IS THERE A WAY TO IMPROVE FALSE POSITIVE RESULTS OF
THE ONE HOUR GLUCOSE CHALLENGE TEST IN
OBSTETRICAL PATIENTS?

A Thesis
Presented
to the Faculty of
California State University, Chico

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
in
Nursing

by
Karen B. Callahan
Spring 2009
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Glucose Screening Results of Two Treatments
ABSTRACT

IS THERE A WAY TO IMPROVE FALSE POSITIVE RESULTS OF THE ONE HOUR GLUCOSE CHALLENGE TEST IN OBSTETRICAL PATIENTS?

by
Karen B. Callahan

Master of Science in Nursing
California State University, Chico
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Major health organizations have different recommendations on screening for gestational diabetes. Researchers acknowledge that the screening process needs to be more sensitive, specific, cost effective, and reproducible. This study sought to determine if the fasted or fed state lowered the incidence of false positive results of the one hour glucose screening test.

This study used a quasi-experimental posttest design with two comparison treatments to explore the effects of the fasted or fed state on the one hour glucose challenge test. At 24 to 28 weeks gestation, 181 pregnant women were randomly assigned to either a fasted or fed group. Those with elevated one hour glucose screening tests were further evaluated with a 3 hour glucose tolerance test (GTT), and the proportion of true
positives was noted. Statistical analysis to compare the two groups was performed by using a Z confidence interval for the difference between the proportions at a 95% confidence level.

Study findings showed the Z confidence interval for two treatment groups was (-.0387, .30536). Although statistical significance was not seen when utilizing the diagnostic criteria for GDM set forth by the NDDG, a Z confidence interval of (.08538, .53962) was noted when diagnostic criteria included screening result of \( \geq 200\text{mg/dL} \).

Dietary recommendations are not warranted when the diagnostic criteria for GDM is based solely on the results of the GTT. If providers manage women with IGT as GDM, the false positive rate of the GCT may be reduced if patients are advised to eat prior to the test.
CHAPTER I

IMPROVING THE ONE HOUR GLUCOSE CHALLENGE TEST IN OBSTETRICAL PATIENTS

Introduction

The World Health Organization (2006) defines gestational diabetes mellitus as a “state of carbohydrate intolerance resulting in hyperglycemia of variable severity, with onset or first recognition during pregnancy” (p. 20). It is estimated that gestational diabetes complicates 1% to 14% of all pregnancies in the United States, affecting more than 200,000 women annually (American Diabetes Association [ADA], 2004).

Mothers with gestational diabetes mellitus (GDM) present special challenges to the doctors and nurses who care for them because they are at increased risk for pregnancy related hypertensive disorders, polyhydramnios, cesarean section and stillbirth. Just as important is the fact that these women are at a 33-50% increased risk for recurrence of GDM in subsequent pregnancies and are more likely to develop overt diabetes as they age (American College of Obstetricians and Gynecologists [ACOG], 2006). A summary from a recent international conference on GDM noted that the risk of developing type 2 diabetes following GDM is 35-60% within 10 years (Metzger et al., 2007). Infants born to mothers with GDM are also at risk for complications. Aside from
the immediate risks of fetal macrosomia, reflex hypoglycemia, hyperbilirubinemia, shoulder dystocia, and birth trauma, these children may also be prone to childhood obesity and diabetes (Porter, Lookinland, & Belfort, 2004). Because of the potential immediate and long term risks and complications associated with GDM, health care professionals have sought to find effective ways to screen, diagnose, and treat GDM.

Significance of the Problem

Even though gestational diabetes is one of the more common pregnancy complications, there is conflicting data regarding the most appropriate manner to screen and diagnose the disease (ACOG, 2006; ADA, 2004; World Health Organization [WHO], 2006). Furthermore, leading organizations such as ACOG, the ADA, and the WHO all have different recommendations for screening and diagnosis criteria.

ACOG recommends screening of all women between 24 to 28 weeks of gestation with a random, 50 gm, 1-hour glucose challenge test (GCT). The standard threshold for this test has been set at 140mg/dL, but ACOG acknowledges the use of a threshold of 130mg/dL as acceptable as well. If the threshold is exceeded, the mother goes on to be screened with a fasting 100 gm 3-hour glucose tolerance test (GTT). Results from the 3-hour GTT are interpreted using either the thresholds set by Carpenter and Coustan or the more widely used thresholds set by the National Diabetes Data Group (NDDG) (see Table 1). If the mother has two of four abnormal values she is diagnosed with GDM (ACOG, 2006).

