Gestational Diabetes Mellitus and Nutrient Intake in Regards to Carbohydrate, Fat, Saturated Fat, Protein and Fiber Consumption versus Blood Glucose Levels

by

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A Research Paper

Submitted in Partial Fulfillment of the

Requirements for the

Master of Science Degree

in

Food and Nutritional Sciences

Approved: 6 Semester Credits

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Research Advisor

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The Graduate School
University of Wisconsin-Stout
December 2003

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ABSTRACT

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Gestational Diabetes Mellitus and Nutrient Intake in Regards to Carbohydrate, Fat, Saturated Fat, Protein, and Fiber Consumption versus Blood Glucose Levels
(Title)

Food and Nutritional Sciences	Dr. Carol Seaborn	December 2003	88
(Graduate Major)	(Research Advisor)	(Month/Year)	(# of Pages)

Turbian, Kate. A Manual for Writers of Term Papers, Theses, and Dissertations. 1987
(Name of Style Manual Used in the Study)

Medical management of Gestational Diabetes Mellitus (GDM) has shown that lowering blood glucose levels to normoglycemic may help prevent diabetic complications for infant and mother. The objective of this experiment was to determine if consumption of carbohydrate, saturated fat, total fat, protein, and fiber affected blood glucose levels in pregnant women diagnosed with GDM. The study included forty-two adult women from eight different medical facilities, which included Minnesota, Georgia, Florida, Tennessee, and New Mexico. The women were diagnosed by two abnormal values from an oral glucose tolerance test (OGTT) of 100 grams (g). The additional criteria for inclusion in the study were age 18-45 years, carrying a singleton pregnancy, and entry into trial between 28 to 32 weeks gestation. Three-day food records were collected. Only thirty-four women had the required data completed for final analysis. Means and frequencies were determined for carbohydrate, protein, total fat, saturated fat, fiber, and calorie intake

as well as blood glucose levels at fasting, breakfast, lunch, and supper. Results showed participants in the study had a mean Body Mass Index (BMI) of 29.04 ± 7.27 during the time of diagnosis (28 to 32 weeks of pregnancy). Participants had a mean total caloric intake of 1645.04 kilocalories for six meals throughout the day. Mean total daily intake of carbohydrate, protein, fat, saturated fat, and dietary fiber were 188.31 g, 81.62g, 65.09 g, 22.46 g, and 14.35 g, respectively. Blood glucose levels for fasting, 1 hour postprandial for breakfast, 1 hour postprandial for lunch, and 1 hour postprandial for supper were 90.80, 107.38, 109.26, and 109.01 mg/dL, respectively. Statistical analyses performed included three separate regression analyses and Pearson correlations on blood glucose level after breakfast, dinner, and supper to different combinations of variables that included carbohydrates, total fat, saturated fat, protein, fiber, body mass index, and body weight. Regression analyses indicated that there was a significant negative relationship between pregnancy weight and blood glucose levels, one hour after breakfast ($F= 6.04$, Significance= 0.01), however no correlation was found between BMI and blood glucose. The second regression analyses negatively correlated both pregnancy weight and BMI to carbohydrate intake at breakfast ($F= 2.93$, Significance= 0.05). The final regression analyses showed that protein negatively correlated to breakfast blood glucose levels ($F= 3.2838$, Significance= 0.05). The negative correlation of carbohydrate intake as well as the negative correlation of blood glucose levels at breakfast to body weight supports the medical nutrition practice of limiting carbohydrate intake at the breakfast meal for women with GDM. This practice of limiting carbohydrate at breakfast was further highlighted by the negative correlation of protein to blood glucose. Thus more protein at the breakfast meal decreased blood glucose 1 hour after breakfast.

Strategies are required to decrease Gestational Diabetes Mellitus prevalence among pregnant women throughout the United States and to help maintain normal blood glucose levels. Targeting all health care professionals to educate women on the importance of diet and blood glucose maintain to promote a healthy pregnancy is needed. In this study of women with GDM who were followed closely by Registered Dietitians showed tight regulation of blood glucose levels is possible. When carbohydrate intake was within recommended levels, no relationship of carbohydrate to blood glucose other than the breakfast meal could be identified.

Research was conducted and funded by the International Diabetes Center, Minneapolis, Minnesota. Analyses and interpretation of data was conducted at the University of Wisconsin-Stout.

ACKNOWLEDGEMENTS

It gives me great pleasure to acknowledge the following people who have made the completion of this thesis possible. Dr. Carol Seaborn, my thesis advisor and chair, thank you so much for all of your support, encouragement, dedication, and assistance over the last year; it has really meant a lot to me. You have always been a supportive professor and advisor over the last couple of years and given me the encouragement and guidance to complete this thesis successfully and patiently. Dr. Janice Coker and Dr. Ann Parsons, thank you both for being supportive and patient with me during this time. I appreciate your contributions and words of encouragement and expertise.

Thank you to Diane Reader and the International Diabetes Center in Minneapolis, Minnesota; for providing me with this opportunity to expand on this research project. Thank you for the assistance and guidance to successfully complete this project and thank you to all of those involved in collecting the data for the study, it is greatly appreciated. I could not have completed this thesis without the help from everyone mentioned above and once again thank you all for your contributions, expertise, and guidance.

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CHAPTER ONE

INTRODUCTION

Introduction

Gestational Diabetes Mellitus (GDM) is defined as glucose intolerance of variable degree with onset or first recognition occurring during pregnancy (Fagen, et al., 1995). Factors that can contribute to the risk of developing GDM include obesity, family history of diabetes, previous birth of greater than nine pounds, poor obstetrical history, previous GDM diagnosis, history of glucose intolerance, history of sugar in the urine, over 25 years of age, and severe emotional or physical stress (Moses, et al., 1997). GDM can be screened by drawing a 1-hour glucose level following a 50 g glucose load, but is definitively diagnosed only by an abnormal 3-hour Oral Glucose Tolerance Test (OGTT) following a 100 g glucose load (Fagen, et al., 1995). GDM is diagnosed during pregnancy and in most cases it disappears after birth (Moses, et al., 1997). GDM usually develops because of a faulty physical interaction between the mother and her baby. During the second trimester of pregnancy approximately during 24 to 26 weeks gestation, the placenta begins producing many hormones. One of these hormones may block the action of insulin causing insulin resistance in the mother. Since the mother's insulin isn't as efficient, she now may have difficulty moving sugar out of her blood and into cells and if the mother cannot produce enough extra insulin to overcome the resistance, her blood sugar will rise. The high blood sugar stimulates the baby to make more insulin and move sugar into the baby's cells, causing him or her to gain extra weight (macrosomia). If this condition is unregulated, these changes can have serious and harmful effects on both the mother and her child (Moses, et al., 1997).

There are many different effects that can harm and cause further complications to the baby. The baby, for instance, may grow very large (macrosomia) which results from the increased amounts of sugar the baby is obtaining from the mother's blood. Babies who are macrosomic can cause a difficult and dangerous delivery. Another complication that the baby can develop is Respiratory Distress Syndrome (RDS), or difficulty breathing which is usually due to premature births and underdeveloped lungs. Other complications the baby could develop include jaundice, nervous system conditions, weakness, and possible hypoglycemic shock after birth (Moses, et al., 1997).

The mother can also be affected by GDM. One common condition that can affect the mother is polyhyramnios or too much amniotic fluid in the uterus. Polyhyramnios can cause the uterus to stretch, which takes up abdominal space and results in difficulty breathing (Moses, et al., 1997). Women with GDM can also develop toxemia (Pregnancy Induced Hypertension or PIH), which may result in high blood pressure and swelling (Moses, et al., 1997). Women with GDM may also develop bladder, kidney, and urinary tract infections (Moses, et al., 1997).

Statement of the Problem

Medical Management has shown that lowering blood glucose levels to a normoglycemic level will help prevent diabetic complications (Fagen, et al., 1995). Therefore medical management's main goal is to prevent perinatal morbidity and mortality by normalizing the blood glucose levels to a non-diabetic state. Dietary and Nutritional Therapy is also important in regulating the blood glucose levels in women diagnosed with GDM. Nutritional counseling is the mainstay of therapy for women diagnosed with GDM (Fagen, et al., 1995). The best plan for regulating these blood

glucose levels is to provide a diet that contains calories and nutrients necessary for maternal and fetal health, which results in normal blood glucose levels, prevents ketosis, and results in appropriate weight gain (Fagen, et al., 1995).

Women with GDM should consume approximately 40-50% carbohydrate, 20-25% protein, and 30-40% fat during pregnancy (Fagen, et al., 1995). The recommended diet is believed to normalize blood glucose levels while preventing any other metabolic abnormalities. Therefore the purpose of this study was to identify and examine carbohydrate, saturated fat, total fat, and fiber consumption that either increases or decreases blood glucose levels in pregnant women diagnosed with Gestational Diabetes Mellitus.

Research Objectives

The objective of the study is to determine if consumption of carbohydrate, protein, saturated fat, total fat, and fiber affect blood glucose levels in pregnant women diagnosed with GDM. The study will help distinguish if these particular macronutrients have a positive or a negative effect on blood glucose, which is associated with the development and complications associated with GDM. By obtaining this macronutrient information, medical and nutrition professionals can gain greater knowledge pertaining to this particular condition.

Significance of the Study

Comparisons can be made to determine if these particular macronutrients and their relationship to blood glucose levels promote an increase or decrease in the conditions associated with GDM. Therefore the significance of the study is to provide additional information pertaining to GDM regarding blood glucose levels and the

consumption of macronutrients (carbohydrates, saturated fat, total fat, and fiber). The study will provide information on the amounts of macronutrients consumed in relation to an increase or a decrease in blood glucose levels. This information can help determine whether or not it is safe to consume a certain amount of macronutrients without harming the mother or her baby.

Limitations of the Study

The study does not provide information in regards to patients that were eliminated from the study because a full three days of food records were missing. The study does not include information in regards to monounsaturated or polyunsaturated fat; information regarding fat consumption includes only saturated fat and total fat. All blood glucose levels were self-monitored during the three days by the patients. This relies on accuracy and self-reporting of blood glucose values. Some of the patients did not record all four-blood glucose levels throughout the day; therefore some of the blood glucose data is missing.

Assumptions

The first assumption of the study is that carbohydrate consumption to a certain degree, usually exceeding 55%, does increase blood glucose levels.

The second assumption of the study is that a higher fiber consumption exceeding 25-35 g decreases blood glucose levels.

Importance of the Study

Four percent of all pregnancies in the US and as many as 14% of minority populations are diagnosed with GDM each year. There is little knowledge about this particular disorder; therefore many women go through their pregnancy without proper

diagnosis and treatment. Without proper treatment, medical and physical complications can occur. Thus, it is important to educate and help treat the current disorder to help ensure a healthy, normal pregnancy and delivery. Educating pregnant women on proper consumption of nutrients and a healthier lifestyle will help promote a healthy pregnancy for both the mother and her baby.

CHAPTER TWO

REVIEW OF LITERATURE

Introduction

Gestational Diabetes Mellitus (GDM) also known as hyperglycemia is defined as a carbohydrate intolerance of variable severity with the onset or first recognition occurring during pregnancy (Fagen, et al., 1995 and Moses, et al., 1997). During the third trimester of pregnancy, the mother experiences an impaired ability to metabolize carbohydrates properly. This factor is usually caused by a deficiency of insulin production, which does occur during the third trimester of pregnancy. Kalhan (1998) defined GDM in pregnancy as a disorder of all fuels in the mother wherein decreased insulin secretion in the mother results in increased availability or transport to the fetus of all insulin-dependent substrates. Women who are diagnosed with GDM typically have normal carbohydrate tolerance before pregnancy, and their carbohydrate tolerance returns to normal after delivery as opposed to Diabetes Mellitus Type 1 and Type 2 (Fagen, et. al., 1995). Diabetes Mellitus Type 1 and Type 2 is defined as a lack of insulin secretion or a defect in insulin absorption that occurs for a lifetime once diagnosed.

Epidemiology

GDM occurs in 2-5% of all pregnancies and is associated with increased maternal and fetal-neonatal morbidity and is also a well-known risk factor for metabolic problems later on in life (Caruso, et al., 1999). Tepper and Seldner (1999) stated that GDM affects approximately 4% of all pregnancies in the United States and prevalence rates can reach as high as 14% in the minority populations. Jovanovic and Pettitt (2001) stated that

GDM can affect up to 14% of the pregnant population, which totals to 135,000 women per year in the United States. Caruso et al. (1999) suggested that the prevalence of GDM increases when chronic hypertension is present. Caruso et al. (1999) also suggested that blood pressure influences the degree of insulin resistance in pregnancy and that adiposity is a less strong predictor of insulin resistance than a mean arterial pressure in a population with normal and abnormal carbohydrate metabolism. Jovanovic and Pettitt (2001) stated that the risk of recurring subsequent pregnancies is reported to be 60%-90%, depending on the woman's first trimester weight in those pregnancies. Jovanovic and Pettitt (2001) also stated that after a pregnancy with GDM, the mother has an increased risk of developing type 2 diabetes or impaired glucose tolerance (IGT).

Fraser (2002) stated that most women experience an increased requirement for insulin as pregnancy advances, but this is related to the physiological increase in the insulin resistance associated with pregnancy and resolves almost immediately after delivery. Jovanovic and Pettitt (2001) stated that an insulin resistance occurs in some degree in all pregnancies, but those women who are unable to compensate develop GDM.

Butte (2000) stated that by the third trimester, basal glucose concentrations are 10-15 mg/dL lower and insulin is almost twice the concentration of nongravid women. Butte also stated that postprandial glucose concentrations are significantly elevated and the glucose peak is prolonged as well as an increase in basal endogenous hepatic glucose production to meet the increasing needs of the placenta and fetus. Butte explained that endogenous glucose production remains sensitive to increased insulin concentrations throughout gestation, in contrast with the progressive decrease in peripheral insulin sensitivity.

Butte (2000) stated that during GDM there are alterations in fasting, postprandial, and integrated 24-hour plasma concentrations of amino acids, lipids, and glucose and there is evidence that supports the view that GDM is related to a pronounced peripheral resistance to insulin. Butte discussed the hormonal changes and differences seen in GDM women. It appears that basal endogenous glucose production increases similarly in patients with GDM and in control subjects throughout gestation. Butte stated that an increase in first-phase insulin response was observed in control subjects and in patients with GDM with advancing pregnancy; however, the increase is greater in the control subjects. Butte also noted that in late pregnancy, insulin suppression of hepatic glucose production is less in patients with GDM. Butte found that decreased insulin stimulated glucose disposal preceded the development of decreased insulin response in women with GDM and was evident before pregnancy. Butte stated that the relative decrease in first-phase insulin response, as the first manifestation of beta cell dysfunction, and impaired suppression of hepatic glucose production becomes evident only after progressive decreased insulin sensitivity in late gestation, resulting in hyperglycemia.

Romon, et al. (2001) have shown that a physiologic increase in plasma free fatty acids inhibited insulin-stimulated glucose uptake in healthy pregnant women and suggested that the rise in plasma free fatty acids levels observed during late pregnancy could at least partly explain insulin resistance seem in GDM. During pregnancy this may be enhanced by the high rate of glucose utilization due to the needs of both fetus and placenta. Therefore the mother will then adapt to an increased demand for glucose by increasing gluconeogenesis from glycerol and thus increase lipolysis. If this condition is

not treated properly both the mother and her baby are at risk for serious complications (Romon, et al., 2001).

Complications of Gestational Diabetes Mellitus

Some of the conditions that have a negative impact on the mother include polyhyramnos, premature delivery, pregnancy induced hypertension, and development of bladder, kidney, and urinary tract infections. Polyhyramnos is defined as too much amniotic fluid in the uterus which can cause difficulty breathing. Another condition that can be exhibited by untreated GDM is preeclampsia. Preemclampsia is defined as an abnormal condition of pregnancy characterized by the onset of acute hypertension, proteinuria, and edema after the twenty-fourth week of gestation (Clausen, et al., 2001). Preeclampsia develops as a consequence of a complex interaction among multiplicity of factors originating in two genetically different individuals, the mother and the fetus. Diagnosis includes requiring the presence of proteinuria and pregnancy-induced hypertension. Preeclampsia if untreated, because of its severity, promotes the risk for an increase in premature delivery and prevalence of intrauterine growth retardation. Not only is the mother at risk for complications if GDM goes untreated, the fetus is also at risk for complications (Clausen, et al., 2001).

The risk factor for later onset of Diabetes Mellitus type 2 increases in women when GDM is present in pregnancy. Fraser (2002) stated that the peak incidence of new diagnosis of type 2 diabetes occurs after about 20 years of obesity, particularly when accompanied by poor nutrition and limited physical activity. Fraser (2002) examined a particular population with an average age of 26 and an average parity of slightly less than two. Fraser concluded that it is therefore likely that if any of these obese, white women

chose to have 5 or 6 children and were still reproducing in their late 30's and early 40's, they would also be a high-risk group for gestationally impaired glucose tolerance (GIGT) and GDM.

Complications to Perinatal Outcomes

Negative impacts that affect the fetus include macrosomia, Respiratory Distress Syndrome, jaundiced babies, prenatal mortality, neonatal hypoglycemia, polycythemia (an increase in the number of erythrocytes in the blood that may be primary or secondary to pulmonary disease or heart disease), hypocalcaemia, and hyperbillirubinemia (Fagen, et al., 1995 and Tepper and Seldner, 1999). The most serious complication of undetected and untreated GDM is intrauterine fetal demise. But the most frequent complication of GDM is fetal macrosomia (Fagen, et al., 1995). Macrosomia is defined as an abnormal condition characterized by excessive size and stature. Jovanovic and Pettitt (2001) described macrosomia as a birth weight that is either greater than the 90^{th} percentile for gestational age and sex or 2 SD's or more above the normal mean weight. This may affect up to 40% of the offspring of pregnancies complicated with GDM.

