' gestation	106.6	±11.4	142.1	± 12.6	< 0.001

Table 4: Distribution of the Women in Both Groups by their Anthropometric Measurements Assessment at 37 weeks' gestation

	Study group		Control group		
Anthropometric Measurements at 37 weeks' gestation	X	SD ±	X	SD ±	P-value
Women's Weight	81.560	15.155	85.90	14.105	0.004
Women's BMI	31.136	5.565	34.215	4.210	0.001

Table 5: Distribution of the Women in Both Groups by Their Delivery Complications.

	Study Group		Control Group		
Characteristics	Freq. 18	% 24	Freq. 31	% 41.3	p-value
Prolonged second stage	6	33.3	11	35.5	0.001
Birth canal injury	4	22.2	8	25.8	
Preterm Labor	8	44.5	12	38.7	

Table 6: Distribution of the Neonates in Both Groups by Their Apgar Score in 1st & 5th Minutes

	study Group		Control Group		
Characteristics	X	SD ±	X	SD ±	p-value
1st min. Apgar Score	8.10	1.04	6.67	0.83	0.001
5th min. Apgar Score	8.53	1.20	7.89	1. 61	0.011

Table 7: Distribution of The Neonates in Both Groups According to Apgar Score Outcomes

	Study Group N= 70		Control Group N=66		
Characteristics	Freq.	%	Freq.	%	p-value
No Need for Resuscitation	54	77.1	41	62.1	0.01
Need Close Observation (Oxygen &endotracheal suctioning)	10	14.3	15	22.7	
Need Resuscitation	6	8.6	10	15.2	

*There are one (1) Intrauterine Fetal Death & (4) stillbirth in tne study group and three (3) intrauterine death & (6) stillbirth in the control goup

Table 8: Distribution of the Neonates in Both Groups by Their Neonatal Anthropometric measurements

	Study Group		Control Group		
Characteristics	X	SD ±	X	SD ±	p-value
Length	48.7	3.45	48.6	2.19	0.43
Head circumference	33.6	1.19	33.7	1.98	0.25
Weight	2.96	0.42	4.23	0.88	0.013

Table 9: Distribution of the Neonates in Both Groups by Their Maturational assessment (10th &90th percentile)

	Study Group N=70		Control Group N=66		
Characteristics	Freq.	%	Freq.	%	p-value
Appropriate for gestational age (AGA)	66	94.6	23	34.9	0. 001
Small for gestational age (SGA)	3	4	3	4.5	
Large for gestational age (LGA)	1	1.4	40	60.6	

*There are one (1) Intrauterin Fetal Death & (4) stillbirth in tne study group and three (3) intrauterine death & (6) stillbirth in the control goup

Table 10: Distribution of the Neonates in Both Groups by Their Neonatal Complications

	Study Group		Control Group		
Neonatal Complications	Freq. (15)	% 20	Freq. (28)	% 37.3	p-value
Respiratory distress	8	53.3	17	60.7	0.001
Stillbirth	4	26.7	6	21.4	
Congenital anomaly	2	13.3	2	7.2	
Intrauterine Fetal Death (IUFD)	1	6.7	3	10.7	

Table 11: Distribution of the Neonates in Both Groups by Their Insulin and C-peptide levels

	Study (70)		Control (66)		
Characteristics	Freq.	%	Freq.	%	P
- Insulin					
Insulin < 2.6 µU/ml	7	10	6	9.1	0.001
Insulin from 2.6-25 µU/ml (Normal range)	58	82.9	25	37.9	
Insulin >25 µU/ml (Hypoglycemia)	5	7.1	35	53	
- C-peptide					
C-peptide <0.9 ng/ml	5	7.1	3	4.6	0.001
C-peptide 0.9-4.0 ng/ml (Normal range)	60	85.8	28	42.4	
C-peptide >4.0 ng/ml (hyperinsulinemia)	5	7.1	35	53	

*There are one (1) Intrauterin Fetal Death & (4) stillbirth in tne study group and three (3) intrauterine death & (6) stillbirth in the control goup

DISCUSSIONS

In this research the researchers attempted to find the effect of Gestational *Diabetes Mellitus* Health Education Module on Pregnancy Outcomes. The findings of this research study supported the two research hypotheses which are "Gestational diabetes women who receive health education module will have better maternal outcomes than those who will not" and "Gestational diabetes women who receive health education module will have better neonatal outcomes than those who will not".