WHO recommends screening high-risk women in the first trimester of pregnancy. High-risk criteria are offered in their guidelines. If these women test
Table 1

*Diagnosis Criteria for Gestational Diabetes Mellitus*

<table>
<thead>
<tr>
<th>Status</th>
<th>Plasma or Serum Glucose Level Carpenter/Coustan Conversion</th>
<th>Plasma Level National Diabetes Data Group Conversion</th>
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<tr>
<td>Fasting</td>
<td>95 mg/dL</td>
<td>105 mg/dL</td>
</tr>
<tr>
<td>One hour</td>
<td>180 mg/dL</td>
<td>190 mg/dL</td>
</tr>
<tr>
<td>Two hour</td>
<td>155 mg/dL</td>
<td>165 mg/dL</td>
</tr>
<tr>
<td>Three hour</td>
<td>140 mg/dL</td>
<td>145 mg/dL</td>
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negatively, they along with average risk women should be screened at 24 to 28 weeks gestation. However, WHO recommends screening with a fasting 75gm 2-hour GTT, rather than the random 50gm 1-hour GCT or the fasting 100gm 3-hour GTT. If the results from this test return with a fasting value of ≥126 mg/dL or a 2 hour value of ≥200 mg/dL, the mother is classified as having GDM. The WHO also recommends that women with impaired glucose tolerance (IGT), as identified by a fasting result of ≤126 mg/dL and a 2 hour ≥140 mg/dL but <200 mg/dL, also be treated as having GDM (WHO, 2006).

The ADA encourages risk assessment and early screening for those at high risk. If they are not found to have GDM, then they should be rescreened between 24 to 28 weeks. Women of average risk can be screened at 24 to 28 weeks and women of low risk do not require screening. ADA offers criteria for establishing low risk. The ADA considers a fasting glucose >126mg/dL or a random glucose >200mg/dL on two separate
occasions diagnostic for GDM. The ADA also accepts the standard guidelines from ACOG, going straight to a 3-hr GTT, or even accepts a 2-hr 75 gm test, although they do note that this is not as valid as the 100 gm GTT (ADA, 2004).

Screening tests are designed to be easy to administer, cost effective, cause only minimal discomfort, pose little risk and have acceptable specificity and sensitivity. At a facility in rural northern California, the 1-hour 50 gm GCT is performed on all clients (except those already identified as GDM or type 1 diabetics from first trimester screening) at the patient’s visit that falls between 24 to 28 weeks. The providers do not time the test around meals. The test requires the patient to ingest the 50 gm concentrated glucose solution over a 5-minute time frame and have her blood drawn one hour after ingestion. The patients are asked to remain in the lab area as some women, after ingesting the concentrated glucose solution, can become lightheaded, nauseated, have mild gastrointestinal upset and occasionally vomit. Many women tolerate this test well, but having to repeat a second, longer version is generally an unpleasant experience and incurs additional cost.

Recently, the providers at this clinic felt that there seemed to be a large number of screening tests that were returning abnormal, only to be disproved by the 3-hour GTT. Research by Stamilio, Olsen, Ratcliffe, Sehdev, and Macones (2004) showed that patients with false-positive screening tests might benefit from dietary counseling and closer prenatal surveillance. They performed a retrospective study comparing women who had false-positive screening tests to those who had normal screening tests and looked at adverse perinatal outcomes. From a perinatal database at the University of Pennsylvania Medical Center, they were able to gather information on 1850 patients and
determined that the group with false-positive screening tests had a higher mean birth weight, and higher rates of shoulder dystocia and cesarean births (Stamilio et al., 2004).

The first two steps of the nursing process are assessment and diagnosis. This requires an expanded history and physical and data from all pertinent physical and laboratory findings. When laboratory tests are ordered they should be as sensitive and specific as possible. To plan a meaningful intervention, the nurse relies on the foundation of the first two steps. An intervention and education program based on inaccurate information will not meet the patient’s needs and may even expose them to greater harm or grief. Therefore, it is vital that the tools and instruments we use to diagnose be accurate.

Since the goal of these health care professionals is to provide the best possible care for their patients and not expose them to any undue stress or harm, they began to investigate this problem. The healthcare team wanted to discern whether they should use this opportunity to provide additional counseling and assessments for their patients, or try to refine the screening process.

In a cursory review of charts in the fall of 2006, it was noted that 16.6% (21 of 126) of 1-hour screening tests were positive in the low and average risk population. After the 3-hour GTT was performed, 4 patients were identified as GDM (19%), 15 patients had normal findings (71.43%), and 2 patients were awaiting screening. Although additional dietary counseling will always be helpful to patients, the providers felt that the specificity of the 1 hour screening test could improve. They wanted to determine if administering the test in a fasting or fed state would help in lowering the false-positive rate.
Theoretical Framework

Pregnancy poses a unique time in a woman’s life in which she may be more open to positive health changes. Healthcare providers should take advantage of every opportunity available to educate their patients about positive health choices. Nurses have embraced this concept and have made health education a major component in the nursing process. Nola Pender’s revised Health Promotion Model (HPM) was therefore chosen as the theoretical guide for this study (Pender, Murdaugh, & Parsons, 2006; Tomey & Alligood, 2006).