Jovanovic and Pettitt (2001) observed macrosomia in 17.9% of pregnancies complicated by GDM despite treatment compared with 5.6% of control subjects. Jovanovic and Pettitt stated that macrosomia is associated with an increased risk for birth injuries, a direct result of the large size of the fetus. The risk of shoulder dystocia is increased by as much as 30-fold in diabetic pregnancies when the infants weigh more than 4500 g. When estimated fetal weight is excessive, the risk for a cesarean delivery increases to avoid shoulder dystocia. Jovanovic and Pettitt (2001) stated though that when the obstetrician delivers the infant early to stop the in utero growth, complications

related to prematurity, such as hyperbilirubinemia, hypocalcemia, and respiratory distress may result. Fagen, et al. (1995) suggested that fasting hyperglycemia may be the only abnormality of carbohydrate metabolism in obese, pregnant women and this hyperglycemia is associated with a 20% increase in the risk of macrosomia. Macrosomia is known as the major perinatal morbidity in GDM and there is a consequential increased rate of primary cesarean section (Kalhan 1998 and Gabbe 1998). The risk of macrosomia can be reduced with the use of intensive dietary therapy and glucose monitoring at home, which will be discussed later in this review.

Romon et al. (2001) discussed the relationship of infant birth weight to gestational age and the inverse relationship of smoking to birth weight, suggesting that outside factors can also contribute to the infant's state at birth. Jovanovic and Pettitt (2001) stated that another complication associated with GDM is intrauterine growth retardation that is associated with subsequent diabetes in populations with a high prevalence of malnutrition.

Infants born of women, who are already diabetic, can also exhibit these complications as well as other further complications. Fraser (2002) stated that approximately 30% of apparently well-controlled diabetic women will produce a baby who is hyperinsulinaemic and macrosomic. This would normally be reported as a birth weight greater than 4 kg at term or greater than the 90^{th} percentile of weight for gestational age. Fraser also stated that obstetricians and midwives are all well aware that maternal diabetes continues to be associated with shoulder dystocia and that this complication cannot be competently predicted, therefore it is advised that these women with diabetes should not give birth at home, due to these complications.

Fraser (2002) stated there are other preexisting complications and malformations that occur in infants of diabetic mothers. These congenital malformations include spina bifida, anencephaly (absence of the brain and spinal cord in which the cranium does not close and the vertebral canal remains a groove), cardiac anomalies, low gut atresias, renal anomalies, situs inversus and caudal regression.

Long-term Complications upon Neonate

There are many other factors that not only occur during birth but also affect the infant during childhood and adulthood. Gabbe (1998) discussed that mother's with GDM present during pregnancy increased the likelihood of obesity, glucose tolerance, and neurobehavioral and developmental abnormalities at birth and during childhood for their infant. Jovanovic and Pettitt (2001) also stated that the infant of a woman with GDM is at a higher risk of developing obesity, impaired glucose tolerance, or diabetes at an early age. Bo et al. (2001) suggested that a possible explanation of the association of shortness of stature and GDM could be reduced fetal growth, which was reported to be associated with insulin. Bo et al. further discussed that the prevalent association of short stature with GDM in women with a greater mass of fat did support the hypothesis that low birth weight predisposes to obesity, reduced height and insulin insensitivity in the adult life.

Risk Factors for Gestational Diabetes

When a woman becomes pregnant there are many risks factors she needs to examine if there is a concern of GDM being present. The most common risk factors that are associated with GDM include family history of diabetes, obesity, over the age of 30 years old, personal history of GDM, and belonging to a specific ethnic group. Jovanovic and Pettitt (2001) stated that women at the greatest risk of developing GDM are those

who are obese, older than 25 years, have a previous history of abnormal glucose metabolism or poor obstetric outcome, have first-degree relatives with diabetes, or are members of ethnic groups with high prevalence of diabetes. Ethnic groups that are commonly associated with GDM include Hispanic, African American, Mexican, Native American, South or East Asian, and Pacific Island or Indigenous Australian ancestry.

Caruso et al. (1999) studied the relationship between chronic hypertension and its association with GDM. Caruso et al. discussed that women with GDM have significantly higher weight gain during pregnancy but when compared to women with GDM and chronic hypertension the weight gain was less than expected. Caruso et al. showed that women with chronic hypertensive GDM had significantly higher systolic, diastolic, and mean arterial pressure (MAP) compared with the women with GDM. Caruso et al. reported that chronic hypertensive GDM women had approximately 15% higher body fat than women with GDM. Caruso et al. therefore raised the question as to whether or not increased adiposity could account for an increased insulin resistance during pregnancy. The study by Caruso et al. suggests that an increase in blood pressure influences the degree of insulin resistance in pregnancy and that adiposity is a less strong predictor of insulin resistance than MAP in pregnant women with abnormal carbohydrate metabolism. Caruso et al. questioned whether there is a possibility that GDM could be a risk factor from increased blood pressure and not only an increase in weight. When discussing issues on age and BMI and an increased risk of GDM, Tepper and Seldner's (1999) study demonstrated that women with GDM were older than 27 years of age and had a significantly higher prepregnancy BMI than women without GDM.

Additional risk factors for GDM that could easily be modified include lack of exercise and dietary fat as well as life style habits that adversely influence insulin resistance, such as smoking and certain drug use. Bo et al. (2001) stated that nothing is known about the relationship between dietary habits and the impaired glucose metabolism in Caucasian women who are pregnant, or whether life style habits cause GDM when conventional risk factors for GDM are absent. Bo et al. also demonstrated that GDM patients had higher pre-pregnancy weights and BMI as well as a more frequent history of diabetes in first-degree relatives. The study conducted by Bo et al. also demonstrated that the women with GDM had a higher fat intake, especially saturated fat. Bo et al. analyzed the data using a multiple regression model using age, lower height, familiar diabetes, BMI, and percentages of saturated fat as variables for GDM. The regression model demonstrated that all of these variables were directly associated with the presence of GDM after adjusting for gestation age.

Wang et al. (2000) examined the aspect of increased body weight and the current intake of polyunsaturated fat. Wang et al. demonstrated that both body weight and polyunsaturated fat intake showed significant independent relationships with glucose concentrations such that increased weight and decreased polyunsaturated fat intake were each predictive of the occurrence of GDM.

The risk factors of GDM can also be associated with a recurrence of GDM from previous pregnancies. Moses et al. (1997) discussed that the recurrence rate of GDM in a subsequent pregnancy has ranged from 30-50%. Factors, which in some studies that have been associated with a recurrence of GDM include obesity, weight, gain between pregnancies, and insulin use in pregnancy. While weight gain between pregnancies

appears as the most consistent risk associated with a recurrence of GDM, there are no reports examining whether any dietary differences exist between women who develop a GDM recurrence (Moses, et al., 1997).

Wang et al. (2000) also demonstrated that variations in the dietary intake of fats and carbohydrates can have a profound influence on insulin resistance and sensitivity. Wang et al. (2000) concluded that women who developed a recurrence of GDM had a significantly higher fat intake than women who did not have a recurrence. This would suggest that a high fat diet, by its effect on insulin resistance, may be linked to the development of GDM, and a low fat diet could help protect this condition.

Physiology of Gestational Diabetes

During pregnancy, women can experience many different symptoms related to the changes occurring in their bodies. When GDM is present additional symptoms are noticed during pregnancy. One common symptom not necessarily associated with GDM but that can contribute to complications is "morning sickness". "Morning sickness" usually attenuates for the majority of women by week 17, clearly before the diagnosis of GDM is made (Fagen, et al., 1995). However if morning sickness persists throughout the third trimester, when GDM is present other complications can exist. Fagen et al. (1995) discussed that ongoing morning sickness could present eating difficulties, especially for women who require insulin. This circumstance may make it very difficult to control blood glucose levels, leading to further complications throughout the last trimester of pregnancy.

Another symptom present during GDM is an insulin resistance, especially if there is no decompensation in overall glucose and protein turnover during the fasting state.

Kalhan (1998) discussed that women diagnosed with GDM manifest varying degrees of perturbation in protein metabolism. Kalhan believes that this factor may contribute to persistent fetal morbidity in GDM. Caruso et al. (1999) demonstrated that women with pregnancies complicated by concurrent GDM as well as chronic hypertension are greatly more resistant to insulin when compared with women with GDM alone, suggesting that hypertension has a significant increase in complications related to GDM.

Another symptom occurring during GDM and pregnancy is the alterations in taste perception. Tepper and Seldner (1999) discussed that taste perception is reduced for simple sugars, which could increase the preference for sweet foods in individuals with GDM. As many as 85% of women experience food cravings during pregnancy, which are especially acute for sweet foods such as ice cream, cakes, pies, and fruit and fruit juices. Wijendran et al. (1999) defined hyperglycemia and hyperlipidemia; predominately elevated VLDL triacylglycerol and increased fatty acids, as common symptoms in the third trimester of pregnancies complicated with GDM.

Fagen et al. (1995) defined that pregnancy is a state of changing hormonal milieu that alters maternal metabolism. Maternal blood glucose levels decrease 0.8 to 1.1 mmol/L during pregnancy because of the continuous fetal demand, placental glucose consumption, and urinary glucose losses. Fagen et al. (1995) discussed that the second half of pregnancy is considered a diabetogenic state because elevated gestational hormones and increased maternal weight place a demand on the body for extra insulin. Maternal metabolism usually compensates for this altered state by secreting extra insulin. Fagen et al. (1995) stated that women with GDM, however, decompensate from a euglycemic state to a hyperglycemic state. Three mechanisms for this decompensation

are under study: mutation in the glucokinase gene; insulin resistance related to age, obesity, sedentary lifestyle, and family history; and a defect in the adipocyte glucose transport system to determine the correct pathophysiology related to this condition. Fagen et al. emphasized that carbohydrate, fat, and amino acid metabolism, insulin secretion, and insulin sensitivity are all intrinsic abnormalities in the state of GDM.

Caruso et al. (1999) through previous reports found evidence that, as with Type 2 Diabetes, women with GDM present with decreased insulin sensitivity, impaired suppression of endogenous glucose production by insulin infusion, high levels of triglycerides and free fatty acids, and a low high-density lipoprotein (HDL)-to-cholesterol ratio. Caruso et al. (1999) also discussed the similarity between GDM and type 2 diabetes, both of which are associated with hypertension.

Fraser (2002) stated that when compared to GDM, the incidence of type 1 diabetes mellitus is about 1-2 per 1000 mammalian species. Fraser also stated that although there is some evidence of a slight increase in the incidence of type 1 diabetes, almost all of the explanations for different prevalence of diabetes between populations and ethnic groups are explained by different frequencies of type 2 diabetes mellitus. Epidemiologic studies have shown that the incidence of GDM is significantly higher among women with chronic hypertension than in the general obstetrics population. Caruso et al. (1999) argued that the combination of chronic hypertension and GDM represents a more severe metabolic dysfunction than GDM alone. Wijendran et al. (1999) discussed the association between decreased insulin sensitivity combined with insufficient insulin secretion in GDM result in exaggerated glucose tolerance and alterations in lipid metabolism. Wijendran et al. also discussed that an insulin resistance

coupled with perturbations in general lipid metabolism in GDM may affect essential fatty acid metabolism. This could have important implications for fetal growth and central nervous system development. Hachey (1994) stated that all lipid and lipoprotein components of blood are significantly elevated during the third trimester of pregnancy.

Jovanovic (1999) stated that during GDM as well as diabetes mellitus, cells are deprived of glucose in association with a diminished concentration or insufficient action of insulin, thereby accelerating ketogenesis. During pregnancy ketogenesis is especially accelerated in the third trimester because of a decline in maternal glucose concentrations attributed mainly to fetal glucose utilization, a parallel fall in plasma insulin concentrations, and enhanced mobilization of fatty acids caused by the lipolytic hormones of pregnancy. Jovanovic (1999) stated that hyperketonemia in pregnancy has been implicated in the pathogenesis of congenital malformations and in mental impairment of the offspring of ketogenic mothers. Studies have observed that plasma fatty acid concentrations increased to 50-100% above control values and that plasma beta-hydrobutyrate concentrations increased 3-5 fold in both pregnant women with GDM and type 1diabetes.

Screening and Diagnosis

During pregnancy, all women have to receive a series of tests to help detect any complications that can occur. The American Dietetics Association recommends that all pregnant women be screened for GDM between 24 and 28 weeks of gestation (Fagen, et al., 1995). The 1st International Workshop Conference recommended universal screening, noting that all pregnant women who had not been identified as having glucose tolerance before the 24th week should first have a plasma glucose measurement which is

followed by a glucose load for confirmation between the 24th and 28th weeks of gestation (Gabbe, 1998). The standard screening test at present is measurement of plasma glucose 1 hour after a 50 g glucose load (Fagen, et al., 1995). Women with glucose levels of 7.8 mmol/L or more are then given a 100 g glucose load for a 3-hour oral glucose tolerance test (Fagen, et al., 1995). The diagnosis of GDM is made if there are two abnormal values on the 100 g oral glucose tolerance test. Some studies use a higher load of glucose for oral tolerance testing. The conducted study by Moses's et al. (1997) used a 75 g oral glucose tolerance test in the morning after a 12 hour fast at the beginning of their third trimester of pregnancy to help detect GDM. Bo et al. (2001) study as well as other studies used specific guidelines when screening for GDM. Bo et al. study used a screening test that was completed in the morning after an overnight fast of at least 8 hours but no more than 14 hours and after at least 3 days of an unrestricted diet and exercise. Jovanovic and Pettitt (2001) stated that the World Health Organization's (WHO) criterion was based on a glucose load of 75 g. Jovanovic and Pettitt also stated that with the recommendation that the diagnosis of gestational IGT, the physician should be alerted to the high-risk nature of the pregnancy, and the gestational IGT should be treated in the same way as GDM. Fraser (2002) stated that the WHO criteria for venous plasma glucose diagnosed GDM on a fasting level greater than 7.8 mmol/L and/or a two-hour value above 11.1 mmol/L. Fraser (2002) stated that values in this range can help diagnose GDM and decrease the incidence of complications to the mother and the fetus.

Another way to help detect GDM in the third trimester of pregnancy is to use a urea tracer dilution method. Kalhan's (1998) study used the urea tracer dilution method in overnight fasting subjects and observed a significant decrease in the rate of urea

synthesis, which helps detect an increase in protein metabolism during pregnancy. Kalhan (1998) also used the Hemoglobin A1c test to help detect GDM in the pregnant subjects. This method of testing helps examine the blood glucose levels over a longer period of time than just a few hours. Gabbe (1998) discussed that the diagnosis of GDM would be made when two or more of the following plasma glucose concentrations were met or exceeded: fasting, 105 mg/dL; 1-h, 190 mg/dL; 2-h, 165 mg/dL; and 3-h, 145 mg/dL. Elevated plasma fasting glucose level of greater than 105 mg/dL was identified as increasing the likelihood of poor prenatal outcome. Gabbe's (1998) study determined though that the cutoff for the screening test of 140 mg/dL (7.8mmol/L) could fail to detect approximately 10% of women with GDM. Gabbe (1998) noted that these screening tests need to be more specific in order to make an accurate diagnosis of GDM.

Glycosuria is another form of screening and diagnosis for GDM during the third trimester of pregnancy. Fraser (2002) stated though that glycosuria becomes an unreliable monitoring test in pregnancy because of the low renal threshold for glucose, thus not making an accurate GDM diagnosis.

Medical and Nutrition Therapy

Once GDM is diagnosed, both medical and nutrition therapy needs to be initiated. Proper medical and nutrition management will help reduce problems that are associated with GDM. The main common goal of medical management is to reduce the perinatal morbidity and mortality that is associated with GDM through control of maternal blood glucose level (Fagen, et al., 1995). Jovanovic and Pettitt (2001) reported on three studies that suggest that the risk of fetal macrosomia increases as the maternal postprandial glucose increases. Jovanovic and Pettitt therefore stated that keeping a 1-hour

postprandial blood glucose level between 120 mg/dL and 140 mg/dL minimizes the risk of macrosomia. Jovanovic and Pettitt also stated that although therapy begins with diet, insulin therapy should be initiated when peak postprandial response exceeds this target. Jovanovic and Pettitt stated that using a continuous glucose monitoring system has enabled the detection of previously missed postprandial blood glucose peaks in GDM. Jovanovic and Pettitt used this continuous glucose monitoring system in 10 women with GDM and discovered that, on average, the women spent 1.8 hours per day with glucose concentrations 120 mg/dL or greater. In these women, the continuous glucose monitoring system has revealed high postprandial blood glucose levels, which were previously unrecognized by intermittent finger stick evaluation, thus concluding how important continuous monitoring during GDM is for both the mother and her fetus.

Another method of medical management is measuring the HbA1c levels in the pregnant women. The HbA1c test is used to help determine more accurate blood glucose levels over a longer period of time, thus establishing whether or not the patient's blood glucose levels indicate GDM. Fraser (2002) stated that a useful clinical guideline is to measure the HbA1c (glycated hemoglobin) in a patient who is planning a pregnancy and advise her to continue her usual method of contraception and modify her diabetic control until the HbA1c percentage has fallen into the non-diabetic range.