The research findings indicated that there was statistical significant difference between study and control groups regarded to mean body weight & mean body Mass Index at base line assessment (Before intervention) as compared to at 37 weeks' gestation (After intervention) (p=0.004 & 0.001 respectively). This may be related to the women adherence to the nutritional counseling & dietary intervention; and the commitment with nutrient needs to ensure normal fetal growth, maternal health and optimal glycemic control. These findings are similar to a Randomized controlled trials study which was carried out by Muktabhant *et al.* [26] to evaluate the effectiveness of diet or exercise, or both interventions for preventing excessive weight gain in pregnancy, their Interventions involving low glycemic load diets, supervised or unsupervised exercise only, or diet and exercise combined, all led to similar reductions in the number of women gaining excessive weight in pregnancy, also, women who receiving diet or exercise, or both interventions were more likely to experience low weight gain than those in control groups. Moreover, a study carried out by Artal *et al.* [27] who assessed whether a weight-gain restriction regimen, with or without exercise, would impact glycemic control, pregnancy outcome and total pregnancy weight gain among subjects with gestational diabetes mellitus. Results showed that Weight gain per week was significantly lower in the exercise & diet (ED) group than in the diet (D) group (0.1 ± 0.4 kg vs. 0.3 ± 0.4 kg; $p < 0.05$). On the same line, A prospective cohort study carried out by Olson *et al.* [28] who assessed the efficacy of an intervention to prevent excessive gestational weight gain, found a significant reduced risk of excessive gestational weight gain (OR = 0.41, 95% CI = 0.20–0.81) in women who were enrolled in education programme about a healthy diet and exercise during pregnancy. However, Kinnunen *et al*. [29] studied 132 non-obese primiparous women, divided in an intervention group and a control group. The lifestyle counseling helped pregnant women to increase vegetable, fruit and fiber intake, but was unable to prevent excessive weight gain. Moreover, Verbeke and Bourdeaudhuij [30] found the same results in low-income women in a randomized design (Nutritional counseling vs. control). Although dietary behavior was significantly changed in the intervention group, this did not result in decreased weight gain.

Findings of this research indicated that there was statistical significant difference between study and control groups regarded to mean blood glucose levels at two weeks and 37 weeks' gestation after intervention (p=0.001). Women with GDM who received educational module about diet, exercise and changing lifestyle had decreased blood glucose levels than those who didn't. This may be related to well-balanced eating module aimed at supporting the pregnancy and promoting blood sugar control. Also, consistency in meal and snack timing as well as consuming a variety of nutrients offered through individualized meal planning, as this can help promote normal glycemia in pregnancy and improve maternal and fetal outcomes. These findings are in agreement with a randomized trial of the effects of dietary counseling on gestational weight gain and glucose metabolism in obese pregnant women with GDM carried out by Wolff *et al*. [31] who reported that women in the intervention group successfully limited their energy intake and restricted the

gestational weight gain to 6.6 kg vs a gain of 13.3 kg in the control group (P= 0.002, 95% confidence interval (CI): 2.6–10.8 kg); the fasting blood-glucose was reduced by 8% as compared with the control group (0.3 mmol l1, 0.6 to 0.0, P =0.03).

The research findings indicated that polyhydramnios, preterm labor, pregnancy induced hypertension, premature rupture of membranes and vaginal infection were the most common pregnancy complications with higher percentages in the control group that might be correlated to the effect of health education module received by the study group. This result is matched with Wang, *et al.* [32] who carried out a systematic review and compared outcomes between women who received treatment for GDM and those who not received. On the same line Landon *et al*. [33] reported that treatment of GDM compared with usual care was also associated with reduced rates of preeclampsia and gestational hypertension as well as optimizing maternal glycemic control in women with GDM decreases the risk of preeclampsia, fetal macrosomia, shoulder dystocia and Caesarean section.

The results revealed a highly statistically significant difference between study and control groups in relation to the effect of the GDM health education module on mode of delivery, that more than three quarters of the control group had cesarean section deliveries. This might be due to multiple factors such as macrocosmic baby and the fear from the risk of shoulder dystocia & birth trauma, failure of progress of labor, hospital routine recommended for previous cesarean section. These findings are congruent with Wang *et al*. [32] who reviewed incidence of adverse outcomes associated with gestational diabetes mellitus in low- and middle-income countries; they reported that in the Iranian study there was the highest rate of cesarean delivery (87.1%) in women with GDM. There are several possible explanations for these high rates, one of which is that cases of diabetes are diagnosed late or managed poorly. Moreover, these findings matched with Mylonas and Friese [34] who indicated that caesarean section (CS) was hence reserved for those diabetic women who had fetal Macrosomia, history of previous C-section or had more than one risk factor. In addition, on the same line with Gasim [35] who reported that, higher rate of CS in the GDM women associated with increased incidence of LGA for neonates.

Results of this research revealed that statistical significant differences were found between both groups regarded to complications during labor, as prolonged second stage, birth canal injury and preterm labor which were found with a higher percentage in the control group than in the study group (p=0.001). This results might be due to the interventions given to the study group that improve insulin sensitivity which may help prevent these complications. These findings are similar to the study carried out by Landon *et al*. [33] who found that cesarean delivery was less often performed in treated group (26.9%) as compared with control group (33.8%); a lower rate of shoulder dystocia in treated group (1.5%) as compared with in control group (4.0%) and lower rates of preeclampsia (8.6%) as compared with control group (13.6%). Moreover, results are at the same line with Cheng *et al.* [36] who reported that women diagnosed with GDM who had gestational weight gain exceeding 15 pounds had a higher risk of preterm delivery, Macrosomia and cesarean delivery. Also, Artal *et al.* [37] found that women with diet-controlled GDM who were obese had an increased risk for fetal Macrosomia compared with women of normal weight with GDM.