In her works, Dr. Pender notes that there are three groups of influencing factors that affect health actions (Pender et al., 2006; Shin, Yun, Pender, & Jang, 2005). The first are influenced by past behavior and biological, psychological and sociocultural personal characteristics. These direct and indirect influences affect the person’s ability to choose and put into practice health promoting behaviors.

The second group of influencing factors is behavior-specific cognitions and affect. Such factors would include the person’s perceptions of the benefits and barriers to their action, their perception of their ability to carry out such an action (self-efficacy), and the positive and negative feelings that surround their carrying out the action. Pender et al. states that situational influences as well as the interpersonal influences from family, friends, and health care providers impact the individual’s willingness to take on health promoting behaviors (Pender et al.).

Lastly, there are the influences that precede the actual behavior. First there must be a commitment to act. This requires a planned strategy to implement the health behavior. Next, there may be demands or preferences which will compete with the plan
of action. Some of these the patient has great control over, such as the decision to exercise or the type of food one might choose to eat. Others are harder to control such as family or work responsibilities. The ultimate goal of health-promoting behaviors is to optimize health. This can mean physical, spiritual, emotional, and social health (Pender et al.; Tomey & Alligood, 2006; Shin et al., 2005).

Since Pender et al.’s HPM speaks directly to the process involved in health promotion, it presents an excellent framework from which doctors and nurses can work to promote optimal health through pregnancy and beyond. This is especially true of the pregnant patients who present with GDM. The implications of how a patient performs on the 1 hour screening test however may be far more reaching then just those with the diagnosis of GDM. Healthcare providers therefore should use this opportunity to promote positive health behaviors in all patients.

The standard protocol for this OB clinic at intake included counseling on the standard dietary recommendations during pregnancy, expectant weight gains for the patient’s stature, and ways to incorporate exercise in their daily routine throughout pregnancy. If patients are found to have abnormal glucose screening results, they could require referrals to the dietician for dietary modifications and possibly an ADA diet, and to a diabetic nurse instructor for instruction on sugar testing. They could also need additional appointments and possible ultrasound testing to monitor the growth of the fetus.

Research Purpose and Question

Despite multiple studies designed to improve screening recommendations for GDM, the review of literature revealed a lack of consensus on the most efficient manner
in which to screen. Studies looking at performing the screening test in a fed or fasting state were over 10 years old, used relatively small sample sizes and included patients already diagnosed with GDM (Coustan et al., 1986; Lewis, McNally, Blackman, Polonsky, & Barron, 1993). The purpose for this study therefore is to compare the false positive rates of the 1 hour glucose screening test when administered in the fasting or fed state.

The research question presented for consideration in this study was: Will administering the 1 hour glucose screening test in a fasting or fed state produce a statistically significant difference in the false positive results in obstetrical patients at a clinic in rural northern California? This study explored the best method for screening in the very diverse population which accesses this clinic. The researcher controlled for the dietary intake of the study participants undergoing the screening test. The fasting and fed states were the dietary modifications implemented for this study.

The two independent variables identified for this study were the fasting and fed state. Conceptually, these states are biological influences which could affect the outcome of a test, potentially leading to a need to implement a health behavior. The fasting state was operationally defined as nothing by mouth after midnight on the day preceding the exam. The fed state was operationally defined as the ingestion of a 510-570 calorie meal the morning of the exam (Coustan et al., 1986). Four meal choices were offered and the participant arrived at the lab one hour after ingestion of their chosen meal and proceeded with the screening test. The meal choices were developed in collaboration with an experienced registered dietician, who is a certified diabetic educator (CDE), and
are based on recommended percentages of calories and carbohydrates for glucose challenge tests.

The dependent variable for this study was the 1-hour blood sugar test results. The concept of blood sugar control requires coordination of a functioning pancreas, adequate amounts of exercise and a balanced diet. Several influences affect one’s ability to achieve this and there must be a planned strategy and commitment to maintain a regimen. Blood sugar levels were measured on blood plasma by the Dimension RXL at the clinic’s laboratory. Measurements were obtained one hour after the ingestion of a 50 gram glucola solution.

The extraneous variables collected for review by the researcher were; body mass index (BMI), age, previous GDM or glucose intolerance, ethnicity, previous macrosomia (>4500gms), and first degree relatives with diabetes (see Appendix A for how these variables affect risk). All these factors fall into the direct and indirect influences which Pender suggests can affect a person’s ability to practice health promoting behaviors.