Nutrition intervention is considered the cornerstone of treatment for all women diagnosed with GDM (Fagen, et al., 1995 and Wag, et al., 2000). To initiate proper nutrition management, a registered dietitian assists the patient with GDM to set proper goals towards eating healthy and right to help maintain blood glucose levels. The registered dietitian's most crucial and important goal is achieving normal blood glucose

levels while maintaining appropriate nutritional status and adequate dietary intake for fetal growth and development. The Registered Dietitian should then prescribe a meal plan that should promote normal blood glucose levels and promote adequate glucose monitoring to assess these blood glucose levels. Fagen et al. (1995) discussed the Sweet Success program to help maintain blood glucose levels. This program recommends avoiding fruit juice, processed and refined starch products, and sugar containing condiments. The Sweet Success program recommends a patient should consume three meals and three snacks a day and to self monitor glucose levels to normalize blood glucose throughout the last half of pregnancy.

It is also advisable that women measure ketone levels daily to ensure that adequate carbohydrate and/or energy are being consumed and to prevent ketosis (Fagen, et al., 1995 and Jovanovic, et al., 1999). The nutrient needs for pregnancy should also be met to promote a healthy pregnancy. Women should be assessed to determine whether or not a prenatal multivitamin and mineral should be started to meet any needs that are deficient. Regular exercise sessions should be initiated in order to help regulate blood glucose levels. Fagen et al. (1995) suggested the use of a food diary and blood glucose log to help assess the patient's ability to follow a meal plan and an opportunity to judge the effectiveness of the prescribed diet. Fagen et al. (1995) concluded that nutrition education needs to be covered at follow-up visits. Nutrition education should include portion sizes, recognizing sugar as an ingredient in prepared food, and eating out techniques. Visual aids such as food models, food labels, recipes, and fast food exchanges are also helpful to the learner.

Tepper and Seldner (1999) discussed the aspect of low energy diets that have been used with some success, but are controversial because of safety concerns for the developing infant. Romon et al. (2001) stated in their study that the first goal of management in GDM is to promote optimal growth and development through adequate nutrition and avoiding low birth weight or macrosomia. The second objective discussed is to normalize blood glucose levels and the third objective is to prevent excessive weight gain in obese women. Clinical studies have shown that energy restriction in GDM associated with obesity controls glycemia and reduces the incidence of macrosomia, but severe energy restriction is associated with increased levels of beta-hydroxybutyrate (Romon et al., 2001, Hachey, 1994, and Jovanovic and Pettitt, 2001). Romon et al. (2001) stated that in normal pregnant women, high carbohydrate and high fiber diets improve glucose homeostasis. Other studies have suggested that a high fiber diet is associated with impaired glucose tolerance during pregnancy. Romon et al. (2001) concluded that a careful distribution of carbohydrates throughout the day and the use of low glycemic index foods may help in limiting postprandial hyperglycemia. Of course, energy intake must be adjusted to achieve an appropriate weight gain according to prepregnancy BMI. Wang et al. (2000) stated that short term intervention studies have shown improved glucose control on diets emphasizing high monounsaturated fat intake compared with a high carbohydrate diet, whereas population based studies have shown either neutral or adverse effects of monounsaturated fat intake on measures of insulin action and glycemic control.

If nutrition and diet are unsuccessful during this period, insulin may need to be initiated. Fraser (2002) stated that many women experience an increased requirement for

insulin as pregnancy advances, but this is related to the physiological increase in the insulin resistance associated with pregnancy and resolves almost immediately after delivery. For those who do need insulin therapy, the type of insulin chosen should be based on the specific glucose abnormalities; the frequency of monitoring and the criteria for initiation of insulin are controversial. Jovanovic and Pettitt (2001) stated that a report showed that insulin does decrease the incidence of macrosomia, but does not decrease the cesarean delivery rate. Jovanovic and Pettitt also stated that some obstetricians believe that women who require insulin therapy are at a higher risk for difficulties during delivery, thus criteria for caesarean delivery should be liberalized. Others have shown that decreased incidence of macrosomia decreases the cesarean delivery rate if the indications for operative delivery are not changed for the woman with GDM who requires insulin.

Jovanovic and Pettitt (2001) stated that the type of insulin and its dosage schedule should be prescribed to lower the baseline and postprandial glucose levels. The basal level need may be given by using an insulin pump or multiple doses of isophane insulin (neutral protamine Hagedorn) (NPH). Jovanovic and Pettitt (2001) stated that the meal related hyperglycemia peaks should be treated with rapid acting insulin. Insulin lispro, an analog of human insulin, possesses unique properties that facilitate lowering the postprandial glucose concentration and is a valuable therapeutic option in the treatment of GDM. Jovanovic and Pettitt stated that the rapid absorption of insulin lispro allows for a faster peak insulin concentration versus regular human insulin. This effect more closely mimics the physiological first-phase insulin release and results in lower postprandial glucose concentrations.

Fraser (2002) discusses the aspects of insulin therapy not only for the diagnosis of GDM, but for diabetes mellitus type 1 and type 2. Fraser stated that management is very similar and indeed in most clinics the women with type 2 diabetes would be switched from oral hypoglycemics to insulin for the duration of the pregnancy. Jovanovic and Pettitt (2001) stated that both the American College of Obstetricians and Gynecologists and the American Diabetes Association do not recommend the use of oral hypoglycemic agents during pregnancy. More research is needed before the initiation of oral agents can be administered during GDM, until then diet therapy and insulin therapy are used to treat GDM. Fraser (2002) stated that insulin treatment requires different regimens, as many of these women are obese and very insulin resistant. Fraser (2002) also stated that sometimes these women require four or five times more units of injected insulin per day to obtain the same sort of control as a type 1 diabetic. In the post-natal period where breastfeeding has been chosen, the women with diabetes may need fairly intensive supervision of her insulin dose. The requirement for insulin may fall quite dramatically on a short-term basis because of the diversion of energy into the process of lactation.

When looking at proper medical management, exercise is a useful treatment to help prevent hyperglycemia and to promote a healthy pregnancy. Clapp (1998) observed that women who continue regular, moderate to high intensity, weight-bearing exercise throughout pregnancy deliver lean infants who weigh about 300 g less than controlled subjects. Clapp (1998) concluded that the type of dietary carbohydrate in a healthy, physically active woman's diet influences both her postprandial blood glucose profile and her blood sugar response to exercise in both the pregnant and nonpregnant state.

Dietary management has been used to treat pregnancies complicated by diabetes since the 19th century. Peterson and Jovanovic-Peterson (1991) have stated that since the early years of insulin therapy, the recommended carbohydrate content of the diet has steadily risen form 35% of calories to the current recommended level of 50-60% of calories. Peterson and Jovanovic-Peterson stated that dietitians base their guidelines for nutritional management on a combination of nutrient requirements in pregnancy combined with dietary management of diabetes and self-monitoring of blood glucose. Peterson and Jovanovic-Peterson demonstrated that increasing dietary carbohydrates from 40-60% resulted in deterioration in glycemic control and a fall in plasma high-density lipoprotein cholesterol concentrations, but did not lower low-density lipoprotein cholesterol concentrations. Peterson and Jovanovic-Peterson also demonstrated that the high monounsaturated fat diet produced better glycemic control than the high carbohydrate diet and did not adversely affect plasma lipoprotein.

When dealing with GDM, there are other management strategies that need to be handled, such as obstetric management. This form of management deals with issues related to both the mother and her fetus, which includes proper fetal monitoring, intrapartum and postpartum management, Cesarean delivery, breast feeding recommendations, weight gain, and monitoring blood glucose levels. Fagen et al. (1995) mentioned two studies that showed an improvement in glycemic response during lactation. In a study of women with recent GDM, the fasting and 2-hour postprandial glucose levels improved in lactating women compared with nonlactating women. In addition, high-density lipoprotein levels were noted to be elevated in the lactation group. Fagen et al. stated that at 6 to 10 weeks postpartum, a 75 g, 2-hour glucose tolerance test

is recommended to detect impaired glucose tolerance or diabetes mellitus. Fagen et al. also stated that lactation lowers fasting concentrations of estradiols, plasma glucose, and insulin and may, therefore, mask true glucose intolerance in the lactating state.

Postpartum care includes education about the increased risk of development of diabetes mellitus type 2, the importance of achieving and maintaining desirable body weight, and the need for annual glucose tolerance screening (Fagen et al., 1995 and Romon et al., 2001). Counseling should be provided about contraception and the need for planning future pregnancies. Fagen et al. (1995) concluded that continued follow-up sessions for evaluation of the women's food diary, postprandial blood glucose levels, weight changes, and results of urine ketone testing are necessary for making adjustments to the meal plan to promote a healthy pregnancy and delivery. Gabbe (1998) stated that it is recommended that women with a diagnosis of GDM should be followed postpartum at periodic intervals to detect the onset of diabetes early in its course.

When discussing the consequences and management of GDM, prognosis comes to mind. Prognosis discusses the risk of developing diabetes mellitus type 2, obesity, or glucose tolerance in the future for example. Fagen et al. (1995) discussed the possibility that a women diagnosed with GDM in her first trimester may have had undiagnosed non-insulin diabetes mellitus type 2 before conception and has a higher risk of birth abnormalities. Moses et al. (1997) stated that the recurrence rate of GDM in a subsequent pregnancy has ranged from 30 to 50%. Moses et al. reported that the relative risk of developing diabetes mellitus type 2 was increased if the usual diet contained foods with a high glycemic index and low fiber content.

Macronutrient Content of Diet

Other studies have shown that long-term ingestion of a high fat diet, particularly one containing either an increased amount or a proportion of saturated fats, can be associated with insulin resistance and a progression to glucose intolerance and diabetes. Gabbe's (1998) study concluded that it is recommended that women in whom GDM was diagnosed should be followed postpartum at periodic intervals to detect the onset of diabetes early in its course. Furthermore, evidence was presented that obesity and impaired carbohydrate tolerance may develop in offspring of diabetic mothers (8). Bo et al. (2001) discussed that it has recently been shown that women with recurrent GDM had a higher overall intake of fat (as percentage of energy) than those without recurrences. Fat consumption and GDM as well as obesity could be very well linked as further developing prognosis for diabetes mellitus type 2.

GDM can be easily prevented if the right goals and habits are set. Many studies have suggested lowering carbohydrates and increasing fat and protein to maintain glucose levels, but not enough evidence is available to prove these guidelines. Other studies discuss a decrease in overall energy to help prevent weight gain and maintain blood glucose levels to help prevent GDM. Short-term studies have shown that severe energy restriction (50% or 33% energy restriction) improves glucose tolerance but is associated with high levels of beta hydroxybutyrate (Romon et al., 2001). Other studies have reported that energy restriction results in decreased maternal weight gain and fewer macrosomic infants in obese women with GDM. However, it has recently been demonstrated in pregnant women that a high carbohydrate meal (55 to 60% of energy intake) induced no significant change in the glycemic response, if the meal consisted of

low glycemic index carbohydrates. Therefore further research is needed to cover all aspects of proper prescribed diet and nutrients recommended during pregnancy.

Jovanovic and Pettitt (2001) stated that diabetic fetopathy, which is a result of maternal postprandial hyperglycemia, can be minimized when the peak postprandial response is blunted. Jovanovic and Pettitt stated that this is best accomplished by carbohydrate restriction. Jovanovic and Pettitt believe that the optimal dietary prescription though provides the caloric and nutrient needs to sustain pregnancy but does not cause postprandial hyperglycemia. Jovanovic and Pettitt stated that the American Diabetes Association's diet for nonpregnant persons suggests that meal plans could have up to 60% carbohydrate composition.

Instituting this high carbohydrate diet for GDM could result in the need for insulin therapy in greater than 50% of women. Jovanovic and Pettitt (2001) stated that the National Academy of Sciences concluded that healthy obese pregnant women (greater than 150% of ideal body weight) should only gain 6.75 kg; the subsequent infant birth weight was optimized if the maternal weight gain was minimized to less than 3 kg or if no weight is gained. Jovanovic and Pettitt compared a study based on a calorie-restricted diet in GDM. The two diets used for this study reported a comparison of a 2400 kilocalorie diet versus a 1200 kilocalorie diet. Jovanovic and Pettitt reported that ketonemia developed in the calorie-restricted group after one week on the 1200 kilocalorie per day diet. Jovanovic and Pettitt also described a 33% carbohydrate restricted diet that was studied, resulting in normal range birth weight infants and no maternal ketonemia. Jovanovic and Pettitt also discussed another study where the presence of ketouria, which develops in 10% to 20% of all pregnancies after an overnight

fast and may protect the fetus from starvation, was seen. Jovanovic and Pettitt examined the two studies and concluded that neonatal complications to maternal ketones were only present in mothers with ketonemia from hyperglycemia, not from starvation. Jovanovic and Pettitt concluded by stating that pregnancy is a time when metabolic changes are carefully regulated to provide optimum substrate to both mother and fetus, thus subtle perturbations in metabolism during pregnancy can have implications not only for the mother and fetus but also for future generations.

Fraser (2002) discussed the issues in regards to pregnant women not only diagnosed with GDM, but women who are already diagnosed with diabetes mellitus type 1 and type 2. Fraser examined the different aspects of care for these pregnant women to provide a healthy pregnancy and birth by initiating proper nutrition. Fraser stated that the primary care team needs to be aware of these cases because of increased risks of hyperglycemia secondary to efforts to enhance control, or when nausea and vomiting interrupt the normal meal plan. Fraser stated that diabetic ketoacidosis (DKA) is fortunately relatively rare in pregnancy, but it is of considerable importance because it can rapidly lead to intrauterine fetal death. Fraser also stated that diagnostic confusion can arise because ketonuria and vomiting are common in pregnancy anyway. Fraser stated that there can also be a group in whom interventions based on lifestyles, particularly diet and exercise, might have a major benefit in terms of their long-term health and freedom from diabetes and its associated complications. Fraser therefore concluded that throughout pregnancy, but particularly in the peri-conceptional period and in the third trimester, outcomes for pregnancy are likely to be optimized by enhanced diabetic control. For example, miscarriage is more common when diabetes is poorly

controlled in early pregnancy, but there is no excess of miscarriage in well-controlled diabetics. Fraser stated that similarly, on the basis of a number of quasi-randomized studies it is likely that the four to five-fold increases in major congenital malformations seen in pregestational diabetes can be reduced by about 70% by enhanced periconceptional control.

There are many other aspects of GDM and macronutrient consumption that can help contribute to the treatment and prevention. Fat intake and GDM has been examined in many different studies to look at the overall nutrition aspects of maintaining blood glucose levels. Moses et al. (1997) reported that women who develop a recurrence of GDM have a significantly higher fat intake as a percentage of total energy than women who did not have a recurrence (Moses et al., 1997 and Bo et al., 2001). The proportions of polyunsaturated, monounsaturated, and saturated fats were the same in both groups in a study conducted by Moses et al. (1997) and there were no differences in the dietary sources of fat. Bo et al. (2001) study reported that GDM patients ate a significantly higher percentage of saturated fat and a lower intake of polyunsaturated fat. The percentage of saturated fat was an independent predictor of metabolic abnormalities in patients and the fact that the few women with an exceptionally high consumption of saturated fat all had glucose abnormalities is an intriguing confirmation of this condition. According to other literature, a higher proportion of polyunsaturated fat is associated with enhanced insulin action. The findings of Bo et al. (2001) agree with recent data on dietary fat subtypes and insulin resistance supporting a link between higher saturated fat intake and insulin resistance, progression to glucose intolerance and diabetes. In fact, a high proportion of long chain unsaturated fatty acids and a low proportion of saturated

fatty acids in the phospholipids of the skeletal muscle membranes have been related to a high insulin sensitivity and seem to affect the glucose stimulated insulin secretion. Wang et al. (2000) concluded that glucose intolerance and GDM were associated as expected with increased body weight and BMI, but unexpectedly and independently were associated with a reduced intake of polyunsaturated fats. Wang's et al. study has shown improved glucose control on diets emphasizing high monounsaturated fat intake compared with a high carbohydrate diet, whereas population based studies have shown either neutral or adverse effects of monounsaturated fat intake on measures of insulin action and glycemic control. Hachey (1994) stated that lowering total fat and cholesterol intakes may be possibly an effective means by which to alleviate chronic illnesses.

To be most effective, the dietary modifications would have to be implemented during pregnancy, and the safety and efficacy of the diets would have to be evaluated in controlled clinical studies (Hachey, 1994). In association with this higher percentage of fat intake, there was also a proportionate reduction in the amount of carbohydrate and fiber eaten (Moses et al., 1997).

Protein studies have also been examined to determine their role in GDM development and treatment. Kalhan (1998) reported that these studies show that pregnancy related nitrogen conservation occurs early in pregnancy and that the down regulation of leucine nitrogen turnover observed in normal pregnant women was decompensated in the women with GDM. The rate of leucine nitrogen turnover was higher in GDM women than in normal subjects and was similar to that observed in nonpregnant subjects. Thus, both the data reported in the literature and unpublished data

suggest significant alterations in maternal protein and amino acid metabolism in GDM women.

