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TECHNIQUES FOR MONITORING BLOOD GLUCOSE DURING PREGNANCY FOR WOMEN WITH PRE-EXISTING DIABETES

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ABSTRACT

Self-monitoring of blood glucose has revolutionized the overall management of diabetes. SMBG allows individuals with diabetes to determine if glycemic goals have been achieved and their own individual response to therapy. Pattern management of diabetes may be achieved by evaluating the results of SMBG in relation to food intake, physical activity, exercise, and insulin administration. In addition, episodes of hypo- and hyperglycemia may be detected with the opportunity for appropriate intervention.

KEYWORDS: blood glucose, pregnancy, pre-existing diabetes.

INTRODUCTION

Approximately 700,000 women give birth in England and Wales each year, and up to 5% of these women have either pre-existing diabetes or gestational diabetes. Of women who have diabetes during pregnancy, it is estimated that approximately 87.5% have gestational diabetes (which may or may not resolve after pregnancy), 7.5% have type 1 diabetes and the remaining 5% have type 2 diabetes.

The prevalence of type 1 diabetes, and especially type 2 diabetes, has increased in recent years. The incidence of gestational diabetes is also increasing as a result of higher rates of obesity in the general population and more pregnancies in older women. Diabetes in pregnancy is associated with risks to the woman and to the developing fetus. Miscarriage, pre-eclampsia and preterm labor are more common in women with pre-existing diabetes. In addition, diabetic retinopathy can worsen rapidly during pregnancy. Stillbirth, congenital malformations, macrosomia, birth injury, perinatal mortality and postnatal adaptation problems (such as hypoglycemia) are more common in babies born to women with pre-

existing diabetes. This guideline contains recommendations for managing diabetes and its complications in women who are planning pregnancy and those who are already pregnant.[1]

The guideline focuses on areas where additional or different care should be offered to women with diabetes and their newborn babies. Where the evidence supports it, the guideline makes separate recommendations for women with pre-existing diabetes and women with gestational diabetes. The term 'women' is used in the guideline to refer to all females of childbearing age, including young women who have not yet transferred from pediatric to adult services.[2]

BACKGROUND

Description of the condition Types of diabetes There are three main types of diabetes mellitus: Type 1, Type 2 and gestational diabetes (GDM). Type 1 or insulin-dependent diabetes results from the body's failure to produce sufficient insulin and accounts for a minority of the total burden of diabetes in a population. Type 2 diabetes results from a failure of the body to utilize insulin, causing high blood sugar levels. In GDM, women who were not previously diabetic develop carbohydrate intolerance resulting in hyperglycemia with first onset or detection occurring during pregnancy.[3]

GDM develops in one in 25 pregnancies worldwide and it can lead to the development of Type 2 diabetes post-pregnancy. Type 2 diabetes alone constitutes about 85% to 95% of all diabetes globally.[4]

Type 2 diabetes is a serious and growing global health problem which has evolved in association with rapid cultural and social changes, aging populations, increasing urbanization, dietary changes, reduced physical activity and other unhealthy lifestyle and behavioral patterns (WHO 1994). Prevalence of diabetes Diabetes mellitus can be found in almost every population in the world and it is estimated that 6.6% of the global population in the age group of 20 to 79 years old had diabetes in 2010.

By 2030, it is estimated that 7.8% of the adult population will have diabetes.[5] Diabetes mellitus complicates about 2% to 3% of all pregnancies. Approximately 90% of diabetes in pregnancy is accounted for by GDM. Pre-existing Type 1 and Type 2 diabetes accounts for the remaining 10% of diabetes during pregnancy.[6]

This review considers only the management of pre-existing diabetes in pregnant women as there is an existing Cochrane review on gestational diabetes mellitus being prepared.[7]

Complications of diabetes in pregnancy: for mother and baby Women with diabetes of any kind are at increased risk of morbidity and mortality during pregnancy. Pregnancy outcomes for women with pre-existing diabetes and their infants are poor compared to those for women who do not have diabetes (NICE 2008). The risks to both women and infants include fetal macrosomia, preterm birth, birth trauma (to mother and infant), induction of labor or cesarean section, miscarriage, congenital malformation, stillbirth, transient neonatal morbidity, neonatal death, obesity and/ or diabetes developing later in the baby's life.[8]

Women with diabetes have increased the risk of an early miscarriage and are at increased risk of having a baby with malformations. Both of these risks are associated with less than optimal glycaemic control around the time of conception and in the first trimester. The risks appear to be approximately equivalent for women with Type 1 and Type 2 diabetes. The increased rate of spontaneous miscarriages and fetal malformation appear to be low when glycaemic control is moderately raised and higher with increasingly poor glycaemic control.[9]