Qualifications of Researcher

The researcher who conducted this study is enrolled in the MSN program at California State University, Chico. She has completed courses in advanced nursing research and theory, role development, healthcare issues and ethics, and educational theory. This thesis is the culminating activity of her master’s degree program. She received her BSN in 1979 from California State University, Long Beach and has held positions as a pediatric diabetic instructor, charge nurse in Labor and Delivery, and has
worked for the last 18 years as an Obstetrical/Gynecological (OB/GYN) Nurse Practitioner.

This study is a quantitative study to determine if there is a way to improve screening of pregnant patients for gestational diabetes. The researcher hopes to use this information to tailor the care and education of obstetrical patients. The upcoming review of the literature will reveal the controversies and pitfalls of the current screening methods, as well as what is being purposed to improve screening.
CHAPTER II

REVIEW OF LITERATURE

Over the decades researchers have proposed different ways to improve the screening method for GDM but as stated earlier there has been little consensus on the best method. The dilemma regarding screening continues to affect patient care and has become the focus of this research study. Pregnancy induces a state of reduced insulin sensitivity, resulting in a mild fasting hypoglycemia, postprandial hyperglycemia, and hyperinsulinemia (Cunningham et al., 2001). Taking into consideration the normal physiological changes that occur in pregnancy, health care professionals have adopted the use of glucose challenge testing in the second half of pregnancy as the best choice for screening. There has been confusion however, over the appropriate thresholds used and the variations of the tests mainly because there are many different organizations which have set standards. Because of this confusion, researchers have looked to additional blood markers and dietary influences that might help increase the sensitivity and specificity of testing.

Screening Methods

Nicholson, Fleisher, Fox, and Powe (2005) reviewed four screening strategies to assess the cost and effectiveness for both maternal and neonatal outcomes. They compared the sequential strategy (defined by ACOG), the 75 gm 2-hour GTT, the
100 gm 3-hour GTT, and a no-screening strategy. They concluded the sequential screening was the most cost effective strategy for mothers and infants, but the 3-hour GTT was also highly favorable because it may be more useful in higher risk populations. They did not find the 2-hour GTT or the no-screening strategy viable methods (Nicholson et al.)

Agarwal, Dhatt, Punnrose and Koster (2005c) conducted a prospective study to evaluate the use of the fasting blood glucose level as a screening test for GDM. A cohort of 1685 Middle-Eastern and Indian women was screened for GDM at 24 to 28 weeks using the 2-hour 75 gm GTT. Although the prevalence of GDM in this population is high, the cohort varied widely in age (16–48 years) and BMI was only slightly higher in the GDM group. The researchers identified 1352 (80.2%) with normal GTT test results and 333 (19.8%) women who met the WHO criteria for GDM. The authors stratified the fasting plasma glucose (FPG) for the entire cohort to determine the rates of true positive, false positive, true negative, and false negative results. A range of fasting thresholds from 3.9 mmol/l (75 mg/dL) to 6.1 mmol/l (110 mg/dl) was examined. The authors determined that although using the threshold of 4.7 mmol/l (85 mg/dl) had a sensitivity (proportion of actual positives correctly identified) of 78.1%, the specificity (proportion of negatives correctly identified) was 32.2%. The researchers concluded that FPG by itself would not be a cost effective screening tool as well over half of the women would have to undergo further confirmatory testing (Agarwal et al., 2005c).
Improving Current Methods

Several researchers have looked at ways to make glucose screening tests more sensitive and specific (Khan, Sobki, & Alhomida, 2006; Li & Yang, 2006; Perea-Carrasco et al., 2002). In a study by Perea-Carrasco et al., additional plasma markers were measured along with glucose levels to help reduce the rate of false positive results. The first stage of the study enlisted 138 pregnant women who were screened at 24 to 28 weeks with the standard 1-hour screening test. Along with serum glucose, total protein and fructosamine were also measured. All participants then had the 3-hour GTT with dietary and activity counseling given prior to the test. GDM was determined by the standard ACOG criteria on the 3-hour GTT. The authors then devised a formula to calculate the index “I” using the three plasma markers to distinguish between those who had GDM and those that did not. They established a statistical cut-off for index I and then enlisted 642 women and used the index I to screen for GDM. They found that the sensitivity for I as a screening test was 98% and the specificity was 89%. This reduced the false-positive rate in their study from 24% to 10% (Perea-Carrasco et al., 2002).