Carbohydrate intake has the most controversy and literature available when discussing GDM treatment and maintenance. Romon et al. (2001) reported that the main finding in their study was that the macronutrient composition of the diet affects the outcome of pregnancy in women with carbohydrate intolerance during pregnancy. Infant birth weight is inversely related to carbohydrate intake. Fiber intake has also been examined and discussed in regards to GDM. Bo et al. (2001) stated that fiber intake has a slight protective role in women with conventional risk factors for GDM. The diets that have been prescribed to lower glucose concentrations may be the same diets that create the other metabolic abnormalities associated with GDM (Jovanovic, 1999).

Jenkins et al. (2000) stated that several epidemiological studies have linked consumption of fiber rich foods to a reduced risk of type 2 diabetes mellitus and Coronary Heart Disease (CHD). Jenkins et al. believed that fiber rich foods contain different types of fibers as well as other potentially beneficial compounds, and many foods naturally high in fiber have a low glycemic index, possibly due to food form. Jenkins et al. stated that many beneficial effects seen with pharmacological doses of isolated viscous soluble fiber, including insulin sensitivity, decreased LDL cholesterol levels, and decreased clotting factors. Kendall et al. (2002) discussed that the glycemic index concept is an extension of the fiber hypothesis, suggesting that fiber consumption reduces the rate of nutrient influx in the gut. Kendall et al. suggested that early studies have shown that starchy carbohydrate foods have very different effects on postprandial blood glucose and insulin response in healthy diabetic subjects, depending on the rate of

digestion. Kendall et al. further stated that consumption of low glycemic index diets have been associated with higher HDL cholesterol concentrations and, in large cohort studies, with decreased risk of developing diabetes and cardiovascular disease. Kendall et al. (2002) concluded that despite inconsistencies in the data, sufficient, positive findings have emerged to suggest that the dietary glycemic index is of potential importance in the treatment and prevention of chronic diseases.

Effects of Carbohydrate and Fiber on Blood Glucose

When dealing with GDM, medical and nutrition therapy is initiated to normalize blood glucose levels. Many studies have suggested decreasing carbohydrate intake or increasing fiber intake to treat GDM. Are these suggestions safe and will they help normalize blood glucose levels and treat existing GDM?

Butte (2000) stated that studies have shown an increased contribution of carbohydrate to oxidative metabolism in late pregnancy. Butte explained that carbohydrate oxidation as a percentage of nonprotein energy expenditure decreases from 66% to 58% from late pregnancy to six months postpartum. Butte also stated that absolute rates of carbohydrate oxidation are significantly higher in pregnancy than postpartum. Butte suggested that these observations therefore agree with the increased glucose production reported in fasted pregnant women, despite lower fasting plasma glucose concentration. The higher respiratory quotient may reflect the obligatory glucose use of the fetus, which uses an estimated 20-25 g glucose/d in late gestation, well within the increment in carbohydrate oxidation seen in our study. Butte examined total energy expenditure, basal metabolic rate, and whole body net carbohydrate and fat utilization and concluded that they did not differ significantly between insulin treated patients with

GDM and control subjects. Butte emphasized that recent findings from the Diabetes in Early Pregnancy Trial indicated that the postprandial glucose concentrations, not fasting concentrations, are predictive of birth weight. The American Diabetes Association concluded that the percentage of carbohydrate in the diet is dependent on individual eating habits and the effect on blood glucose and percentage of body fat depends on assessment and treatment goals. Butte (2000) stated that many studies have shown that the lower percentage of carbohydrate blunts the postprandial hyperglycemia. Butte (2000) also noted that one study indicated that carbohydrate restriction improved glycemic control, decreased the insulin requirement, decreased the incidence of large for gestational age infants, and decreased cesarean deliveries for macrosomia. However, more evidence is needed in order to determine carbohydrate intake and its relationship to blood glucose levels.

Hallfrisch and Behall (2000) stated that consumption of a number of grains and grain extracts has been reported to control or improve glucose tolerance and reduce insulin resistance. Dietary goals recommend the consumption of three or more servings per day of whole grains, but the average consumption in the United States is less than one serving per day. Hallfrisch and Behall stated that there are a number of mechanisms by which grains may improve glucose metabolism and delay or prevent the progression of impaired glucose tolerance to insulin resistance and diabetes. These mechanisms appear to be related to the physical properties and structures of grains. The composition of the grain, including particle size, amount and type of fiber, viscosity, amylose and amylopectin content all affect the metabolism of carbohydrates from grains. Hallfrisch and Behall stated that increasing the whole grain intake in the population can result in

improved glucose metabolism and delay or reduce the risk of developing type 2 diabetes mellitus. Hallfrisch and Behall also stated that a number of whole grains are beneficial in reduction of insulin resistance and improvement in glucose tolerance. Hallfrisch and Behall concluded that recent research using various grains and grain products effective in improving insulin resistance or lowering glycemic index is still being studied for further information.

In conclusion, the steps in treatment and prevention of GDM involve detection, nutrition counseling and education, and slightly modifying overall daily lifestyle factors. This may include changing diet patterns and incorporating exercise into a daily schedule, since a moderate part of the pregnant population is not exercising. Including these steps into a women's lifestyle can significantly play a part in decreasing the risks for both the mother with GDM and the baby.

CHAPTER THREE

MATERIALS AND METHODS

Study Design

This study is part of a wider spread prospective study involving the Nutrition Practice Guidelines initiated by the American Dietetics Association, conducted from February 9, 1999 to the spring of 2001. The protocol, "Field Test Evaluation of Nutrition Practice Guidelines of Gestational Diabetes Mellitus (GDM)", was reviewed and approved by the Protocol Review Committee of the International Diabetes Center (Appendix A). There was Facility Consent form, a Volunteer Dietitian Consent form, and a Patient Consent form that were completed at each site (Appendixes B, C, and D). Each volunteer dietitian received instructions for obtaining consent, recruitment, authorization for release of information by patient, and a summary of the study (Appendix E). Each site had a separate start and end date, with separate IRB approval. The study involved nine sites throughout the United States. The states involved in the study included Massachusetts, Iowa, Wisconsin, Texas, Minnesota, Georgia, Florida, Tennessee, and New Mexico. The study involved a total of 42 participants who met the established criteria. The patients involved in the study were diagnosed with Gestational Diabetes Mellitus (GDM) based upon specific criteria when assessed during their third trimester of pregnancy. In order to determine a diagnosis, the study protocol required that the patient had to be diagnosed according to the standards set by their institution at approximately 28 weeks gestation, which typically used the 100-gram OGTT (oral glucose tolerance test) (at the time of the study, there were 2 sets of blood glucose levels used and they did not differentiate). At least 2 of the values from the OGTT needed to be

abnormal in order for the women to be diagnosed with GDM (ie fasting: ≥ 105 mg/dL, 1 hour ≥ 190 mg/dL, 2 hours ≥ 165 mg/dL, 3 hours ≥ 145 mg/dL). The additional eligibility criteria initiated for this study included being in the age range of 18-45 years, carrying a singleton pregnancy, and entry into the trial from 28 to 32 weeks gestation. Factors that excluded the subjects from the study included already being diagnosed with type 1 or type 2 diabetes mellitus, having a diagnosis of sickle cell anemia, thalassemia, or other hemoglobinopathy, medical conditions prior to pregnancy (e.g., lupus, hypertension, thyroid disease, cardiovascular disease, transplants, renal disease, or other serious medical conditions), or being precipitated with current infectious diseases (HIV, active TB, or other similar diseases).

Nutrition Component

The dietitian spent approximately one hour with each woman to assess and gather appropriate data regarding medical history, anthropometric data, laboratory data, lifestyle factors, appetite, eating pattern, infant feeding plans, food recall, and exercise. The Dietitian required that the women obtain a three-day food record (Appendix F) in order to evaluate their overall diet patterns in regards to carbohydrates, fats, protein, and fiber and to compare these nutrients to their self recorded blood glucose levels.

Once the data were collected and examined, the dietitian was able to provide appropriate nutrition counseling and education to the women. The dietitian provided nutrient recommendations, which included sufficient calories to promote adequate weight gain, carbohydrate control to ensure maintenance of blood glucose levels, protein needs for pregnant women, fat intake, and any other pertinent factors related to nutrition. Approximately 40-45% carbohydrate, 20-25% protein, and 30-40% fat was

recommended as appropriate intake during this period. The women were instructed to follow a food plan that included 3 small to moderate sized meals and 2-4 snacks per day. The meals typically contained 45-60 grams of carbohydrate and 15-30 grams of carbohydrate at snacks. Elimination of foods containing large amounts of carbohydrates such as sweets and soft drinks was also recommended at this time to help control blood glucose levels. During the session, the dietitian also instructed the woman on how to properly complete a three-day food record by providing examples to help ensure nutrition management throughout the remainder of their pregnancy. Blood glucose levels were also monitored and recorded four times a day (fasting, 1 hour postprandial (PP) for breakfast, lunch, and supper) by the women to ensure adequate maintenance. Maintenance goals for blood glucose levels were defined as 95 mg/dL fasting, less than 140 mg/dL one hour postprandial, and less than 120 mg/dL two hour postprandial.

The women were seen later in their pregnancy by the dietitian for a follow-up encounter. The women were instructed to bring a copy of their food and blood glucose records for further evaluation. At each follow-up session, the dietitian assessed records of food intake, blood glucose testing, weight change, patient's ability to follow instruction, and any questions or concerns needing to be addressed. The dietitian discussed and explained the progression of the therapy during the session to ensure appropriate care standards throughout the remainder of the pregnancy. The women were finally instructed to follow their specific food plan and continue to monitor blood glucose levels up until delivery.

Data Analysis

All information was sent and collected by the International Diabetes Center (IDC) in Minneapolis, Minnesota for initial examination and evaluation. Demographic and diagnostic information was collected at enrollment of the patients at each facility. At the first initial visit with the Registered Dietitian, Hemoglobin A1c was obtained, and prior to delivery at approximately 36-38 weeks gestation. The food records, which included meal pattern and number of meals and snacks consumed were gathered at each individual site and then sent to the IDC for further evaluation. Each Registered Dietitian involved in the study, sent a copy of the three-day food records and blood glucose checks to the IDC for further data collection. Once all of the data was gathered by the IDC; total carbohydrate, protein, fat, and calories were calculated for examination and analysis.

The University of Wisconsin-Stout Institutional Review Board for Protection of Human Subjects approved the use of the data. After all of the pertinent macronutrient and non-macronutrient data was collected, data was analyzed using SPSS. Statistical analysis included frequencies, means, standard deviations, maximum, and minimum. Regression analysis and Pearson correlation were performed on grams of carbohydrate, grams of fiber, grams of protein, grams of total fat, BMI, and pregnancy weight before delivery versus blood glucose. Three separate regression analysis were conducted using different variables in the analysis versus blood glucose. Pearson correlations were performed on the variables utilized in the regression analysis.

CHAPTER FOUR

RESULTS

Calorie Intake

Three-day food records were collected from pregnant women during their third trimester of pregnancy, who were diagnosed with Gestational Diabetes Mellitus (GDM). Three day means of total calories as well as calories and grams of carbohydrate, protein, fat, saturated fat, and fiber for breakfast, am snack, lunch, pm snack, supper, and bedtime snack were calculated. Mean calorie intake is presented in Table 1. The mean daily calorie intake was 1645 kcals (Calories). Mean caloric distribution between breakfast, am snack, lunch, pm snack, supper, and bedtime snack was 301.3 kcals, 128.8 kcals, 450.2 kcals, 124.2 kcals, 509.3 kcals, and 131.2 kcals, respectively.

Table 1: Three-Day Mean Calorie Intake Obtained between 28-32 Weeks Gestation of Pregnant Women with Gestational Diabetes Mellitus

Meal Time	Number	Mean (Calories)	Standard Deviation	Minimum	Maximum
Breakfast	135	301.27	129.16	0	800.00
AM Snack	135	128.81	106.02	0	451.20
Lunch	135	450.23	188.58	0	1253.18
PM Snack	135	124.21	116.82	0	551.52
Supper	135	509.31	195.85	0	1061.50
Bedtime Snack	135	131.24	120.68	0	552.30
Total	135	1645.04	377.89	652.00	2453.00

Macronutrient Distribution

The three-day mean of macronutrients expressed as a percent of total calories is presented in figure 1. Mean intake of protein, fat, and carbohydrate were 20%, 35%, and 45% of total calories, respectively.

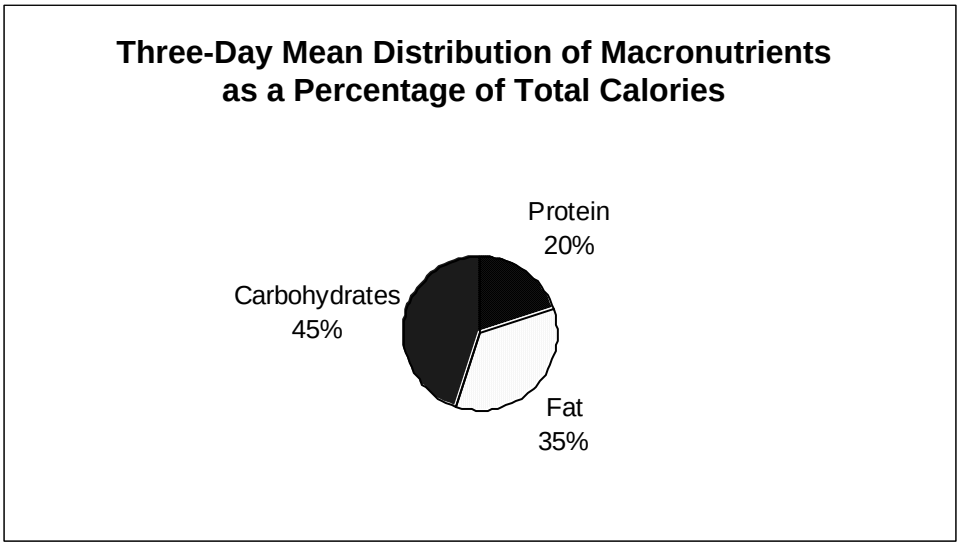

Figure 1: Mean Distribution of Macronutrients Expressed as Percentage of Total Calories Consumed between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus

Carbohydrate Intake

The carbohydrate intake is presented in Table 2. The mean daily carbohydrate intake was 188.3 g (grams). This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 33.7 g, 19.5 g, 49 g, 19 g, 48.8 g, and 18.3 g, respectively. Figure 2 presents the mean carbohydrate consumed at each meal throughout the day expressed as a percentage of total carbohydrate consumed. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 18%, 10%, 26%, 10%, 26%, and 10%, respectively.

Table 2: Three-Day Mean Carbohydrate Intake Obtained between 28-32 Weeks Gestation of Pregnant Women with Gestational Diabetes Mellitus

Meal Time	Number	Mean (Grams)	Standard Deviation	Minimum	Maximum
Breakfast	135	33.75	13.98	0	85.35
AM Snack	135	19.50	15.78	0	69.10
Lunch	135	48.79	22.10	0	145.19
PM Snack	135	19.14	16.43	0	66.07
Supper	135	48.77	24.28	0	135.74
Bedtime Snack	135	18.36	16.50	0	63.65
Total	135	188.31	55.49	51.58	342.16

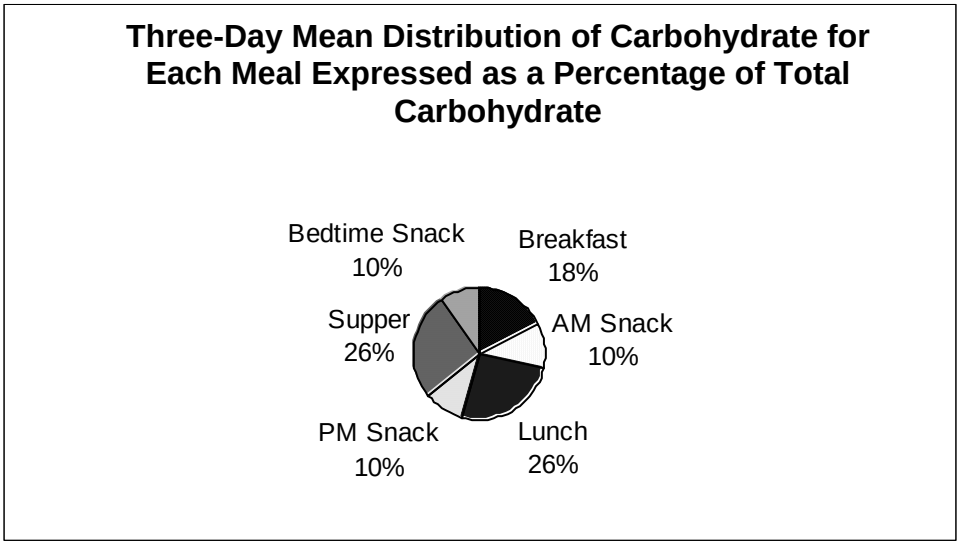

Figure 2: Three-Day Mean Distribution of Carbohydrate Intake Consumed (100% Carbohydrate Divided throughout the day) between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

The percentage of energy from carbohydrate for each meal is presented in figure 3. The mean daily percentage of carbohydrate was 46% of total calories. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 8.2%, 4.5%, 11.9%, 4.6%, 11.9%, and 4.5% of total calories, respectively. Figure 4 shows carbohydrate intake at each meal as a percentage of total calories as well as the carbohydrate intake at each meal expressed as a percentage of total carbohydrate consumed.