Women with diabetes should be encouraged to obtain the best possible glycaemic control before conception. Women with uncontrolled glycaemic levels should be discouraged from becoming pregnant until their control can be improved. Macrosomia, defined as infant birthweight greater than 4.5 kg, remains the commonest complication of pregnancy in women with diabetes.[10]

Macrosomia occurs in 27% to 62% of infants of diabetic mothers compared with 10% of non-diabetic mothers.[11] Nationwide studies from the Netherlands, United Kingdom, and Denmark confirm that the risk of delivering a large for gestational age, or macrosomic infant in women with Type 1 diabetes ranges from 48.8% to 62.5% (Kitzmiller 2008). Recent data confirm that women with Type 2 diabetes have an equally high risk of delivering a macrosomic infant.[12]

For mothers with diabetes, macrosomia leads to an increased risk of perineal lacerations, complications in labor, and delivery by cesarean section. There are increased risks for the infants of intracranial hemorrhage, shoulder dystocia, neonatal hypoglycemia, jaundice, and respiratory distress[13] as well as the longer-term health risks of insulin resistance, obesity, and Type 2 diabetes.[15] Overt diabetes is an undisputed factor for preterm birth.[14] Fetal hyperglycemia causes fetal hypoxia and acidosis, which may explain the excess stillbirth

rates observed in poorly controlled diabetic women.[16] Infants with macrosomia due to poor maternal glycaemic control and fetal hyperinsulinemia are more likely to develop obesity and glucose intolerance later.[17] Long-term (five to 15 years) follow-up studies of infants of diabetic mothers suggest that poor glycaemic control during pregnancy has a negative influence on intellectual and psychomotor development.[18] Both findings highlight the prolonged effects on offspring of intrauterine exposure to diabetes.[19]

Glycemic control prior to pregnancy Women with diabetes have an increased risk of an early miscarriage and are at increased risk of having a baby with malformations. Both of these risks are associated with less than optimal glycaemic control before or around the time of conception and in the first trimester. Maternal hyperglycemia during the first few weeks of pregnancy is strongly associated with increased spontaneous abortions and major congenital malformations.[20]

After 12 weeks' gestation, hyperglycemia induces fetal hyperinsulinemia, accelerated growth, and excess adiposity in animal models and diabetic women. These risks appear to be approximately equivalent for women with Type 1 and Type 2 diabetes. The increased rate of spontaneous miscarriages appears to be low when the HbA1c is modestly raised and higher with increasingly poor glycaemic control.[21]

The same pattern is also found with respect to the rate of fetal malformations.[22]

Women who improve their glycaemic control before conception have a reduced rate of fetal malformation.[23] Therefore, women with diabetes should be encouraged to obtain the best possible glycaemic control before conception.[24] Description of the intervention Techniques of blood glucose monitoring Glucose readings supply trend information that helps to identify and prevent unwanted periods of hypo- and hyperglycemia that can bring adverse effects to both mother and baby. Women with Type 1 and Type 2 diabetes are advised to self-monitor their blood glucose throughout pregnancy.[25] Techniques of blood glucose monitoring to be considered in this review will include self-blood glucose monitoring, continuous glucose monitoring and clinic monitoring (for which timing and frequency of monitoring will also be considered). Self Blood Glucose Monitoring (SMBG) - A glucose meter (glucometer), with or without memory, can be used to measure capillary glucose. Conventional intensified glucose monitoring is de ned as three to four blood glucose measurements per day.[26]

Postprandial glucose during pregnancy has been identified as the best predictor of neonatal macrosomia.[27] Therefore, SMBG protocols for women with Type 1 or Type 2 diabetes during pregnancy stress the importance of measuring blood glucose after meals (Jovanovi 2009) while for non-pregnant diabetics, preprandial values are recommended. Continuous Glucose Monitoring - The Continuous Glucose Monitors currently available measure blood glucose either with minimal invasiveness through continuous measurement of interstitial uid (ISF) or with the non-invasive method of applying electromagnetic radiation through the skin to blood vessels in the body. The technologies for bringing a sensor into contact with ISF include inserting an indwelling sensor subcutaneously (into the abdominal wall or arm) to measure ISF in situ or harvesting this uid by various mechanisms that compromise the skin barrier and delivering the aid to an external sensor.

After a warm-up period of up to two hours and a device-specific calibration process, each device's sensor provides a blood glucose reading every 1 to 10 minutes for up to 72 hours with the minimally invasive technology and up to three months with the non-invasive technology. Continuous glucose monitoring can provide up to 288 measurements a day.

Clinic Monitoring refers to routine glucose monitoring during ante-natal visits either using capillary or whole blood. Timing and frequency of glucose monitoring Postprandial glucose monitoring have been shown to be able to reduce the risk of neonatal hypoglycemia, macrosomia, and cesarean delivery[28] as well as to reduce the incidence of pre-eclampsia and neonatal triceps skinfold thickness.