Two recent studies have looked at measuring fructosamine by itself and in conjunction with fasting blood glucose (FBG) as screening tools for GDM or IGT (Khan et al., 2006; Li & Yang, 2006). Fructosamine, like hemoglobin A1C (HbA1c), measures blood glucose control over a period of time. Generally HbA1c gives an indication of the glucose control over the past three months, while fructosamine averages the glucose control over the past 2 to 3 weeks. In pregnancy where placental hormones can vary as the placenta grows and when tighter control of glucose levels is indicated to prevent adverse effects, some feel monitoring fructosamine may be more precise (Li & Yang,
Li and Yang studied blood samples of 161 pregnant women receiving care in a university hospital in Peking. They divided the women by gestational age into three groups (16-20 weeks, 28-34 weeks, and 37-41 weeks) and further divided each group into two subgroups depending on the results of their GCT (normal vs. GDM or IGT). The subgroups of women with GDM or IGT were treated with diet, insulin, or both to achieve fasting sugars of 5.6 mmol/l (100 mg/dL) and postprandial sugars of 6.7 mmol/l (120 mg/dL). When the researchers reviewed fructosamine levels for all the participants, they found that in general fructosamine levels decreased with gestational age, but it was only in the group at 28–34 weeks where there was significant separation between those with GDM or IGT and the women with normal glucose tolerance (Li & Yang, 2006). The authors did not offer specifics about the control of the patients with GDM or IGT, only that they did not have an increase in neonatal macrosomia and there were no stillbirths in the study. The researchers felt that serum fructosamine could only be used to screen for GDM between 28-34 weeks gestation.

Building on the work by Agarwal et al. (2005c), Khan et al. conducted a study to combine the use of FBG and fructosamine for screening. A cohort of 51 Saudi women was screened with a FBG and serum fructosamine at each antenatal visit. A total of 211 blood samples were analyzed for levels of fructosamine and FBG. Each patient was screened a minimum of 3 times, while 1 patient was screened as many as 9 times. Using Pearson’s test, the researchers noted a significant correlation between FBG and fructosamine. Analysis of variance (ANOVA) however, showed the critical values (CVs) of FBG and fructosamine did not correlate, indicating that the variables functioned independently of each other. At a FBG threshold of >5.3 mmol/l (95 mg/dL),
hyperglycemia was ruled out in 62.74% of the women. This percentage increased by another 25.49% when fructosamine levels of over 2.5 mmol/l (45 mg/dL) were added to the screening criteria. In all, this would have dropped the number of women needing GTT from 20 to 7. The authors therefore felt that the use of FBG and fructosamine could increase both the sensitivity and specificity of testing when obtained together rather than separately (Khan et al.).

Other serum markers such as HbA1c and adiponectin (Weerakiet et al., 2006). Can adiponectin predict gestational diabetes have been studied but have not been shown to produce more reliable results than the current testing methods. Adiponectin is a hormone that has insulin sensitizing properties and is negatively correlated to diabetes. Although studies by Tsai et al. (2005) and Weerakiet et al. (2006) did show lower levels of adiponectin in Women with GDM, neither study concluded that screening for plasma adiponectin was superior to the GCT (Tsai et al., 2005; Weerakiet et al., 2006). HbA1c as a screening tool has been considered by Kilpatrick (2005) and Agarwal, Dhatt, Punnose, and Koster (2005a). Kilpatrick noted that HbA1c levels have been shown to vary depending on the age and BMI of nonpregnant patients and therefore thresholds would be difficult to set with diverse populations. Agarwal et al. (2005a) also confirm that HbA1c as a screening or diagnostic test lacked merit after their study showed poor correlation of HbA1c with both the 2 hour GTT and FBG.

Dietary Influences

Dietary influences and their effect on serum glucose tests have also been studied. Two studies (Buhling et al. 2004; Takizawa, Kaneko, Kohno, Fukada, & Hoshi,
2003) looked at preparatory diets in evaluating their effect on testing, however neither of these studies were set up to look at the effect on the 1-hour screening test. Takizawa et al. pointed out that even the dietary intake the day prior to testing can affect testing results. They hypothesized that a low carbohydrate meal the night before testing could result in a false positive GTT. The researchers recruited 27 Japanese women between 20-30 weeks gestation to participate in the study. They randomized the participants into two groups each of which underwent GTT testing twice in a crossover design. The first group’s initial test was performed after consuming a low carbohydrate (6.7%) meal the evening prior to the test, then repeated a second time following a high carbohydrate (85.7%) meal the night before testing (low/high). The second group underwent similar testing, only they started out with the high carbohydrate meal first (high/low). Participants were given strict instructions regarding the prescribed meals and testing requirements. The researchers discovered that following the low carbohydrate meal, fasting blood sugar was significantly lower than following the high carbohydrate meal. However, at the 1 and 2 hour marks, the blood sugars following the low carbohydrate premeal were significantly higher than with the high carbohydrate premeal. The authors concluded that consuming a low carbohydrate meal prior to the GTT can erroneously lead to diagnosis of impaired glucose tolerance (Takizawa et al., 2003)

Buhling et al. (2004) conducted a similar prospective crossover design study with 34 pregnant patients and reviewed the effect of a high vs. low carbohydrate preparatory diet for a week prior to the 2-hour GTT. Each group ate a prescribed diet of either 40% carbohydrates (low) or 50% carbohydrates (high) for 1 week prior to their 2-hour GTT. The following week they switched to the alternate diet and repeated the GTT
once again. The researchers did not observe any significant difference in the results of the tests of the two groups. Although this study used a relatively small sample size of Caucasian women, the researchers utilized a diet plan which may be more in line with what a normal pregnant population would eat in comparison to the previous study conducted by Takizawa et al. (Buhling et al., 2004).