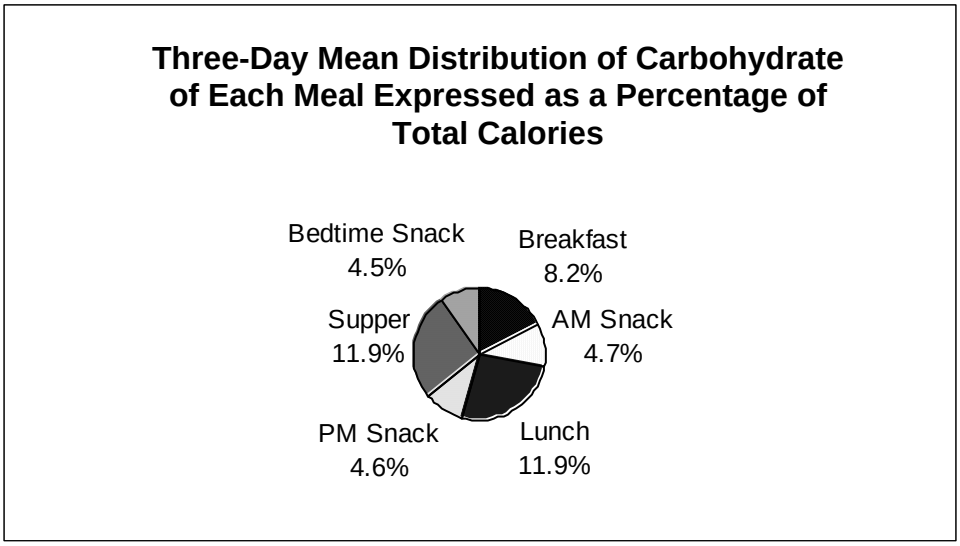

Figure 3: Three-Day Mean Distribution of Carbohydrate Intake Consumed (45% divided throughout the meals) between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus

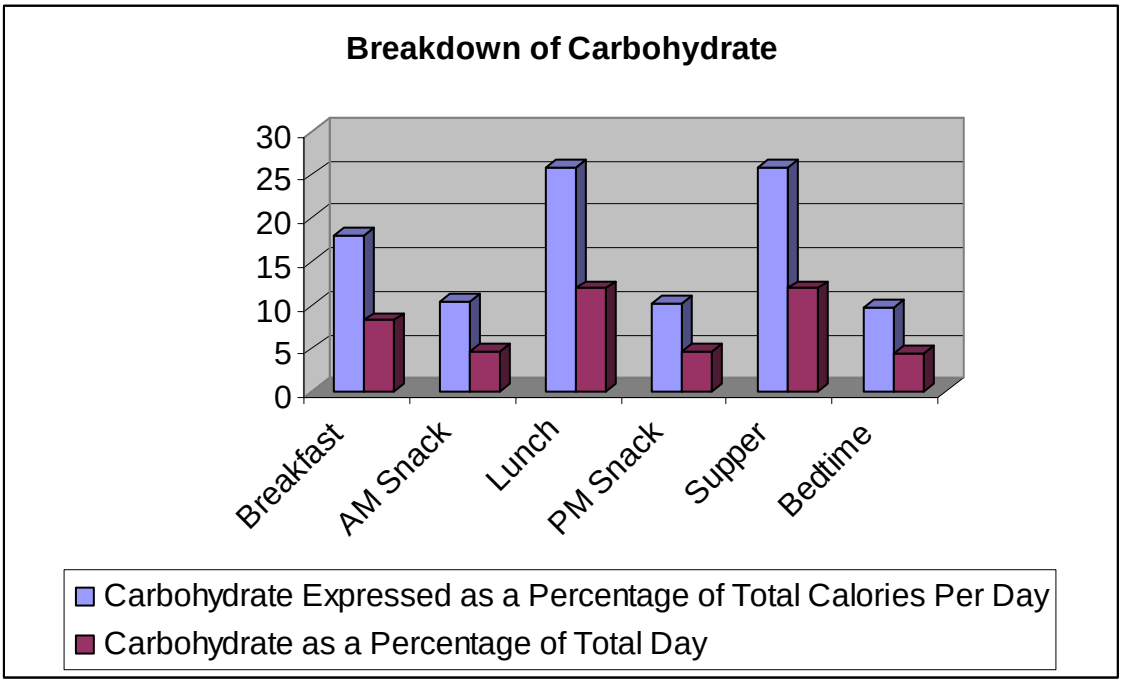

Figure 4: Three-Day Mean Distribution of Carbohydrate Intake at Each Meal Expressed as a Percentage of Total Calories and Carbohydrate Intake at Each Meal Expressed as a Percentage of Total Carbohydrate Consumed between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

Protein Intake

The protein intake is presented in Table 3. The mean daily protein intake was 82 g (grams). This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 13.7 g, 4 g, 23 g, 4 g, 31.9 g, and 5 g, respectively. Figure 5 presents the mean protein consumed at each meal throughout the day expressed as a percentage of total protein consumed. This was distributed between breakfast, am snack, lunch, pm snack, supper, bedtime snack as 17%, 5%, 28%, 5%, 39%, and 6%, respectively.

Table 3: Three-Day Mean Protein Intake Obtained between 28-32 Weeks Gestation of Pregnant Women with Gestational Diabetes Mellitus

Meal Time	Number	Mean (Grams)	Standard Deviation	Minimum	Maximum
Breakfast	135	13.79	7.15	0	35.74
AM Snack	135	4.03	4.57	0	18.85
Lunch	135	22.88	13.05	0	73.69
PM Snack	135	4.02	5.69	0	32.66
Supper	135	31.90	15.81	0	82.69
Bedtime Snack	135	5.00	5.58	0	30.28
Total	135	81.62	24.54	33.91	145.53

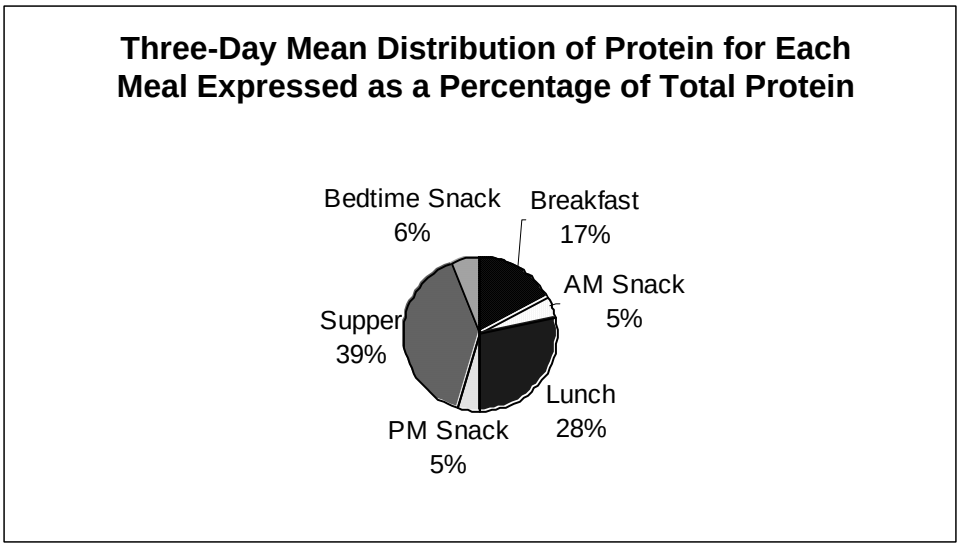

Figure 5: Three-Day Mean Distribution of Protein Intake Consumed (100% Protein Divided throughout the day) between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

The daily mean of energy from protein divided between meals is presented in figure 6. The three-day mean daily percentage of protein was 20% of total calories. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 3.4%, 0.9%, 5.6%, 0.9%, 7.8%, and 1.2% respectively. Figure 7 shows protein as a percentage of total calories at each meal as well as the protein intake at each meal expressed as percentage of total protein consumed.

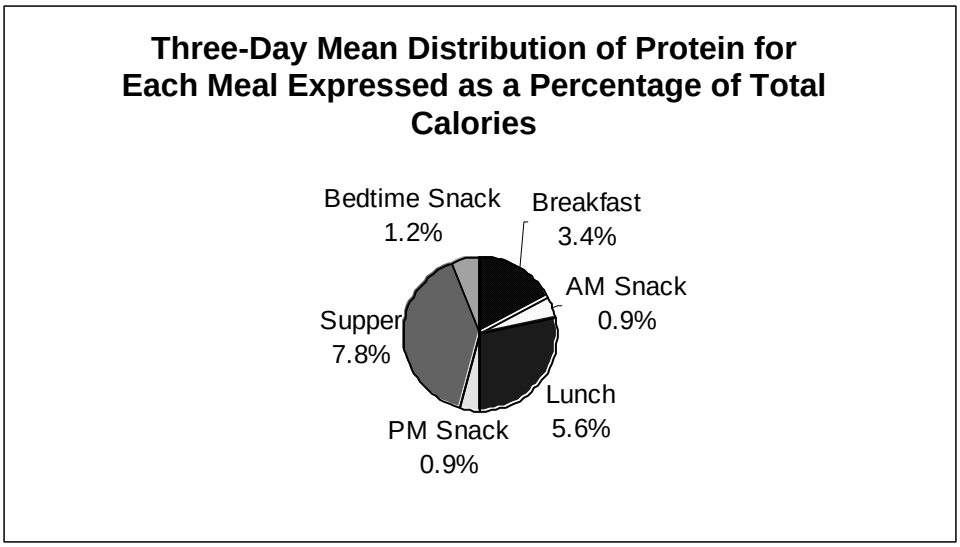

Figure 6: Three-Day Mean Distribution of Protein Intake Consumed (20% divided throughout the meals) between 28-32 Weeks Gestation Consumed by Pregnant Women with Gestational Diabetes Mellitus

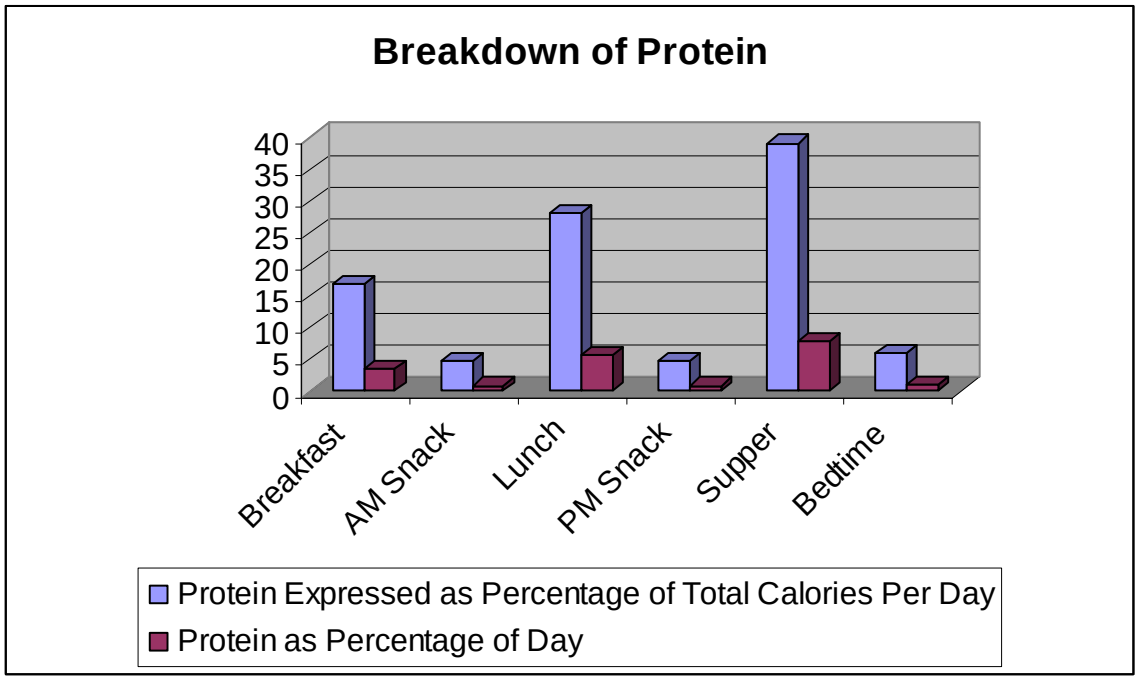

Figure 7: Three-Day Mean Distribution of Protein Intake at Each Meal Expressed as a Percentage of Total Calories and Protein Intake at Each Meal Expressed as a Percentage of Total Protein Consumed between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

Fat Intake

The fat intake is presented in Table 4. The mean daily fat intake was 65 g. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 12.7 g, 4.3 g, 18.5 g, 4.2 g, 21 g, and 4.3 g, respectively. Figure 8 presents the mean fat consumed at each meal throughout the day expressed as a percentage of total fat consumed. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 20%, 7%, 28%, 6%, 32%, and 7%, respectively.

Table 4: Three-Day Mean Total Fat Intake Obtained between 28-32 Weeks Gestation of Pregnant Women with Gestational Diabetes Mellitus

Meal Time	Number	Mean (Grams)	Standard Deviation	Minimum	Maximum
Breakfast	135	12.74	8.73	0	48.26
AM Snack	135	4.28	5.42	0	22.09
Lunch	135	18.54	11.35	0	60.10
PM Snack	135	4.19	0.76	0	28.16
Supper	135	21.01	12.74	0	59.00
Bedtime Snack	135	4.33	5.70	0	25.26
Total	135	65.09	23.00	21.58	138.23

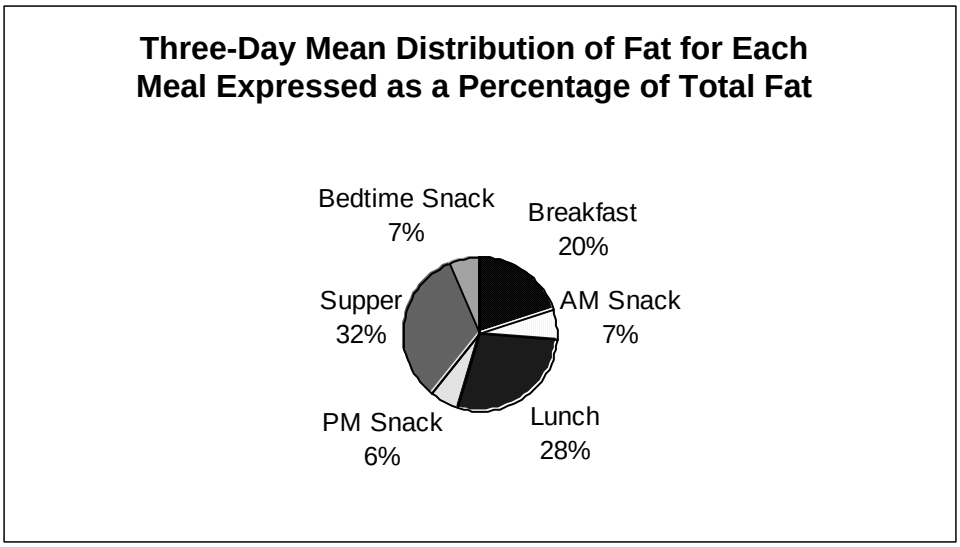

Figure 8: Three-Day Mean Distribution of Total Fat Intake Consumed (100% Total Fat Divided throughout the day) between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

The daily mean of fat intake as a percentage of total calories that was consumed is presented in figure 9. The three-day mean daily percentage of fat was 35% of total calories. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 7.1%, 2.3%, 10.1%, 2.3%, 11.5%, and 2.3%, respectively. Figure 10 shows fat intake at each meal as a percentage of total calories as well as the fat intake at each meal expressed as a percentage of total fat consumed.