Postprandial glucose values were most strongly associated with increased birth weight in the studies in which both pre- and post-meal glucose were measured. According to NICE 2008, pregnant women with diabetes mellitus are advised to test fasting and one-hour postprandial blood glucose levels after every meal during pregnancy. Women taking insulin are encouraged to test their blood glucose before going to bed at night. The American Diabetes Association also recommends SMBG before and after meals and occasionally at night time, to provide optimal results in pregnancy.[29] However, the frequency of glucose monitoring will greatly depend on the compliance of these women. Educational approaches incorporating additional glucose testing after meals to improve glycaemic control in late gestation have shown potential to reduce birth weight. The optimal frequency and timing of home glucose testing during pregnancy is, however, unknown with few women managing to carry out the 10 daily tests required to document most glucose estimations.[30]

Blood glucose control essential

Optimal blood glucose control is important throughout pregnancy, both for the mother's health and the babies. Glucose in a mother's blood crosses the placenta to her baby, affecting the baby's blood glucose level. (The placenta, a flat circular organ, links the unborn baby to the mother's uterus, to provide oxygen, nutrients, and the elimination of wastes.)[31]

The baby begins making its own insulin around 13 weeks gestation. If the baby is constantly exposed to high levels of glucose, it is as if the baby were overeating: The baby produces more insulin to absorb the excess glucose, resulting in weight gain and an increase in size. Under these conditions, the baby can become too large, a condition known as macrosomia. Macrosomia is associated with difficult vaginal delivery, which can lead to birth injury and/or asphyxia, a condition in which the baby doesn't get enough oxygen.[32]

Another reason that blood glucose control is important right up to the day of delivery is that if an unborn baby has high levels of insulin on a consistent basis, or if the mother's blood glucose level is high during labor, the baby may experience hypoglycemia (low blood sugar) or other complications when the umbilical cord (and the maternal blood supply) is cut. The details of managing blood glucose levels during pregnancy may be different for women who already have either type 1 or type 2 diabetes before pregnancy and for those who are diagnosed with diabetes during pregnancy, or gestational diabetes, the recommended blood glucose goals, however, are the same.

It is important to note that the blood glucose goals suggested by the American Diabetes Association (ADA) for pregnant women are lower than those for the general population with diabetes. (See sidebar: “Blood Glucose Goals During Pregnancy.”) In addition, the ADA suggests that pregnant women check their blood glucose levels up to eight times per day: once before each meal, again one hour after each meal, at bedtime, and once in the middle of the night. (Any woman who is taking insulin or certain kinds of blood glucose-lowering pills would need to do additional checks before driving, and if she experienced any symptoms of low blood sugar.) Your health-care team may recommend a somewhat different monitoring schedule depending on the type of diabetes you have and how you treat it. However, frequent self-monitoring is needed to ensure that blood glucose levels remain within the recommended range.[33]

In addition to blood glucose monitoring, daily urine ketone testing is often advised for pregnant women with diabetes. Ketones are acid substances that collect in the bloodstream if the body is unable to break down glucose for energy. This can occur if there is not enough insulin to break down glucose in the bloodstream or if there is not enough glucose available to meet energy needs. In either case, the body begins to use stored fat for energy, a process that yields the acidic byproducts called ketones. If the body is unable to get rid of the ketones fast enough (via the lungs and urine), they build up and can cause a potentially deadly condition called ketoacidosis.[34]

Ketones in the blood during pregnancy are associated with decreased intelligence in the baby, and an episode of ketoacidosis during pregnancy greatly increases the risk of the fetus dying in the uterus. Diabetic ketoacidosis may develop rapidly, and at lower blood glucose levels in women who are pregnant than in those who are not. The best approach for preventing this outcome is to closely monitor blood glucose levels outside the recommended range for pregnancy and to promptly treat elevated blood glucose levels, as directed by your diabetes management team. Notify your diabetes health-care team immediately if you detect ketones in your urine and have a high blood glucose level.

Ketones that occur when there isn't enough glucose in the bloodstream are called “starvation ketones.” They may occur in women with gestational diabetes, as well as in those with type 1 or type 2 diabetes. A woman with starvation ketones would typically have a blood glucose reading in the normal range or lower than normal. If you are getting starvation ketones, your medical team may advise you to increase the number of calories and carbohydrate in your meals and snacks.[35]

During your pregnancy, if you are not already seeing an endocrinologist, your obstetrician may refer you to one. Most likely, you would see the endocrinologist at least once a month during the first and second trimesters (approximately the first six months of pregnancy) and every two weeks in the third trimester (the last three months). In addition to your scheduled appointments, you should discuss specific guidelines for prompt follow-up if blood glucose levels are not staying within recommended ranges. Your obstetrician will likely evaluate the growth and condition of your baby throughout your pregnancy with tests such as ultrasound to monitor your baby's size and the non-stress test, which measures a baby's heart rate in response to his or her own movements. Additional testing to monitor your baby's health, or

yours, may be recommended by your obstetrician or by members of your diabetes health-care team.