Fasting Versus Fed State

Two earlier research studies looked at performing the 1-hour screening test in a fasting vs. fed state (Coustan et al., 1986; Lewis et al., 1993). Both studies had relatively small sample sizes (70 and 22 respectively) and included patients with the diagnosis of GDM. The inclusion of patients with GDM and use of small sample sizes confirms the need for larger studies which exclude diabetics.

Coustan et al. (1986) studied 50 presumed normal pregnant patients and 20 patients already diagnosed as GDM. The results from the two groups were considered separately. Each group was separated into two smaller groups and then scheduled to have the 1-hour screening test performed twice, once in the fasting state and once 1 hour after completing a meal. Patients who had a screening value over 130 mg/dL on either test were referred for 3-hour GTT. In the 50 presumed normal patients, there was no significant difference in the fasting vs. fed state and 4 patients met the criteria for GDM. In the group of known GDM however, there was a significant increase in the screening test results when the test was administered in the fasted state as compared to the fed state. The authors also pointed out that as the level of the threshold increased (range observed was 130, 135, 140, 145 and 150 mg/dL), sensitivity in the fasted group ranged from 96%
to 83%. In the fed group however, the sensitivity declined from 83% to 46%. Thus the researchers concluded that if the threshold is set at 130 mg/dL, the test can be administered in the fed state, but if the threshold is set higher, the patient should fast (Coustan et al., 1986).

Lewis et al. also reviewed results of the screening test in a fasting, 1-hour postprandial and 2-hour postprandial state. The cohort consisted of 22 pregnant patients, 10 of whom were already diagnosed as GDM. Each participant had the screening test performed three times; fasting, 1-hour postprandial, and 2-hours postprandial. The authors noted that although the nondiabetic patients had a lower initial glucose level in the fasting state, they had a higher 1-hour glucose level as compared to the 1-hour and 2-hour postprandial studies. These results were attributed to the Staub-Traugott Effect in which the fed state promotes an increase insulin sensitivity which in turn causes increased glucose disposal and therefore would produce a lower glucose level after the preload of the diet. The researchers concluded that eating prior to the screening test may significantly alter the test (Lewis et al.).

A study by Perucchini et al. (1999) enlisted 558 women that were given the 1-hour screening test between 24 and 28 weeks. It was noted when the women had last eaten at the time the first blood was drawn. All patients then returned for a 3-hour GTT and results were interpreted by using the Carpenter and Coutan criteria (see Table 1). The researchers then reviewed the values for the fasting state and calculated that a threshold of 86mg/dL in the fasting state had better sensitivity compared to the 1-hour screen, but the specificity lowered to 76% vs. 91%. The investigators also found that eliminating the 3 hour value did not affect the sensitivity of the test significantly. The research team
therefore proposed that at 24 to 28 week the patient arrive in a fasting state. If their fasting glucose is \( \geq 86 \text{mg/dL} \), they should proceed directly to a 2-hour GTT (Perucchini et al., 1999).

Moving Forward With Screening

In an article looking at the past, present, and future of screening, Hanna and Peters (2002) discussed the controversies surrounding screening and noted that more research is needed to resolve major issues. These researchers acknowledged the limitations of HbA1c, fasting plasma glucose, and the glucose screening test. They suggested further research needs to address universal screening, the limitations of the glucose tolerance test, how factors such as age and ethnicity affect testing, ways to improve sensitivity and specificity of testing, and the lack of consensus on screening methods by the major organizations (Hanna & Peters, 2002).

Agarwal, Dhatt, Punnose, and Koster (2005b) expressed similar sentiment. These researchers have conducted numerous studies in the United Arab Emirates which has a very high prevalence of type 2 diabetes (20.1%), the second highest in the world. Their concern regarding a lack of consensus to screening and diagnosis led them to investigate the diagnostic criteria of six major international panels from the United States, Australia, Canada, Europe, New Zealand, and the WHO. Although the GTT is the accepted first line tool, these researchers expressed concern over the drawbacks and lack of reproducibility of the GTT. They therefore encouraged continued research to help clarify diagnostic criteria and assist in the formation of an international consensus for the diagnosis of GDM (Agarwal et al., 2005b).
It is evident from the review of literature that there still is much controversy on what is the best screening method for GDM. Studies using additional markers appear promising, but have been done on relatively smaller samples from ethnic populations and may not be generalized to a larger or ethnically different population (Khan et al.; Li & Yang, 2006; Perea-Carrasco et al., 2002). Studies on preparatory diets have only been done for the 2-hour GTT test and have generally used small sample sizes. Also there was a wide range in what the researchers considered low and high carbohydrate meals (Buhling et al., 2004; Takizawa el al.). The studies that have looked at the nutritional state before the 1-hour screening test have not been recently replicated with larger sample sizes and with controls that exclude diabetic patients (Coustan et al. 1986; Lewis et al.).