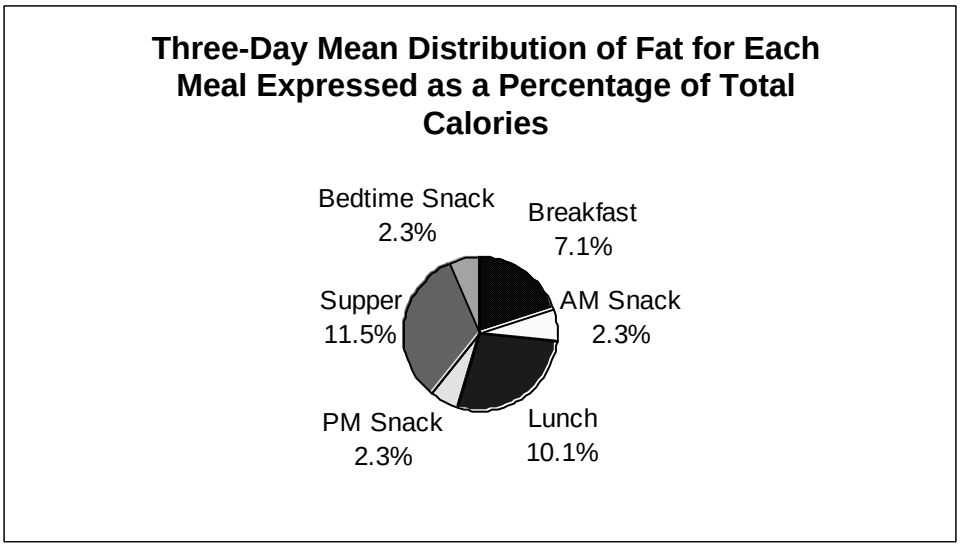

Figure 9: Distribution of Fat Intake Consumed (35% divided throughout the meals) between 28-32 Weeks Gestation Consumed by Pregnant Women with Gestational Diabetes Mellitus

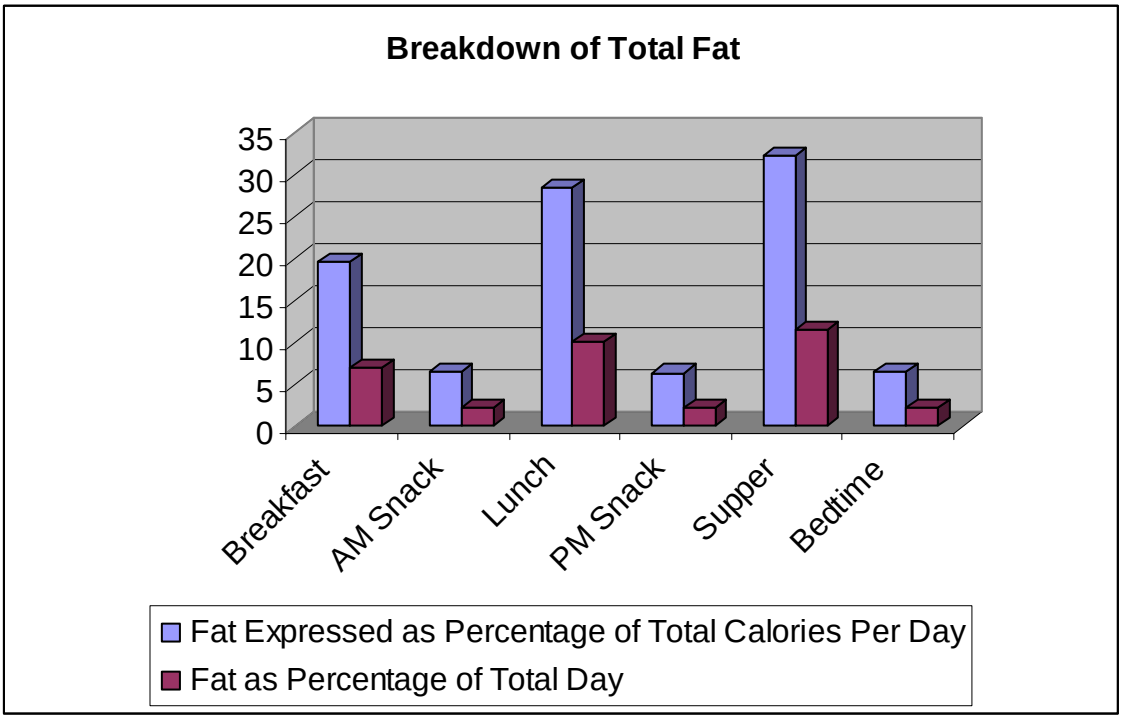

Figure 10: Three-Day Mean Distribution of Fat Intake at Each Meal Expressed as a Percentage of Total Calories and Fat Intake at Each Meal Expressed as a Percentage of Total Fat Consumed between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

Saturated Fat Intake

The saturated fat intake is presented in Table 5. The mean daily saturated fat intake was 22.5 g. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 4.8 g, 1.4 g, 6.3 g, 1.2 g, 6.9 g, and 1.9 g, respectively. Figure 11 presents the mean percent of fat consumed at each meal throughout the day expressed as a percentage of total calories consumed. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 22%, 6%, 28%, 5%, 30%, and 9%, respectively.

Table 5: Three-Day Mean Saturated Fat Intake Obtained between 28-32 Weeks Gestation of Pregnant Women with Gestational Diabetes Mellitus

Meal Time	Number	Mean (Grams)	Standard Deviation	Minimum	Maximum
Breakfast	135	4.82	3.81	0	26.36
AM Snack	135	1.38	2.11	0	9.52
Lunch	135	6.29	4.39	0	21.76
PM Snack	135	1.20	1.85	0	9.18
Supper	135	6.87	4.63	0	22.84
Bedtime Snack	135	1.90	2.73	0	11.77
Total	135	22.46	9.23	6.12	48.55

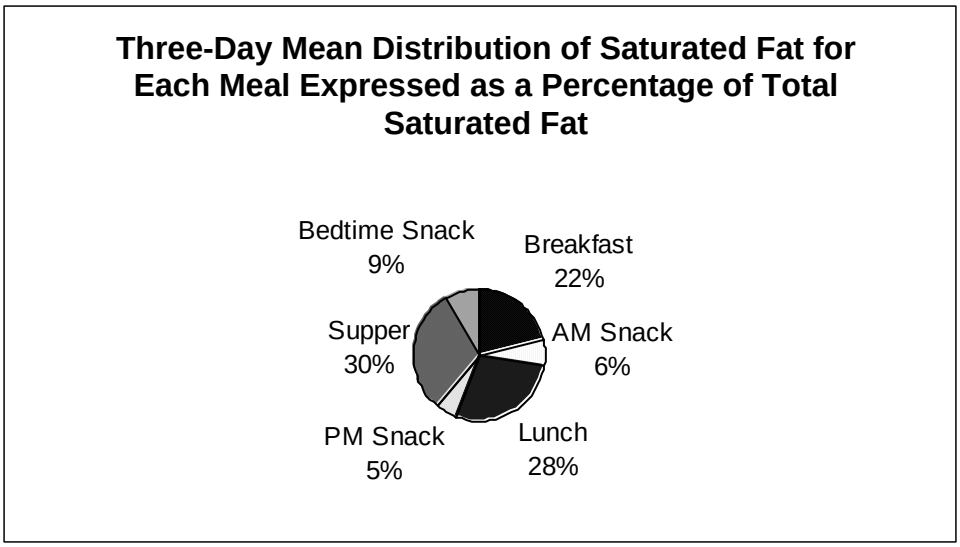

Figure 11: Three-Day Mean Distribution of Saturated Fat Intake Consumed (100% Saturated Fat Divided throughout the Day) between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

The percentage of saturated fat intake is presented in figure 12. The mean daily percentage of saturated fat was 12%. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 12%. 2.6%, 0.8%, 3.4%, 0.7%, 3.8%, and 1%, respectively. Figure 13 shows saturated fat intake at each meal as a percentage of total calories as well as the saturated fat intake at each meal expressed as a percentage of total fat consumed.

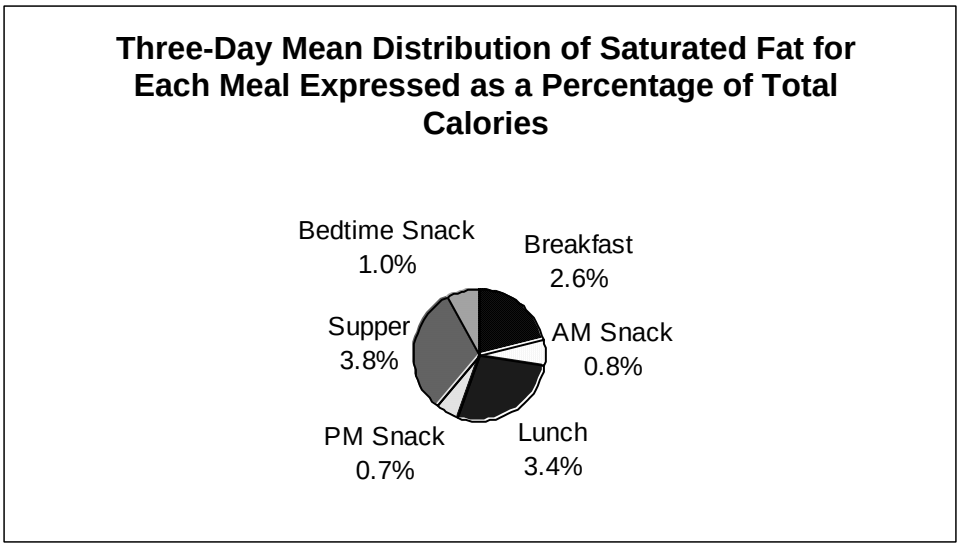

Figure 12: Three-Day Mean Distribution of Saturated Fat Intake Consumed (12% Divided throughout the Meals) between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus

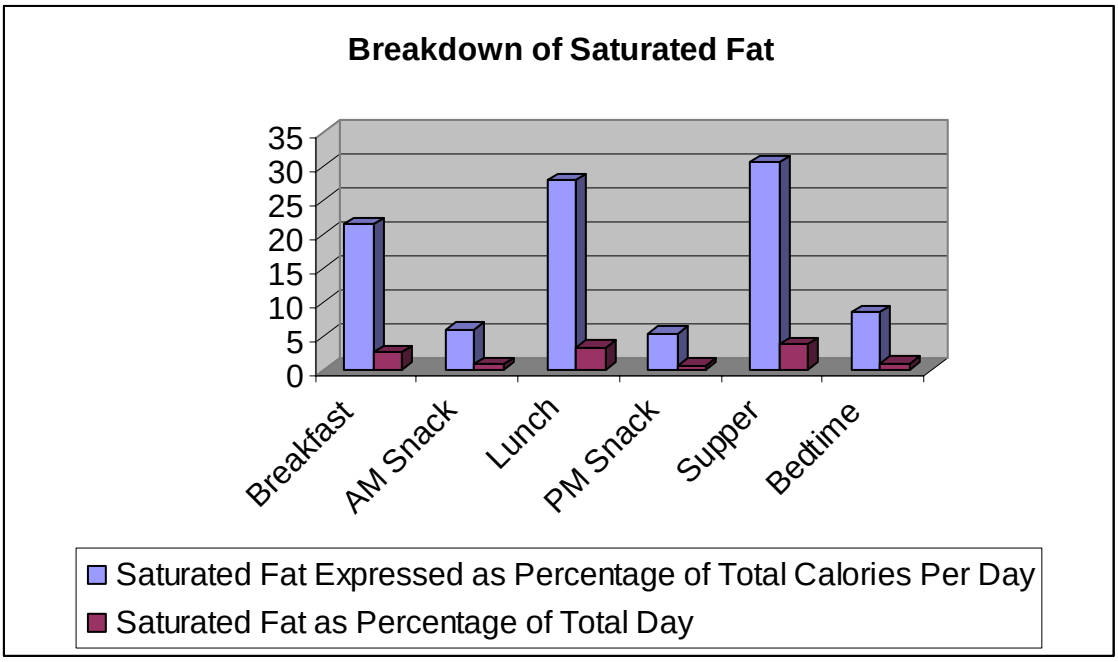

Figure 13: Three-Day Mean Distribution of Saturated Fat Intake at Each Meal Expressed as a Percentage of Total Calories and Saturated Fat Intake at Each Meal Expressed as a Percentage of Saturated Fat Consumed between 28-32 Weeks Gestation by Pregnant Women with Gestational Diabetes Mellitus.

Fiber Intake

The fiber intake is presented in table 6. The mean daily fiber intake was 14.3 g. This was distributed between breakfast, am snack, lunch, pm snack, supper, and bedtime snack as 2 g, 1.3 g, 4.3 g, 1.5 g, 4.4 g, and 0.8 g, respectively.

Table 6: Three-Day Mean Fiber Intake Obtained between 28-32 Weeks Gestation of Pregnant Women with Gestational Diabetes Mellitus

Meal Time	Number	Mean (Grams)	Standard Deviation	Minimum	Maximum
Breakfast	135	2.06	1.35	0	7.95
AM Snack	135	1.33	1.60	0	8.83
Lunch	135	4.29	3.78	0	17.01
PM Snack	135	1.50	1.69	0	6.93
Supper	135	4.39	2.45	0	11.85
Bedtime Snack	135	0.78	1.22	0	5.96
Total	135	14.35	5.73	2.99	29.60

Blood Glucose Levels

The blood glucose levels are presented in table 7. Blood glucose was self-recorded by the participants at fasting, 1 hour postprandial for breakfast, lunch, and supper. The mean values obtained were 90.8 mg/dL, 107.4 mg/dL, 109.3 mg/dL, and 109 mg/dL, respectively. The maximum blood glucose occurred one hour after breakfast and the minimum blood glucose occurred one hour after supper.

Table 7: Three-Day Mean Blood Glucose Level Obtained between 28-32 Weeks Gestation of Pregnant Women with Gestational Diabetes Mellitus

Time Obtained	Number	Mean (mg/dL)	Standard Deviation	Minimum	Maximum
Fasting	107	90.80	13.24	64.00	140.00
Breakfast (1 Hour After)	130	107.38	25.26	65.00	202.00
Lunch (1 Hour After)	121	109.26	24.68	56.00	187.00
Supper (1 Hour After)	124	109.01	21.85	43.00	170.00

Regression Analysis

In a regression analysis using Body Mass Index (BMI) and pregnancy weight before delivery versus blood glucose (one hour after breakfast); pregnancy weight negatively correlated to glucose one hour after eating breakfast (F= 6.04, Significance= 0.01) however, BMI did not correlate with blood glucose after breakfast. The negative correlation of pregnancy body weight to blood glucose is plotted in Figure 14. However, neither BMI nor pregnancy weight before delivery correlated to blood glucose one hour after lunch or one hour after supper. Pregnancy Body Weight is presented in Figure 14.

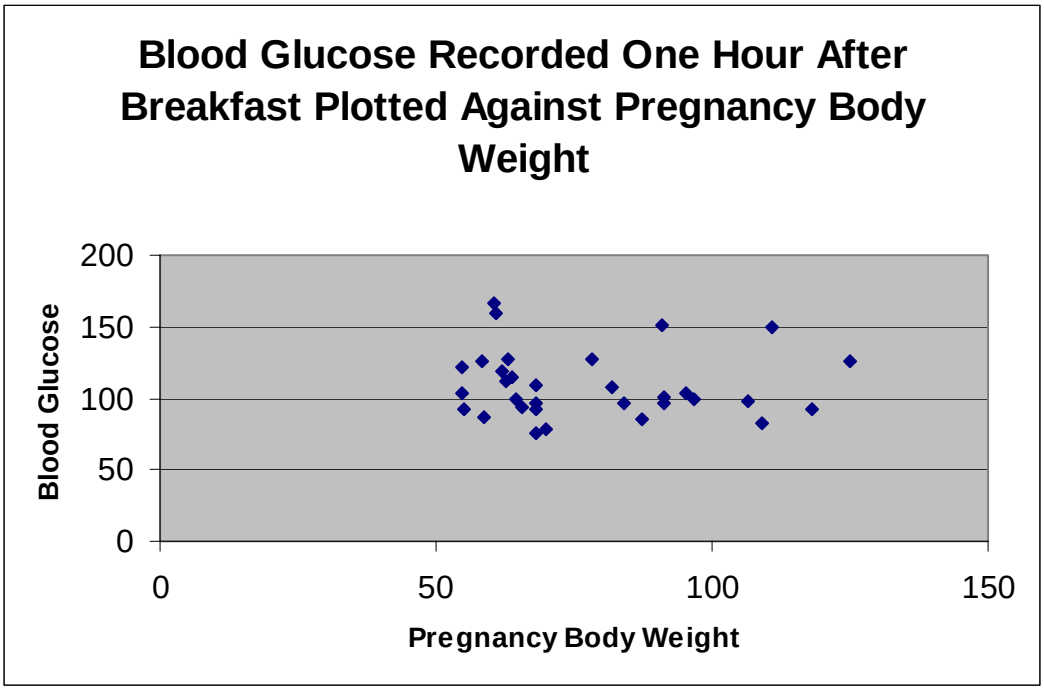

Figure 14: **Blood Glucose Recorded One-Hour After Breakfast Plotted Against Pregnancy Body Weight.**

A second regression analysis was also performed using pregnancy weight before delivery, carbohydrate grams, grams of fiber, and BMI versus blood glucose one hour after breakfast. Pregnancy weight negatively correlated to grams of carbohydrate consumed at breakfast. Figure 15 shows the plot of the negative correlation of pregnancy weight versus grams of carbohydrate. Similar to pregnancy weight, BMI was also negatively correlated to grams of carbohydrate consumed at breakfast (F= 2.93, Significance= 0.05). Grams of fiber did not correlate to blood glucose (one hour after breakfast). None of the variables, BMI, pregnancy weight before delivery, carbohydrate grams, or grams of fiber correlated to blood glucose one hour after lunch or one hour after supper.

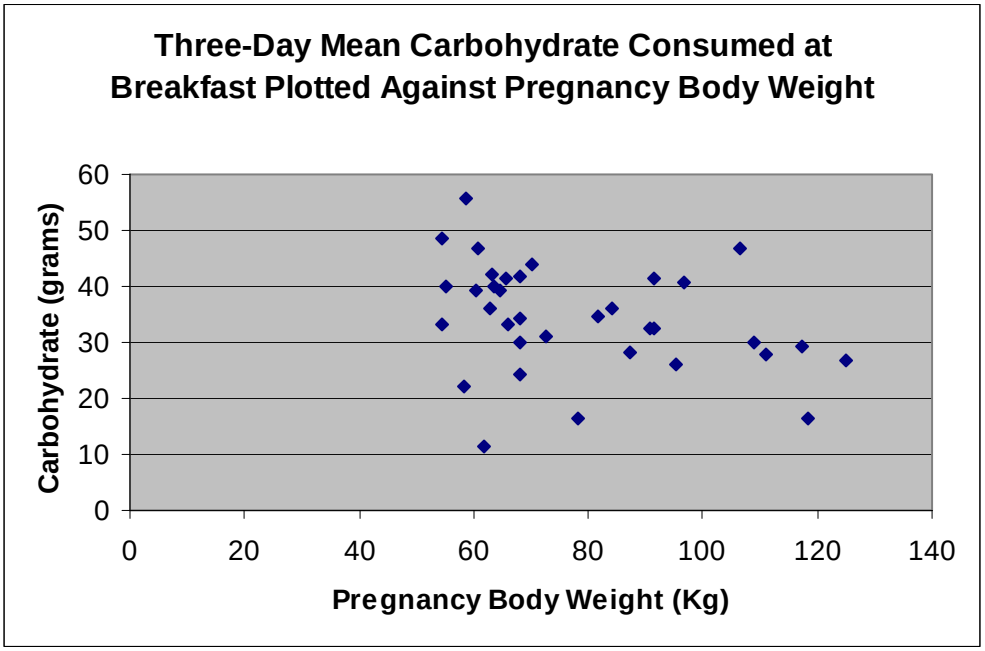

Figure 15: Three-Day Mean Distribution of Grams of Carbohydrate Consumed at Breakfast Plotted Against Pregnancy Body Weight.