Insulin needs during pregnancy

During any pregnancy, a woman's insulin needs change, because the normal hormone production and weight gain that occur during pregnancy increase insulin resistance. (See sidebar: "Insulin Requirements During Pregnancy.") In women who do not have or develop diabetes, blood glucose levels remain stable because the pancreas is able to produce more insulin to accommodate the increased demand. In women with preexisting diabetes, or who develop gestational diabetes, the pancreas cannot keep up with the increased demand, so blood glucose levels rise unless steps are taken to lower them.[36]

In women with preexisting diabetes, insulin needs during the first several weeks of pregnancy are not usually that different from those before conception. However, in the latter part of the first trimester, women with preexisting diabetes may have a higher risk of hypoglycemia because of an increase in sensitivity to insulin, rapid fetal growth, and a reduction in eating associated with "morning sickness." Around the 16th week of pregnancy, insulin needs gradually increase, due to increasing levels of hormones, including human placental lactogen (hPL), a form of "growth hormone" for the baby.

All women with type 1 diabetes and most with type 2 either inject or infuse insulin during pregnancy. Women with gestational diabetes also have to take steps to control their blood insulin level, but not all will have to inject insulin. Some women with gestational diabetes can keep their blood glucose at recommended levels with changes in diet and moderate exercise. Many, however, must eventually use insulin.[37]

Control before conception

In women with type 1 or type 2 diabetes, optimal blood glucose control is essential prior to conception, because it is hard to be absolutely certain of when conception takes place. The incidence of fetal malformations is reduced significantly in women who have near-normal glycosylated hemoglobin (HbA1c) levels before they become pregnant. The rate of miscarriage in women with preexisting diabetes is also reduced by keeping blood glucose as close to normal as possible in the first trimester.[38]

Ideally, you should strive for a near-normal HbA1c test result at least three months prior to pregnancy. It is important to discuss any plans to become pregnant with your diabetes health-care team, particularly if you have vascular complications related to your diabetes, such as eye or kidney disease. In this situation, pregnancy is a potential risk to your health. For women with no vascular complications, a thorough physical exam, good nutrition (including a folic acid supplement), and excellent blood glucose control before you become pregnant will help minimize any health risks to you and your baby. Be sure you are using a reliable method of birth control, as you work toward optimal blood glucose levels.[39]

Gestational diabetes

Gestational diabetes is a form of glucose intolerance (difficulty metabolizing blood glucose) that is first recognized during pregnancy. It affects almost 7% of all pregnancies. Factors that may contribute to a high risk of gestational diabetes include overweight, a history of gestational diabetes with a prior pregnancy, GLYCOSURIA (glucose in the urine, which would be found in a routine urine test) and a strong family history of diabetes. In addition, women who are African-American, Hispanic, or from certain Native American groups, as well as women with polycystic ovary syndrome (PCOS) have shown a higher risk for gestational diabetes.

Screening tests should be recommended between 24- and 28-weeks' gestation for any woman considered at risk of gestational diabetes by her obstetrician. These tests usually involve drinking a pre-measured glucose solution and then having blood samples drawn and checked for glucose level, to determine if the body tolerates the glucose load normally. Test levels that are out of the normal range may indicate that the mother's blood glucose levels are likely to rise as the pregnancy progresses.[40]

If you are diagnosed with gestational diabetes, your obstetrician may refer you to a diabetes educator or to an endocrinologist (or both), for help managing your diabetes and your pregnancy. Because blood glucose control is essential during pregnancy, weekly follow-ups with the health professional managing your diabetes are usually recommended.

Most cases of gestational diabetes disappear after delivery because two of the primary factors that contribute to insulin resistance and high blood glucose levels are either diminished (the extra weight gained during pregnancy) or gone (the hormones produced by the placenta). If your blood glucose levels were normal prior to the pregnancy, they will most likely return to

normal after delivery. However, once you have had gestational diabetes, you are likely to develop it again in another pregnancy. You also face a greater risk of developing type 2 diabetes later in life.[41]

Tools for control

The tools used to maintain blood glucose control during pregnancy are the same tools used to control any case of diabetes. They include a meal plan, an exercise plan, and possibly an insulin plan.