The review of literature confirms that hormonal changes in pregnancy produce a decrease in insulin sensitivity. There is uncertainty however, as to which thresholds should be used to judge if the mother is unable to compensate for the resultant insulin resistance. Also, researchers continue to investigate if additional markers or dietary influences can make the screening process more sensitive, specific, cost effective, and reproducible. This quantitative study was designed to build on the prior research of Coustan et al. (1986) and Lewis et al. by providing an updated study on the effects of the fed or fasting state on the 1-hour screening test with a larger cohort. The next chapter will explain the research methods that were employed to study which screening technique for GDM has more accurate results.
CHAPTER III

FINDING A BETTER WAY

Research Design

The research design chosen for this study was a quasi-experimental posttest design with two comparison treatments. This design allows for comparison of two approaches to a situation. Because this type of design is used to examine causality, but does not require the strict controls needed in a true experimental design, it fit the investigator’s setting and needs. The researcher had controls in place for the evaluation of blood sugar measurements (the dependent variable) through the clinic’s lab, but did not have the same controls over patient’s dietary intake (the independent variable). Using this design, the researcher was able to compare the 1-hour glucose levels of both groups (posttest) after the independent variables were put into place. The researcher was then able to compare which method of testing gave the most accurate results. These results were reviewed by the clinic’s providers to determine if new guidelines for prescreening instructions were warranted and to determine what further counseling might be beneficial for the patients to promote optimal health.

Study Sample

The study took place at a rural OB clinic in northern California. The clinic is part of a larger multispecialty group. The obstetrical department consists of six doctors
and one nurse practitioner. The town which this group serves has a primarily agricultural base and patients who are seen at this clinic have a very diverse ethnic makeup. Caucasian, Hispanic, and East Indian backgrounds are all represented in large numbers in this population. Table 2 shows the racial backgrounds of the study participants by their assigned treatment group.

**TABLE 2**

*Racial Backgrounds of Study Participants*

<table>
<thead>
<tr>
<th>Race</th>
<th>Fed</th>
<th>Fasting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>55.8%</td>
<td>48.9%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>26%</td>
<td>30%</td>
</tr>
<tr>
<td>East Indian</td>
<td>9.4%</td>
<td>8.9%</td>
</tr>
<tr>
<td>Hmong</td>
<td>5.5%</td>
<td>7.8%</td>
</tr>
<tr>
<td>Other/Biracial</td>
<td>3.3%</td>
<td>4.4%</td>
</tr>
</tbody>
</table>

From the population of pregnant women receiving care at the clinic, the researcher recruited 186 women to participate in the study. This number was obtained by reviewing charts to elicit the available number of pregnant women within the required gestational ages, and also on the need to have an adequate sample size to test for statistical significance. Patients who met inclusion criteria were between 24 to 28 weeks gestation, and less than 35 years of age. Women with a previous history of GDM or glucose intolerance or who already had been identified as having diabetes mellitus were
excluded from the study. Additional demographic data such as BMI, ethnicity, family history and previous macrosomia were obtained to further identify risks within the sample (see Appendix A).

At the first prenatal visit, the potential participants were given a flyer informing them of the study (see Appendix E). By 20 weeks, the providers discussed the study further with their patients, and referred to the researcher all those that met criteria and expressed interest in participating in the study. The researcher explained the study, detailed the instructions for each treatment group, answered all questions, and reviewed the consent form with the patients. Once the patient agreed to participate and signed the consent, the researcher gave her a copy of the sample diets. On the diet sheet was written the participant’s name, the address of the clinic laboratory, and the dates between which she was to report to the lab for testing. Below the diet choices, the researcher also wrote the word “fasting” and again included the participant’s name, dates for testing and the laboratory address. To ensure that each treatment group was representative of the target population and to reduce the risk of sampling error, the researcher used simple random sampling to divide the women meeting inclusion criteria into two groups. The first treatment group was designated as those who performed the screening test in a fasting state. The second treatment group was designated as those who performed the screening test 1 hour after completion of a meal.