In another regression analysis comparing protein, fat, BMI, and pregnancy weight before delivery versus blood glucose, only protein negatively correlated to blood glucose at breakfast (F= 3.2838, Significance= 0.05). There were no correlations of any of these variables to blood glucose one hour after the lunch or supper meals.

CHAPTER FIVE

DISCUSSION

This study is part of a wider spread prospective study involving the Nutrition Practice Guidelines initiated by the American Dietetics Association, conducted from February 9, 1999 to the spring of 2001. Three-day food records and blood glucose values for four time periods were recorded and obtained by pregnant women during their third trimester of pregnancy who were diagnosed with Gestational Diabetes Mellitus (GDM). The results collected included total calories, carbohydrate, protein, fat, saturated fat, fiber, and blood glucose levels- fasting; breakfast, 1 hour postprandial; lunch, 1 hour postprandial; and supper, 1 hour postprandial. The results were later complied and analyzed at the University of Wisconsin-Stout using SPSS.

Kilocalorie Intake

Kilocalories (kcals) ranged from 652 to 2453 per day with a mean value of 1645 kcals. The current recommendations for pregnant women with Gestational Diabetes Mellitus (GDM) is between 1700-1800 kcals per day to gain appropriate weight during the final trimester and to also prevent ketoacidosis (American Dietetic Association, 2001). Twenty-six out of thirty-five participants included in this study obtained less than the recommended intake of 1700-1800 kcals per day. The mean weights ranged from 54 kilograms (kg) to 125 kg with a mean value of 79 kg. The mean body mass index ranged from 19 to 48 with a mean value of 29. The current standard for normal non-pregnant BMI is between 19.8 and 26.0. There were 19 out of 35 participants included in this study who had a BMI outside the current standard normal range.

Macronutrient Content

Mean macronutrient content expressed as a percentage of total calories was 45%, 20%, and 35% for carbohydrate, protein, and fat, respectively. The current recommendations for macronutrient content for pregnant women with GDM is 40-45%, 20-25%, and 30-35% for carbohydrate, protein, and fat, respectively (American Dietetic Association, 2001). Therefore the mean intake of all macronutrients fell within these ranges.

Carbohydrate Content

Total carbohydrate content of diet ranged from 51 g to 342 g total per day with a mean value of 188 g. It is recommended that women consume at least 100 g of carbohydrate throughout the day to prevent ketosis from occurring. A total of 94% of pregnant women in this study met the recommended amount for preventing ketosis, while 6% of the women did not. A lower intake of 15-30 g of carbohydrate is recommended at breakfast for women with GDM due to a lower tolerance during pregnancy and abnormal hormonal balance causing an increase in blood glucose levels in the morning (American Dietetic Association, 2001). The largest intake of carbohydrate as total kcals was at lunch and supper. The smallest intake of carbohydrate as total kcals was at breakfast. The results of the study showed that the participants indeed were following the current recommendations. According to the Food and Nutrition Board, the recommendation for carbohydrate during an uncomplicated pregnancy is 45-65% or 175 g per day (National Academy of Sciences, 2002). Based on this finding, 60% consumed 175 g or more, while 40% did not meet this recommendation. However, the recommended carbohydrate intake for women with GDM is 40-45%. Carbohydrate is the primary source of energy for the

brain and is a source of kcals to help maintain body weight and to gain the appropriate amount of weight during pregnancy (National Academy of Sciences, 2002).

Fiber Content

Fiber content of diet ranged from 3 g to 30 g per day with a total mean value of 14 g. Based on recommendations from the Food and Nutrition Board, it is recommended that pregnant women consume 28 g of fiber per day (National Academy of Sciences, 2002). Therefore the majority of women in this study did not obtain the recommended amount of fiber. Fiber is important during pregnancy to help improve lactation, reduce the risk of coronary heart disease, and assist in maintaining normal blood glucose levels as well as reducing constipation and hemorrhoids (National Academy of Sciences, 2002).

Protein Content

Protein content of diet ranged from 34 g to 146 g per day with a total mean value of 82 g per day. The current recommendation of grams of protein per day is 10 g above the Recommended Dietary Allowances (RDA) of 0.8g/kg of Desired Body Weight (DBW). The current consumption recommendation for the US population for protein is 10-35% of total kcal or 71 g per day (National Academy of Sciences, 2002). Based on this finding, 64% met protein consumption recommendations, while 36% did not meet criteria. The mean protein consumption as a percent of total kcals was 20% in this study, which is in line with the current recommendations for women with GDM. Protein consumption is important because it serves as the major structural component of all cells in the body and functions as enzymes in membranes as transport carriers, and as some hormones (National Academy of Sciences, 2002). Research has shown that blood glucose levels do not increase after protein ingestion, thus protein is often added to

increase calories without affecting blood glucose levels (American Dietetic Association, 2001).

Fat Content

Fat content of the diet ranged from 22 g to 138 g per day with a total mean value of 65 g per day. The current recommendation for fat intake is 20-35% of total calories during pregnancy (National Academy of Sciences, 2002). The mean intake of fat as a percent of total calories was 35% in this study. Based on the findings, 56% of the women did not meet the recommended intake, while 44% met criteria. Fat consumption is important because it serves as an energy source and when found in foods, is a source of omega 6 and omega 3 polyunsaturated fatty acids (National Academy of Sciences, 2002). Its presence in the diet increases absorption of fat-soluble vitamins and precursors such as vitamin A and provitamin A carotenoids (National Academy of Sciences, 2002). The increase in fat in this study is due to a decrease in carbohydrate intake and increased protein intake, which inherently adds fat (American Dietetic Association, 2001). Adequate fat intake is needed during pregnancy to provide essential fatty acids needed for fetal brain development (American Dietetic Association, 2001). Because GDM is a short-term condition, the total amount of fat is not designed for long-term chronic disease prevention (American Dietetic Association, 2001). However, large amounts of fat consumption should be avoided to prevent excessive weight gain, which in turn can result in further insulin resistance (American Dietetic Association, 2001).

Saturated Fat Content

Saturated fat content of diet ranged from 6 g to 49 g per day with a total mean value of 22 g or 12% per day. The current recommendations for saturated fat intake

indicate that less than one third of the fat calories each day should come from saturated fat and less than one third from polyunsaturated fats; the balance should come from monounsaturated fats (American Dietetic Association, 2001). Saturated fat has no required role in the body other than as an energy source; the body can synthesize its need for saturated fatty acids and cholesterol from other sources (National Academy of Sciences, 2002).

Regression Analysis

Based upon data obtained from the regression analysis, pregnancy weight before delivery negatively correlated to blood glucose at breakfast. Whereas a second regression analysis showed that carbohydrate intake at breakfast also negatively correlated with pregnancy weight before delivery. It appears that pregnant women diagnosed with GDM, in this study, who had a lower pregnancy weight consumed more grams of carbohydrate at breakfast resulting in an increase in blood glucose level. Conversely pregnant women diagnosed with GDM with a higher weight consumed less grams of carbohydrate at breakfast, resulting in lower blood glucose levels. The negative correlation of carbohydrate at breakfast to body weight and the negative correlation of body weight to blood glucose 1 hour after breakfast supports the current practice of limiting carbohydrate at the breakfast meal for women with GDM.

The final regression analysis showed that protein negatively correlated with blood glucose levels 1 hour after breakfast. This appears to be a result of higher protein consumption and lower blood glucose levels, which shows that the participants in the study followed the basic guidelines of consuming more protein at breakfast to help keep blood glucose at tight control.

The mean blood glucose levels 1 hour after breakfast, lunch, and supper were 107, 109, and 109, respectively. This is because the participants of the study followed the current recommended diet set by the American Dietetic Association and the International Diabetes Center. The participants were also seen by Registered Dietitians throughout the third trimester of their pregnancy that assisted the women with dietary compliance and with tight control of blood glucose levels. These practices allowed for tight control of blood glucose, which is the goal of current practice.

Recommendations

The objective of this study was to determine if consumption of carbohydrate, protein, fat, saturated fat, and fiber affect blood glucose in pregnant women diagnosed with Gestational Diabetes Mellitus. Through the dietary counseling by Registered Dietitians and their scrutiny of blood glucose records during pregnancy, few of the pregnant women demonstrated blood glucoses values out of normal range. This reflects that dietitians are vital to success of these pregnancies. Unfortunately, in order to achieve the above objective, blood glucose would need to be out of normal range to correlate the macronutrients. This is bad news. The good news is that follow up by dietitians does help pregnant women maintain tight control of their blood glucose, which could result in better pregnancy outcomes.

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Appendix A

Approval of Gestational Diabetes Mellitus Protocol

Institute for Research and Education
HealthSystem Minnesota

Health Research Center
3800 Park Nicollet Boulevard
Minneapolis, MN 55416-2699
Tel (612) 993-3525
Fax (612) 993-3741

February 9, 1999

Diane Reader,
International Diabetes Center
3800 Building 5 North

Dear Ms. Reader:

The protocol, *Field test evaluation of nutrition practice guidelines for gestational diabetes mellitus (GDM)*, was reviewed by the Protocol Review Committee on February 2.

The protocol was approved as submitted to the PRC. The Health Research Center study number assigned to this protocol is: **1319-99-E** Please refer to this number in any future correspondence about this study to the PRC or IRB.

If you have any questions please contact me, 993-3379, or Margaret Healey, PhD, 993-3005.

Sincerely,

Renner Anderson

Renner Anderson, MD
Chairperson
Protocol Review Committee

RA:swl

Appendix B

Facility Consent Form

Evaluation of Nutrition Practice Guidelines of Gestational Diabetes
Consent Form: Facility

Your Facility and Registered Dietitians are invited to participate in the Field Test of Nutrition evaluation of Nutrition Practice Guidelines for Gestational Diabetes. You were selected as a possible site because your registered Dietitian responded to a recent request for volunteers. Please read this form before agreeing to participate in the study.

Splett & Associates of St. Paul, MN, are conducting the study for the Diabetes Care and Education and Perinatal Nutrition Practice Groups of the American Dietetic Association.

Background Information:

The purpose of the study is to evaluate, in a variety of health care settings across the country, nutrition practice guidelines for gestational diabetes.

Procedure:

If you agree to have your facility as a field test site, the following will happen:

1. The dietitian will complete an Information Form providing demographic data about herself and the facility. She will also complete brief midpoint Evaluation Form, and a monthly report of the number of women enrolled.
2. All women diagnosed with gestational diabetes will be informed about the study and invited to participate.
3. The dietitian will provide either Usual Nutrition Care or care according to new Nutrition Practice Guidelines to women in the study.
4. The dietitian will obtain a finger stick for hemoglobin A1c at the initial visit and between 36-38 weeks gestation using a kit provided by the researchers.
5. After delivery the dietitian will complete a medical record audit to collect data on nutrition care and outcomes using women's and infants' medical records.

Risks and Benefits of Being in the Study:

1. The risks involved in participating in the study are no greater than nor less than those of routine nutrition practice.
2. Implementation of nutrition practice guidelines care may require 1 to 3 additional visits. This may represent additional visits to the site for scheduling and dietitians time.
3. You will be contributing to the American Dietetic Association's and the Diabetes Care and Education and the Perinatal Nutrition Practice Groups' efforts to determine effective medical nutrition therapy in gestational diabetes.

Confidentiality:

All records of this study will be kept confidential. Any materials sent to the researchers (other than this consent form) will not include your name or that of the facility. Participant dietitians and women in the study will be assigned a code number. Reports produced from the study will not include any information that will make it possible to identify the facility, dietitian, or individual patients. Research records will be kept in a locked file; only the researchers will have access to the records. All records will be destroyed within three years.

Voluntary Nature of the Study:

Your decision whether or not to participate will not affect your current or future relationships with Splett & Associates, the Diabetes Care and Education and Perinatal Nutrition Groups, or the American Dietetic Association. You are free to withdraw from the study at any time without affecting those relationships.

Contacts and Questions:

The researchers conducting the study are Patricia L. Splett, PhD. and Diane Reader, RD. CDE. If you have any questions, now or at any time, you may contact them at:

Patricia L. Splett	Diane Reader
Splett & Associates	International Diabetes Center
3219 Midland Ave.	3800 Park Nicollet Blvd.
St. Paul, MN 55110	Minneapolis, MN 55416
Telephone: (651) 779-0554	(612) 993-3840
Fax: (651) 779-8099	(612) 993-1302
Email: splet004@tc.umn.edu	readed@hsmnet.com

There are two copies of this consent form. One copy is for you to keep for your records. Please give the other copy to your dietitian who will forward it to Splett & Associates.

Statement of Consent:

I have read the above information. I have asked and received answers to any questions I have. I consent to have this health care facility participate in the study.

Signature: _____ Date: _____

Print Name: _____ Title: _____

Clinic / Hospital: _____

Appendix C

Volunteer Dietitian Consent Form

Evaluation of Nutrition Practice Guidelines for Gestational Diabetes
Consent Form: Volunteer Dietitians

You are invited to participate in the field test of Nutrition Practice Guidelines for GDM. You were selected as a possible participant because you responded to a recent request for volunteers. Please read this form before agreeing to participate in the study.

The study is being conducted by Splett & Associates of St. Paul, MN for the Diabetes Care and Education and the Perinatal Practice Groups of the American Dietetic Association.

Background Information:

The purpose of the study is to evaluate, in a variety of health care settings across the country, a nutrition protocol or nutrition practice guidelines.

Procedure:

If you agree to be in the study, you will be asked to:

1. Complete an Information Form, which will collect demographic information about you and your facilities.
2. Recruit women with GDM refined to your practice and secure their permission to participate in the study.
3. Provide nutrition therapy according to either your Usual Nutrition Care or according to a specific Nutrition Protocol. You will be assigned to one kind of care by random assignment.
4. Obtain a finger stick A1c at the initial visit and between 36-38 weeks gestation.
5. Complete an Evaluation Form after two months.
6. After 6 months, complete a Medical Record Audit Form for each resident enrolled in the study.

Risks and Benefits of Being in the Study:

1. The risks involved in participating in the study are no greater than nor less than those of routine nutrition practice.
2. You will be contributing to the American Dietetic Association's and the Consultant Dietitians in Health Care Facilities Practice Group's efforts to assess the protocol for effective medical nutrition therapy for unintentional weight loss.

Compensation:

All dietitians who participate in the field test will receive a final draft copy of the Nutrition Practice Guidelines for GDM.

Confidentiality:

All records of this study will be kept confidential. Any materials sent to the researchers (other than this consent form) will not include your name. Participants will be assigned a code number. Reports produced from the study will not include any information that will make it possible to identify you or your facility. Research records will be kept in a locked file; only the researchers will have access to the records. All records will be destroyed within three years.

Voluntary Nature of the Study:

Your decision whether or not to participate will not affect your current or future relationships with Splett & Associates, the Diabetes Care & Education or Perinatal Practice Group, or the American Dietetic Association. You are free to withdraw from the study at any time without affecting those relationships.

Contacts and Questions:

The researchers conducting the study are Patricia Splett, PhD, RD, and Diane Reader, RD, CDE. If you have any questions, now or at any time, you may contact them at the following address:

Patricia Splett
3219 Midland Ave.
St. Paul, MN 55110

Telephone: (612) 779-0554
Fax: (612) 779-8099

There are two copies of this consent form. One copy is for you to keep for your records. Please send the other copy to the researchers.

Statement of Consent:

I have read the above information. I have asked and received answers to any questions I have. I consent to participate in the study.

Signature:_____

Print Name:_____

Name of Health Care Facility:_____

Date:_____

Appendix D

Patient Consent Form

Evaluation of Nutrition Care in Gestational Diabetes
PATIENT CONSENT FORM

Purpose and Background

The clinic or hospital and the registered dietitian who works here are participating in a study to find out what kind of nutrition care works best for women who develop gestational diabetes in pregnancy. The study is part of a national study being carried out in many places across the United States. I am being invited to be a part of the study because I have gestational diabetes.

Procedures

If I agree to be in this study, the following will happen:

1. I will receive one of two types of nutrition care from a registered dietitian (either Usual Nutrition Care or Practice Guidelines Nutrition Care).
2. At the first visit with the registered dietitian, and two to four weeks before the end of my pregnancy, a blood sample will be drawn from my finger. Each sample will be one drop or approximately 5 microliters of blood.
3. After my baby is born, the dietitian will check my medical records to gather information about my pregnancy, delivery, and my baby's weight and health. This information will be sent in a confidential manner to the researcher conducting the study.

Participation in the study will take about two hours over a period of 10 to 12 weeks. All procedures will be done at this clinic or hospital.