Meal plan. Whether you have preexisting diabetes or gestational diabetes, you should work with a registered dietitian to design an individualized meal plan for your pregnancy. The plan should focus on foods that provide good nutrition for you and your baby, and that help keep your blood glucose level in the desired range. Because carbohydrate has the most immediate impact on blood glucose levels, your meal plan should specify how much carbohydrate to eat and when to eat it. Carbohydrate is found mainly in foods such as bread, cereals, pasta, starchy vegetables, fruits, and sweets. Frequent blood glucose monitoring will help you determine the appropriate amount and timing of carbohydrate.[42]

Your dietitian can also suggest how many calories you need each day based on your recommended weight gain. The amount of weight you should gain during pregnancy depends on your weight before pregnancy. In general, a woman at a healthy weight before pregnancy should gain 25 to 35 pounds during her pregnancy. Your health-care team may advise you to gain more if you are underweight, or less if you are overweight. Keep in mind, however, that pregnancy is definitely not a time to try to lose weight. Most mothers require about 100 extra calories per day during the first trimester and an additional 300 calories per day during the remainder of the pregnancy to ensure the ideal weight gain for the mother and birth weight for the baby. (See sidebar: "Weight Gain During Pregnancy," which illustrates how pregnancy weight gain is distributed).[43]

In most cases, your dietitian will recommend that you eat three meals a day with two to four between-meal snacks. An evening snack is particularly important to prevent hypoglycemia during the night and urine ketones or nausea in the morning.

You may be concerned about the safety of consuming sugar substitutes during pregnancy. At this time, research shows that the four most commonly used sugar substitutes (acesulfame-K,

aspartame, saccharin, and sucralose) are safe to use in moderation during pregnancy. Some of these sweeteners do cross the placenta and can reach the baby, but there is no evidence they cause ill effects. If in doubt, follow the advice of your obstetrician.[44]

For more specifics on the components of a well-balanced diet during pregnancy, see sidebar: "Eating for Two."

Physical Activity

Regular physical activity is essential to diabetes control and to general health and well-being Your health-care team can help you determine a safe level of exercise for you during pregnancy. If you have always exercised in the past, you may be able to continue to exercise at a more moderate level while you are pregnant. If exercise was not part of your pre-pregnancy routine, check with both your obstetrician and endocrinologist before you start, and choose an activity such as brisk walking or swimming, to incorporate into your daily routine. Because exercise usually lowers blood glucose, be alert to the symptoms of hypoglycemia, and check your blood glucose level before and after you exercise.

Insulin management. Insulin is the most common medicine used for blood glucose control during pregnancy. Blood glucose-lowering pills are used much less often because of a lack of data on their safety. However, at least one recent study concluded that glyburide (brand names DiaBeta, Glynase PresTab or Micronase), when taken by women with gestational diabetes during the last six months of pregnancy, did not change the fetal outcome.

Women with type 1 diabetes may prefer to stick with their usual insulin delivery method during pregnancy, or they may decide to try something new, such as insulin pump therapy. For some, using a pump during pregnancy allows them to fine-tune their insulin requirements.

Women with type 2 diabetes who take pills as part of their diabetes treatment plan are usually advised to switch to insulin during pregnancy. In fact, many health care practitioners recommend that women with type 2 diabetes switch to insulin therapy before becoming pregnant. This may help them adjust to insulin therapy and possibly allow them to bring their blood glucose levels into the ranges recommended during pregnancy before they become pregnant.[45]

As mentioned earlier, women with gestational diabetes usually start by seeing how well dietary changes control their blood glucose levels and then add insulin if blood glucose levels do not stay within recommended ranges. Women who must learn to use insulin because of gestational diabetes may find that using an insulin pen is easier than using a syringe. Using premixed insulins, rather than mixing your own, may also simplify your diabetes management.[46]

The most common side effect of insulin therapy is hypoglycemia. Once insulin enters the body and begins working, blood glucose levels may drop lower than recommended if you do not eat to balance the effects, or if you exercise too much. Women using insulin during pregnancy should make sure they receive information about the warning signs and treatment of hypoglycemia. In addition, they should be aware that hypoglycemia unawareness (the inability to detect early signs of low blood glucose) may be more common in pregnant women, especially those with type 1 diabetes.[47]

Labor and Delivery

Most physicians prefer that women with diabetes deliver as close to their due date as possible. Babies delivered after their due date tend to be larger and risk more complications. If natural labor is not timely, and a woman plans to deliver vaginally, a hormone called oxytocin can be given, usually intravenously, to induce labor. If a woman is scheduled for caesarian section, oxytocin is not necessary.

Many women with diabetes are able to deliver vaginally. A caesarian section may be needed if the baby is too large (macrosomic), if the woman's pelvis is too small, or if a woman has vascular complications or blood pressure problems. A caesarian delivery may also be required if a baby is in the breech position (when the baby's feet or buttocks enter the birth canal first).[48]

Labor is an intense, active process, which can lower a woman's blood glucose level. A caesarian delivery, on the other hand, may raise a woman's blood glucose level, because the surgical procedure is a stress on the body. If you have type 1 or type 2 diabetes, your doctor may have you on insulin intravenously during labor and delivery. The IV apparatus continuously infuses quick-acting insulin and may allow for smoother blood glucose control, since adjustments can be made as necessary. The goal is to keep blood glucose levels as normal as possible to prevent hypoglycemia in your newborn. Most women with gestational

diabetes do not require any insulin during the labor and delivery process. After delivery, continuing to maintain blood sugar levels in a near-normal range facilitates the healing process.[49]

Recovery

If you have type 1 or type 2 diabetes, your insulin requirements may return to what they were before your pregnancy within a few weeks of delivery. Check your blood glucose levels frequently, and make adjustments to your insulin dosage as needed.