Results indicated that there was a statistically significant difference in relation to Apgar score at first and fifth minutes after delivery between two groups, this result might be due to higher rate of cesarean section in the control group in which the mechanical expulsion and squeezing of lung fluid through vaginal birth canal was not took place. Unfortunately this result is not congruent with the study of Gasim [35] and Sen and Sirin [38] who reported that, the Apgar scores at 1 and 5 minutes showed no significant difference between the two groups, this might reflect the routine policy of observation and care of these neonates at the hospitals and thus birth weight.

Concerning neonatal admission to neonatal intensive care unit NICU, the neonates of women in the control group were admitted to NICU from 1 to 4 days than in the study group. The causes of admission NICU were ranged from observation for a period of time didn't exceed 2 hours to admission due to respiratory distress syndrome. The result is matched with Srivastava *et al*. [39] who studied Evaluation of Adverse Effects of Hyperglycemia on Pregnancies in the Maternity Unit of Mafraq Hospital and found that 21 babies were admitted to NICU with different diagnoses.

The research results revealed that, the rate of LGA that related to Macrosomia as about two thirds of the neonates in the control group were above 90th percentile. There was a highly statistical significant difference in relation to effect of the education module on birth weight and anthropometric measurements. These results are matched with Gasim [35] who reported that, maternal

hyperglycemia is associated with potential risk factors included maternal age, parity, obesity and excessive somatic growth of the neonates which may affect anthropometric measurements of the neonates. Moreover, Vedavathi *et al.* [40] reported that fetal abdominal circumference (AC), fetal head circumference (HC) and fetal gestational weight (GW) > 90th percentile were found to be significantly high in GDM patients who followed the routine hospital care. Also, the results are matched with the study carried by Al-Khalifah *et al.* [14] who reported that, increase incidence of macrocosmic baby might be due to the effect of hyperglycemia leading to fetal overgrowth. Also, results are similar to the study done by Mitanchez *et al.* [41] who reported that the delivery of macrosomic infants is associated with a higher risk for adverse neonatal morbidity such as birth injury, respiratory distress and hypoglycemia

Regarding hypoglycemia and hyperinsulinemia according to insulin and C-peptide levels, during the first few hours of life occurred in neonates of GDM women. The research results revealed that, more than half of the neonates in the control group had hypoglycemia and hyperinsulinemia. These results might be due to association with excess adiposity of fetal hyperinsulinemia; abnormal defect of beta cell that increase insulin production in relation to hyperinsulinemia. A statistical significant difference was found between both groups regarded to insulin and C-peptide levels. These results were matched with the study of Mimouni *et al.* [42] who reported that, hypoglycemia was the second most frequent complication of infant of diabetic mother, however, the good maternal glycemic control during pregnancy and at the time of delivery will decrease the risk of neonatal hypoglycemia.

Moreover, results are similar to the study findings of Hassanein *et al.* [43] who found that, birth weight of 4000g or greater was associated with a higher incidence of hypoglycemia. Also, the results are congruent with the findings of Begum *et al*. [44] who found that, cord-serum C-peptide and insulin concentrations were higher in the infants of mothers with GDM and were strongly correlated with birth weight. Also these results are similar to Mitanchez *et al.* [41] who reported that neonatal hypoglycemia was strongly associated with elevated cord serum C-peptide levels. The infant of a diabetic mother is at risk of transient hyperinsulinism, which prevents at birth the normal activation of metabolic pathways producing glucose and ketone bodies and causes increased glucose consumption by tissues.

The research results revealed that, more than half of the neonates in the control group had respiratory distress. This result might be due to maternal hyperglycemia and neonatal hyperinsulinemia; high fetal insulin levels also contribute to respiratory distress syndrome in which the enzymes needed for surfactant production are inhibited that lead to delayed lung maturity. This results was matched with Mitanchez *et al.* [41] who mentioned maternal hyperglycemia effect on fetal lung maturation and neonates who sent to the NICU.

The research findings indicted that only 2 neonates had congenital anomalies in both study and control groups, this might be due to the onset of hyperglycemia occurs late in pregnancy when organogenesis is completed; it is not associated with increased incidence of congenital malformation. This result was matched with Farooq *et al.* [45] who found that, the rate of congenital anomalies was 2% in their study and commented that women in whom glucose intolerance develops after mid pregnancy do not expose the developing embryo to hyperglycemia and these infants do not have any increase in malformations; the low rate in this study could hence be due to this fact, as 82% women developed diabetes in late second or third trimester.

CONCLUSION

This research concluded that the pregnant women with GDM who received the gestational diabetes mellitus health education module had better maternal & neonatal outcomes than those who did not.

Recommendations: Based on the research findings, the following was recommended:

- Antenatal screening of GDM is very important as it is a risk factor for the development of type 2 diabetes mellitus later in life and its related maternal and fetal/neonatal complications.
- Health Education Module should be provided for health care providers to increase and update their knowledge related to GDM, its treatment strategies and supporting patients in making lifestyle changes & maintaining self-management.
- Replication of such research on a larger sample to be able to generalize the results of the research findings.

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