Risks and Discomforts

1. The clinic I attend will be randomly assigned to one type of nutrition care. The nutrition care I receive will be either the same or somewhat more than if I were not a part of the study.
2. As a part of my nutrition care, I may be asked to test my blood sugars or urine ketones, and keep written records of what I eat.
3. As a study participant, I must provide two small blood samples at he beginning and end of the study.

Confidentiality

Some information from my medical records and my baby's medical records will be used in the study. This information will be handled in a confidential manner. The people doing the study will have no way to identify my baby or me.

Benefits

There will be no direct benefit to me from participating in this study. I will be helping dietitians find out what kind of nutrition care works best for women with gestational diabetes.

Compensation

There is no special compensation for participating in this study. I will not be charged for the finger-stick blood tests.

Voluntary Nature of the Study

Participation is voluntary. If I choose not to participate in this study, I will receive the routine nutrition care available to women at this clinic with gestational diabetes. My decision will not affect my relationship with the dietitian, physician, or clinic.
If I decide to participate, I can still withdraw at any time.

Questions and Contacts

I will be given a copy of this form to keep. I can ask questions now. If I have any other questions about the study, I may call the study investigator, Dr. Patricia Splett at 651-779-0554 in St. Paul, MN, or the local dietitian _____ at _____.

Statement of Consent

The dietitian or other health professional has explained this study to me. I have had a chance to ask questions and get answers.

By signing here I agree to participate in the study.

_____ _____

Date Patient Signature

_____ _____

Date Person Obtaining Consent

Appendix E

Authorization Form and Summary of the Study

S P L E T T & A S S O C I A T E S

December 11, 1998

Dear Volunteer Dietitians:

On behalf of the Diabetes Care and Education and the Perinatal Nutrition Practice Groups we would like to thank you for volunteering to participate in the Field Test of Nutrition Practice Guidelines for Gestational Diabetes. We appreciate your interest in this exciting outcomes research opportunity. Your participation will help us obtain reliable and valid data about the effectiveness of nutrition care in GDM.

The purpose of this mailing is to provide information about the study so you can make a commitment to participate based on complete information. Please review all the enclosed material.

Your role as a field test dietitian would be to assess and intervene with all women referred with gestational diabetes as you normally do (Usual Care Group) *or* as recommended by new nutrition practice guidelines for GDM (Nutrition Practice Guidelines Group). You will be assigned to one kind of care by random assignment after you return the enclosed consent forms.

In either study group, you will be asked to do some tasks beyond your normal work. The time requirement is dependent on your group assignment, the number of patients enrolled, and the location of patients' medical records. We have tried to keep extra demands to a minimum; however a number of steps are necessary for a sound field test. The special tasks and time estimates are summarized below.

- As a first step you must secure your organization's approval. The enclosed Study Summary and Facility Consent Form are provided to facilitate that process.

- During the recruitment period, you must ensure that all eligible women with GDM are invited to participate in the study. This involves checking for eligibility, explaining the study, and having the women who agree to be part of the study sign Patient Consent and Release of Information forms. The estimated time for this is about 10 minutes per patient with GDM.

- At two points you must collect a finger stick hemoglobin A1c (at the first nutrition visit after the GDM diagnosis, and at 36 to 38 weeks). We will provide mail-in test kits for this purpose.

Process and Outcome Evaluation for Change

3219 Midland Ave. • St. Paul, MN 55110 • 651 779-0554 Fax: 651 779-8099 Email: splet004@tc.umn.edu

AUTHORIZATION FOR RELEASE OF INFORMATION

Reason for Release: The Field Study of Nutrition Practice Guidelines for Gestational Diabetes requests information to evaluate the effectiveness of nutrition care provided to women with GDM.
Information needed includes:

__ hospital delivery summary
__ infant's birthweight and health status

Patient:

Name — Day Phone No.
Address
City — State — Zip
Date of Birth — Social Security Number (or other identifier)

Provider: (delivery hospital, prenatal care provider, pediatric provider)
Health Care Facility

Requestor: The information should be sent to:

Dietitian
Department
Clinic site
Address
City — State — Zip
Phone No.
Fax No.

Revocation: I understand this authorization will be in effect for 12 months unless cancelled by me in writing and that my cancellation will take effect when the provider receives my notice in writing.

Authorization: I authorize the release of information related to my delivery and my infant's health status to the above requestor.

Patient's Signature: _____ **Date** _____

FIELD TEST EVAUATION OF NUTRITION PRACTICE GUIDELINES FOR GESTATIONAL DIABETES MELLITUS (GDM)
STUDY SUMMARY

Principal Investigators:
Diane Reader, RD, CDE, International Diabetes Center, Institute for Research and Education, HealthSystem Minnesota, 3800 Park Nicollet Boulevard, Minneapolis, MN 55416-2699
Phone: 612-993-3840, Fax: 612-993-1302, Email: readed@hsmnet.com

Patricia L. Splett, PhD, RD, Outcomes Research Consultant, Splett & Associates, 3219 Midland Avenue, St. Paul, MN 55110
Phone: 651-779-0554, Fax: 651-779-8099, Email: splet004@tc.umn.edu

Erica P. Gunderson, PhD, RD, Epidemiology Consultant, Representative of the Perinatal Nutrition Dietetic Practice Group, Larkspur, CA
Email: ericagun@uclink4.berkeley.edu.

The study protocol has been submitted for review by the Institutional Review Board (Protocol Review Committee) at the Institute for Research and Education of HealthSystem Minnesota.

Inclusive Dates of Project: January 1999 to September, 1999 (enrollment and intervention)
(analysis continuing to March 2000)

Sponsoring Agency:
Diabetes Care and Education Dietetic Practice Group and Perinatal Nutrition Dietetic Practice Group of The American Dietetic Association, Chicago, IL

Funding:
Funding for the study will come from the operating budget of the Dietetic Practice Groups and may be supplemented by funds requested from private organizations or foundations.

Locations: 24-30 sites across the United States including primary care and high-risk prenatal clinics, diabetes centers, endocrinology clinics, and Indian Health Service/Tribal hospitals and clinics.

Local Site for Field Test: *(to be completed by the field test site)*

Contact Person at Field Site—Name of participating Registered Dietitian

_____

Study Site/Facility—Name of clinic or hospital

_____

FIELD TEST EVAUATION OF NUTRITION PRACTICE GUIDELINES FOR GESTATIONAL DIABETES MELLITUS (GDM)
STUDY SUMMARY

Research Purpose:
This study will compare two types of nutrition care provided to women with gestational diabetes mellitus (GDM) by registered dietitians. The study will answer the question: Does nutrition care delivered according to new nutrition practice guidelines result in better pregnancy outcomes than usual nutrition care provided by registered dietitians?

Significance:
GDM is a serious condition that presents potential health risks for both the mother and the infant. The most common consequence of GDM is fetal macrosomia (large for gestational age), which is associated with infant birth trauma, hypoglycemia, hypocalcemia, polycthemia, hyperbilirubinemia, and in rare cases, stillbirth. For women the most common perinatal morbidity is cesarean section delivery. In addition women with GDM have an increased risk of developing type 2 diabetes in later life, and infants may have an increased risk of childhood or adolescent obesity. GDM occurs at rate of 3 to 5 cases per 100 pregnancies, but varies by race/ethnicity. The rate is 1.5 for whites, 4.5 for Mexican Americans, 7 for Asians and 15 for some Native American groups.

While medical nutrition therapy is considered a cornerstone of therapy for GDM, little information is available about the impact of various types of nutrition intervention on blood sugar levels (blood glucose) and perinatal outcomes (infant health) for women with GDM. This study, conducted in routine clinic settings across the United States, will enable determination of differences in practice and their effects on pregnancy outcomes for women with GDM. The information resulting from this study will be used to recommend appropriate nutrition care for women with GDM. Research is needed to determine which nutrition therapies result in better blood glucose control and improved perinatal outcomes for women with GDM.

Methods:
Dietitians at participating sites will be randomized to either "Usual Nutrition Care" or "Nutrition Practice Guidelines Care." Usual Nutrition Care consists of nutrition care as currently offered to women with GDM by dietitians at the site. Nutrition Practice Guidelines Care consists of care defined by the latest scientific research and expert opinion. The Nutrition Practice Guidelines for GDM were developed by an expert panel and reviewed by practitioners in the fall of 1998. Both types of care allow some tailoring of nutrition care to the woman's unique needs. Nutrition Practice Guidelines Care may involve more dietitian visits or a greater intensity of education and counseling than is currently offered at the site.

All women diagnosed with gestational diabetes over a three month enrollment period will be informed of the study and invited to participate. They will receive either Usual Nutrition Care or Nutrition Practice Guidelines Care (depending on the dietitian's random assignment). Women who participate must agree to have a finger stick test for blood glucose (hemoglobin A1c) at the time of entry into the study (24 to 32 weeks gestation) and again near the end of pregnancy (36-38 weeks gestation). They also must agree to release selected information from their medical records and their infants' medical records so type and amount of nutrition care provided, insulin use, and relevant perinatal outcomes can be determined. A subset of women may be asked to keep and provide records of food intake and self blood glucose monitoring.

Investigators will provide study material including instructions for recruitment, a recruitment log, and medical record audit forms. Investigators will also provide standard, mail-in test kits for the finger stick blood glucose measurement. The blood sample will be mailed into a central laboratory for analysis, and will be completed at no cost to the site or to the patient. Results will be reported back to the sites as baseline and post-intervention means for women enrolled in the study.

Outcomes to be compared between types of nutrition care include:

- change in hemoglobin A1c levels from baseline to the end of pregnancy
- infant birthweight adjusted for gestational age and infant gender
- frequency of perinatal conditions and delivery complications

Study dietitians at each site will be responsible for recruiting women for the study and getting informed consent, providing care according to their group assignment, overseeing collection and mailing of the finger stick lab test, and abstracting data from medical records at the end of the study. In addition, study dietitians will be expected to complete an Information Form providing demographic data about herself and the facility, provide feedback at the midpoint of the study, and send in a brief monthly report of the number of patients enrolled.

Subject Population:

Each participating site will be requested to enroll 15 to 20 women over a three month period. (Sites will be accepted even if their expected case load falls below this desired number.)

A total of 350 study subjects are needed with the following characteristics:

- pregnant women with GDM, ages 18 to 45 years, carrying a singleton pregnancy
- GDM diagnosed with a 50 g GCT value > 200 mg/dl, or 3 hour OGTT with two or more values meeting or exceeding the following--fasting 105, one hour 190, two hour 165, and three hour 145 mg/dl

Women will be excluded if they have:

- Type 1 or Type 2 diabetes
- Sickle cell anemia, thalassemia or other hemoglobinopathy
- Medical conditions prior to pregnancy (lupus, diabetes, preexisting hypertension, thyroid disease, cardiovascular disease, transplants, renal disease, or other serious medical condition)
- Current infectious disease (HIV, TB)

How Subjects will be Identified and Recruited:

Dietitians have been recruited through the Dietetic Practice Groups. Interested dietitians will receive a description of study expectations and this Study Summary. Following institutional review and the opportunity to ask questions of the investigators through a Study Hotline, the dietitian and facility sign informed consent forms and forward a copy to the investigators. (See attached Dietitian and Faculty Consent Forms.) Following consent, participating dietitians/sites will be randomized by the investigators to either Usual Nutrition Care or Nutrition Practice Guidelines Care.

Dietitians and other clinic staff will identify and recruit women diagnosed with GDM as described on the next page.

Risks and Discomforts to Participating Women:
The study calls for two finger stick blood tests requiring a drop of blood each.
Medical records for the mother and infant will be used to get demographic data, nutrition care data, insulin prescription and outcomes of pregnancy. Women will be asked to sign a release of information form to access specific medical data.

Benefits to Participation:
Women with GDM will be encouraged to have contact with a registered dietitian. This could lead to improved nutritional intake during pregnancy, better diabetes control, and a healthier infant.
Women, dietitians, and sites will be contributing to knowledge about the effectiveness of nutrition care in GDM. This may lead to availability of more appropriate nutrition care for women with GDM in the future.

Cost to Subjects and Sites:
Women who receive Nutrition Practice Guidelines care may be asked to return for one to three more visits with the dietitian than Usual Care women. This would involve an additional time commitment for those women. These additional visits may represent additional costs to the site for scheduling and dietitian time.

Compensation:
There are no plans to offer women incentives or compensation for their participation in the study. Dietitians who participate will receive a final draft copy of the *Nutrition Practice Guidelines for Gestational Diabetes*.

Confidentiality:
Medical record data will be abstracted from records by site dietitians and forwarded to investigators with all identifying information (name and clinic number) removed. Data will be maintained in locked files accessible only to investigators. Results will be reported in aggregate with no ability to identify individual women, clinic sites, or dietitians.

Informed Consent Process for Women with GDM:
Dietitians, or other site staff, will go over the information on the consent form with women at the clinic at the time they are diagnosed or at the first dietitian visit. (See attached Patient Consent form.) Women will signify their willingness to participate by signing the informed consent form. Patient Consent forms will be retained on file at the study site. Women who decline to participate will still receive nutrition care consistent with routine procedures at the site.

Attachments:
Dietitian Consent Form
Facility Consent Form
Patient Consent Form
Authorization for Release of Information

Appendix F

Food Record Information and Form

MEMO

To: GDM Nutrition Study Dietitians - Practice Guideline Group

From: Pat Splett, Erica Gunderson and Diane Reader

RE: Food and Blood Glucose Record

In addition to studying the implementation of the GDM nutrition practice guidelines, we are also interested in learning more about patient's actual food intake and how that is associated with better outcomes. For the patients in the nutrition practice guideline part of the study, we would like to collect a four day food record between the second and third visit.

As part of the study we will calculate calories and macronutrient content; then relate that to infant outcomes, A1c levels, blood glucose levels, use of insulin and weight gain.

Procedure: At the second visit, give each woman a food and blood glucose record form to complete and instruct her to return it at the next (third) visit.

Data included (see attached sample):

1. Detailed food intake, with portion size, brand names, method of preparation, toppings, etc. Encourage the patient to provide as much detail as possible.
2. Blood glucose results and time tested- fasting, 1 or 2 hours after meals.
3. Fasting ketone results.
4. Insulin dose, if taking insulin.

After you have collected the food record, write the patient's four digit code on the form and cross out the patient's name. Send in the food and blood glucose record with your monthly recruitment report.

If you have any questions, please call the study hotline: 651-779-0554.
Enclosed: 10 copies of the four-day food and blood glucose record. You may make additional copies as needed.

g/word/gdm/fieldlt

Instructions for Keeping Records.

We would like you to keep very accurate records for 4 days.

1. Record everything you eat and drink.

   a. It is easier to remember what you have eaten, if you write it down immediately after it is eaten.

   b. Fully describe the food eaten
      - record brand names if known.
      - include the method of preparation- fried, breaded, baked
      - record the name of the restaurant- Perkins, McDonalds
      - fully describe the food, such as chicken thigh, without skin or sugar free soda pop, fat-free Frenchsalad dressing
      - list ingredients for sandwiches and mixed dishes, such as macaroni, tomato sauce, and hamburger

2. Blood glucose tests before breakfast and after breakfast, lunch and dinner.

3. Ketone test results from morning urine sample.

4. Insulin dose, if you take insulin.

Name : Your Name

Date: MONDAY, MAY 1

Ketones: Negative

	Food/Amount	Carb. St	Carb. Frt	Carb. Milk	Veg	Mt	Fat
Breakfast Time: 700A FBG: 72 Insulin: BG: 112	2 slices whole wheat Toast 2 eggs, fried using PAM 2 tsp. margarine						
AM Snack Time: 930A	3 graham cracker squares 1 Tb. Peanut Butter						
Lunch Time: 1200 NOON Insulin: BG: 121	Sandwich: 2 Bread - Rye 2 oz. Turkey - Deli 1 tsp. mayonnaise lettuce 1 cup Vegetable Soup 4 Saltine Crackers 1 cup Skim Milk						
PM Snack Time: 300	1 Banana - small ½ cup yogurt, made with Nutrasweet.						
Dinner Time: 600 Insulin: BG: 115	3oz. BAKED COD 1 Med Baked Potato 2 Tb. Sour Cream 1 cup Steamed Brocolli 1 cup Milk - 2% 1 slice Bread with 1 tsp. margarine						
Bedtime Snack Time: 915P	1 cup Cereal 1 cup Milk - 2%						
Totals							
	Recommended daily serving	6+	2-4	3-4	3-5	2-3	3

Gestational Diabetes Record

Name : _____

Date:								
Ketones:		Carb.						
	Food/Amount	St	Frt	Milk	Veg	Mt	Fat
Breakfast **Time:** _____ **FBG:** _____ **Insulin:** _____ _____ _____ **BG:** _____							
AM Snack **Time:** _____							
Lunch **Time:** _____ **Insulin:** _____ _____ _____ **BG:** _____							
PM Snack **Time:** _____							
Dinner **Time:** _____ **Insulin:** _____ _____ _____ **BG:** _____							
Bedtime Snack **Time:** _____							
Totals							
	Recommended daily serving	6+	2-4	3-4	3-5	2-3	3

Date:								
Ketones:		Carb.						
	Food/Amount	St	Frt	Milk	Veg	Mt	Fat
Breakfast **Time:** _____ **FBG:** _____ **Insulin:** _____ _____ _____ **BG:** _____							
AM Snack **Time:** _____							
Lunch **Time:** _____ **Insulin:** _____ _____ _____ **BG:** _____							
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Totals							
	Recommended daily serving	6+	2-4	3-4	3-5	2-3	3

Field Test GDM Nutrition Practice Guidlenes