If you had gestational diabetes, it is likely that your blood glucose level will return to normal almost immediately after your baby is born. But since gestational diabetes puts you at increased risk for developing type 2 diabetes in the future, you should have your blood glucose level measured at your first postpartum checkup (usually four to six weeks after delivery) and yearly thereafter. To minimize your risk of developing type 2 diabetes, eat a balanced diet, exercise regularly, and keep your weight at a reasonable level.

Methods

Eighty-five pregnant women referred to the perinatal diabetes program were included in the convenience sample. All women referred to the diabetes program were instructed on the correct technique for obtaining and recording SMBG. The diabetes educator observed the women's self-monitoring technique and addressed deficits in performance during the educational session. Participants also were provided with written instructions from the manufacturer that included information regarding the use of the memory function.

Meter clocks were set at the appropriate time, and quality controls for the meters were performed. Women were asked to obtain and record their capillary blood glucose testing before and after each meal and at bedtime.

Meters were downloaded at their regularly scheduled office visit using software provided by the meter manufacturers. All women who brought their logbooks and their meters to their follow-up office visit were included in the study sample. Management decisions regarding care were based on the actual blood glucose values, and women were asked at the time of the visit if there was obvious falsification where clinical decision making was affected.

The meter values, the logged values, and the numerically coded demographic information were entered into a spreadsheet. Calibration and control determinations were not included in

the analysis. Data were analyzed using Statistical Package for Social Sciences (SPSS, Chicago, IL). Precision (accuracy of reported values to meter memory values), the rate of logging phantom values, and rate of unreported or unlogged values were analyzed. In addition, precision, the rate of reporting phantom values, and rate of unreported values were compared to diabetes type, age, duration of diabetes, gestational age, economic, marital, and educational status. A p value of equal to or less than .05 was considered statistically significant.

RESULTS AND DISCUSSION

Inaccurate reporting by women with type 1 diabetes was found to be 36.7% (22.7% values lower), type 2 as 8.5% (4.5%values lower), GDMA1 as 21.2% (9.4% values lower), and GDMA2 as 23.4% (12.1% values lower).

An analysis of variance found significant differences between diabetes types in their accuracy of reporting, $F (3, 2379.35) = 3.696$, $p = .015$. In a post hoc comparison, using Tukey's honestly significant difference test (HSD), the difference among groups of women with diabetes was significant between type 1 and type 2 ($p = .008$).

Although the other comparisons were not significant, women with type 1 diabetes appear to be more likely to falsify their log than women with other types of diabetes.

Significant correlations between accuracy and age were found. As age increases, the percent of log values equaling the meter values significantly increases ($r = .251$, $p = .021$) and the percent of log values lower than meter values significantly decreases ($r = .233$, $p = .033$). Overall accuracy in logs improves as age increases. Precision was not found to be affected by the duration of diabetes ($r = –.120$, $p = .274$). Accuracy was not affected by gestational age at the time of data collection.

Accuracy significantly differed in women of different economic backgrounds. Women utilizing state health insurance (Medicaid) were more likely to falsify their blood glucose results, $F (1, 45) = 6.038$, $p = .018$. When comparing the overall percentage of correct values in the log to the meter, those using Medicaid were less likely to report values that equaled the meter values (26.6%), whereas women with private insurance were more likely to be accurate (10.5%). There was no statistical difference in falsification between married versus single

women, F (1, 76) = 3.116, p = .082. Educational status of women was not found to differ in recording accuracy, F (2, 1,252.09) = 1.771, p = .177.

Figure 2 shows the frequency of logging phantom values and unlogged or unreported values. Sixty-eight participants (80%) reported phantom values by entering at least one blood glucose value in the log that was not in the meter memory, which differed by diabetes type, F (3, 81) = 2.737, p = .049. When looking at the means, it appears that women with type 1 diabetes report phantom values more than women with GDMA1. The average number of phantom values was 5.4 overall. This small marginal difference was shown between diabetes type, with women with type 1 reporting on average 7.48 phantom values, type 2 reporting 3.60, GDMA1 reporting 3.22, and GDMA2 reporting 6.73. Four women reported between 22 and 30 values out of 40 to 56 values in their log that were not in the meter. Only 17 (20%) participants did not report phantom blood glucose values (Figure 2). However, there were 7 women who reported more than 20 phantom values (Figure 2). There was no correlation found between reporting phantom values and age (r = –.095, p = .389) or duration of diabetes (r = .162, p = .138). There was a marginal difference between reporting phantom values and economic status, F(1, 45) = 3.567, p = .065. Women with Medicaid seem to report phantom values more than women with private insurance. Marital status did not impact the phantom value reporting rate, F (1, 76) = 1.297, p = .258. The higher her education, the less likely the woman was to report phantom values, F (2, 79) = 3.359, p = .040. Post hoc analysis showed that women with less than high school education overreported more than college-educated women (p = .039).

The majority of women tend not to underreport or omit to report all values obtained. Approximately 30% (26) of the participants had no values missing from the log that was in the meter (Figure 2). Only three women (3.5%) had between 11 and 15 values in the meter that was not in the log (Figure 2). The rate of unlogged values was found to be significant when comparing diabetes types, F (3, 81) = 3.493, p = .019. Post hoc analysis showed that women with type 1 diabetes and GDMA1 differ significantly (p = .029). Results from women with type 1 diabetes approach significance when compared with results from women with type 2 diabetes (p = .068). There was a significant negative correlation between age and values missing from the log (r = –.239, p = .029). The younger the gravid, the more likely she was to omit reporting values that were in the meter. Duration of diabetes (r = .176, p = .106) was not significant. The economic status affected the rate of unreported values, F (1, 45) =

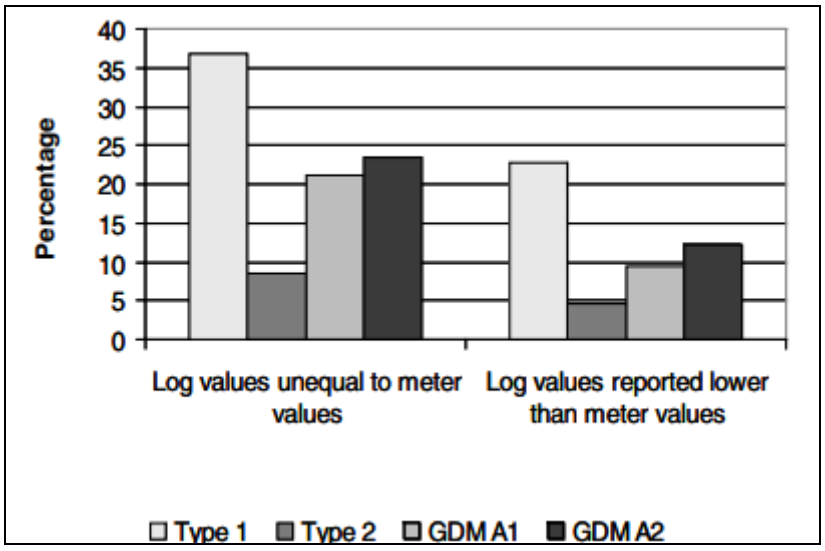
4.527, p = .039. Women with Medicaid were more likely to omit to log all values in their meters. Marital status also impacted the rate of unlogged values, F (1, 76) = 5.549, p = .021. Married women were found to have a lower rate of unlogged values that was significant. Educational status showed only a marginal difference in the unreported rate, F (2, 79) = 3.066, p = .052. Post hoc analysis showed that women with less than high school education tended to underreport more often than women who were college educated (p = .046). Statistical significance was not shown when comparing women who completed high school with those who did not (p = .080) nor when compared with women who attended or completed college (p = .909).

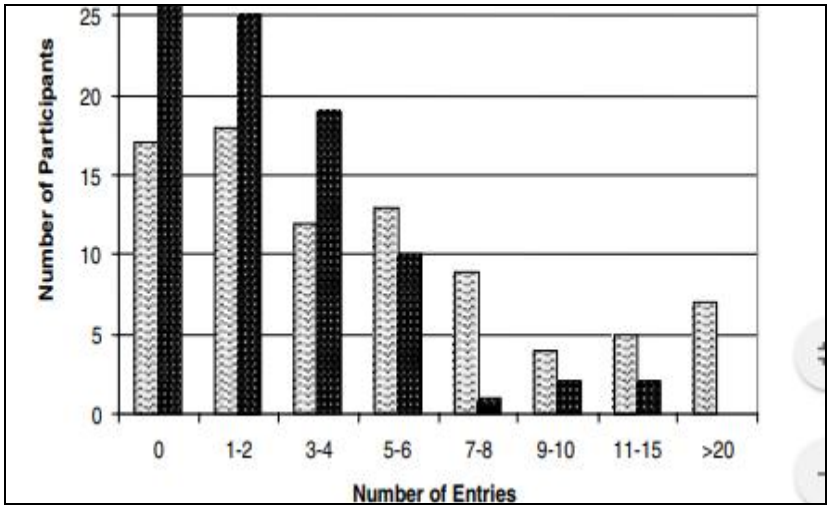
In our study of pregnant women, we found that patient-generated data were unreliable in the majority of our study sample, with the most discordance noted in women with type 1 diabetes and lower economic backgrounds. It should be noted that most women with type 1 diabetes who were included in our study had never had their logbooks verified. Age affected precision and the rate of unreported values and educational status affected the rate of reporting phantom values and unreported values. Marital status was only found to affect the rate of unreporting. When we looked at the discordance rate (>10 mg/dL and >50 mgdL) between values, it was obvious that interventions would not have been based on the actual clinical condition. Reporting phantom values signify complete fabrication. Not reporting all values is not as significant a problem, because some women take additional readings or repeatedly test during hyper- and hypoglycemic periods. We did not evaluate other variables that may impact the reliability of the patient-generated data such as attitudes, health beliefs, behavioral intentions, attendance at office visits, and psychosocial, cultural, and psychological factors. We hope to add a more comprehensive assessment of some of these variables in the near future. In addition, we could not evaluate the relationship between clinical style of the health care team and accuracy, although the overall atmosphere in the office is supportive and utilizes an empowerment approach with the woman as the most significant team member. Our results may not be generalizable but certainly, do suggest the need to verify patient-obtained blood glucose values to appropriately treat diabetes in pregnancy. Prior to the study, we had verified logbooks only randomly. After completion of the study, we now verify patient-generated blood glucose results on all women and document this in the chart. We also follow up during the pregnancy by randomly verifying the accuracy of the results of all women. In addition, we review the memory function in the initial educational session and inform them that we download the meters routinely not for punitive reasons but to gather

more comprehensive data for evaluation. Other issues to explore are the underlying factors that would contribute to the falsification of blood glucose records when education regarding potential poor pregnancy outcomes as a result of hyperglycemia has been provided.

Diabetes is a disease that requires both psychological and behavioral adjustment to achieve treatment goals decreasing the risk of long-term complications.[50]

Pregnancy in women with pregestational diabetes heightens the need for euglycemia to reduce perinatal risk creating the need for further psychological and behavioral adjustment. Anxiety and hostility have been found to be higher in pregnant women with preexisting diabetes than in women with gestational diabetes, but these factors were not found to be associated with the level of glycemic control.[51] The discrepancy in reporting in our study in women with type 1 diabetes may be due to the chronicity of their disease. Women enrolled in the study with type 2 diabetes had been diagnosed with their disease for a shorter duration of time than women with type 1 diabetes. In addition, the glycemic goals for pregnancy usually reflect an ideal that is unrealistic for some women with preexisting diabetes and may contribute to falsification due to guilt. Depression has been found to be higher in individuals with diabetes and has been associated with hyperglycemia and complications in adults with types 1 and 2 diseases.[52] However, this has not been studied in pregnant women with diabetes. The possible link between depression, anxiety, pregnancy, diabetes, and adherence to treatment regimens should be explored and may determine factors that contribute to a lack of reliability in self-monitoring data. Understanding these links would allow for a more supportive and comprehensive approach to care for pregnant women with diabetes.[53]





Between 1% and 14% of all pregnancies in Iraq, are complicated by hyperglycemia? ,z This percentage is changing because of 1) an increase in the number of women with type 1 and type 2 diabetes who are becoming pregnant; 2) a significant rise in the number of adolescents with gestational diabetes mellitus (GDM) and type 2 diabetes; and 3) a rapid rise in the number of women with the insulin resistance syndrome at the time of pregnancy. Over the next decade, there may be a 2-fold increase in the number. Additionally, the prevalence of insulin resistance (obesity, hypertension, dyslipidemia, and/or microalbuminuria) is likely to rise in these populations, especially among adolescents and young adults. These and other factors suggest that the actual proportion of those women with hyperglycemia in pregnancy may be close to 10% (300,000).: ~ One third or more of these pregnancies may experience adverse perinatal, neonatal, and maternal outcomes if persistent hyperglycemia goes undetected or the treatment for hyperglycemia is not sufficiently intensive to achieve near-normal glycemia.[54]

Studies have shown that significant hyperglycemia during the first trimester raises the relative risk of congenital malformation and perinatal mortality to between 2.75 and 2.91. 4'5 For some time, it has been known that maternal hyperglycemia is directly associated with fetal hyperglycemia, which is partially mediated by fetal hyperglycemia. The amplified production of insulin due to augmented maternal nutrients serves as a basis for accelerated fetal growth[55] ~hen fetal growth exceeds the 90th percentile for gestational age, the relative risk of macrosomia rises nearly threefold. The resultant macrosomia or large for gestational age (LGA) fetus often necessitates delivery by C-section. Neonatal hypoglycemia and cardio-respiratory distress are also associated with elevated fetal insulin levels.[56]

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