At the end of each week, the researcher gathered the names of participants who had been recruited during the week and randomly divided them into the two treatment groups by drawing their names from a hat. The participants were notified by phone call or by a note given to them at their subsequent clinic visit as to which treatment
group they had been assigned. The participants took with them to the lab the portion of
the paper that indicated their treatment group. Those that had been assigned to the fed
group circled the diet choice they had eaten that morning. The laboratory personnel
returned the papers to the researcher each month. This process was repeated each week
for the duration of the study.

Protection of Human Subjects

In designing nursing research, it is essential that the rights of the study
participants be protected. Nurses have an ethical responsibility to consider these rights in
all aspects of the design of the study. Procedures should be in place to protect the
participant’s right to self-determination, privacy, anonymity and confidentiality, fair
treatment, and protection from discomfort or harm. To help ensure that these rights were
upheld, this study was approved by the California State University, Chico Institutional
Review Board.

The right to self-determination was protected in this study by giving a
complete description of the study to the perspective participants. Participants were
ensured, verbally and in writing, that their participation was purely voluntary and in no
way would their care be threatened if they chose not to participate. Furthermore, they
were also instructed that they could withdraw from the study at any time without any
threat to their care. No monetary reward was given to participants, since the 1 hour GCT
was part of their routine workup and no additional cost was incurred. Data were collected
on only those that agreed to participate by signing a written consent form (see appendix
B). The researcher acknowledged that pregnant women are considered a vulnerable
population which needed additional protection. The manner in which this study was designed however, posed no additional threat to the mother or fetus than would be incurred during routine prenatal care.

In this study, the right to privacy, anonymity, and confidentiality was protected by the following procedure. All participants were given an identification (ID) number at the onset of the study. The master list and backup disc with ID numbers, as well as the signed research consents were kept in a locked file cabinet in the researcher’s locked office. Results from the laboratory tests and demographic data were obtained by the researcher from the secure electronic medical record already in place at the clinic site. Results were logged onto a collection sheet containing only the ID numbers of the participants. This sheet was kept on the researcher’s personal office computer which requires a password to operate. A second back up disc was developed for this data and kept in the researcher’s locked desk. Although the individual’s provider had access to the test results, they were not able to identify the patients enrolled in the study when reviewing these lab reports. The research report did not contain any personal identifiers.

The right to fair treatment was accomplished by selecting participants based on the inclusion and exclusion criteria only. They were assigned to their treatment group by random selection. Written materials given to participants for this study were translated by the clinic’s certified translators into Spanish and Punjab. Certified translators were also available to clarify any questions the participants may have had. The glucose screening test is recognized, standard protocol for GDM screening in pregnancy. Therefore, the participants were exposed to the same testing as all other non-participants.
Ethics in research dictate that study participants should not be exposed to any greater harm than those of the public. Since both participants and non-participants were to undergo the same test, the researcher did not expect there to be any additional risk to participation in this study. The right to protection from discomfort and harm was however maintained by informing participants of the slight discomfort possible from venipuncture and the glucola solution.

Data Collection Method and Procedure

Once the treatment groups were determined through random selection, the researcher assigned an ID number to the individual participants. This number, along with demographic information taken from the medical record, was entered onto a collection sheet (see Appendix C). As stated earlier, each participant and the researcher met in the researcher’s office to discuss the dietary requirements of the test. Menu choices were given to all participants at that time to ensure that the participants would have the appropriate foods in stock at their homes or enable them to pick an appropriate restaurant to which they could go and order the selected items.

Treatment group 1 was instructed to take in nothing by mouth after midnight the night before the test. They reported to the main clinic lab between 7:00 and 9:00 A.M. for their 1-hour glucose screening test. The fasting state was verified by the phlebotomists through oral and written report from the patient, which the researcher has acknowledged might not always be accurate. They then were giving a 50 gram glucola solution to drink. After waiting one hour in the lab waiting area, they had their blood
drawn. Results were obtained by the researcher through the electronic medical record and entered onto the collection sheet.

Treatment group 2 was instructed to arrive at the lab one hour after their first bite of breakfast, confirm the fed state, and give the phlebotomists the folded paper with their menu choice circled. As with the fasting group, the researcher acknowledged this information might not always be accurate. The researcher provided the participants with four menu choices from which to choose (see Appendix D). These diet choices were developed in conjunction with a Registered Dietician who is a Certified Diabetic Educator and included calories and carbohydrate levels consistent with previous classic studies (Coustan et al. 1986; Lewis et al.). They then proceeded to drink the 50 gram glucola solution. One hour later, they had their blood drawn. Results were obtained and entered onto the data sheet by the researcher.

The blood draw and blood plasma analysis were performed at the clinic’s main laboratory. This was done so no external transportation of the specimen was necessary. State certified phlebotomists obtained the specimens per the laboratory’s protocol (available upon request). The blood was collected in a green top, lithium heparinized tube and was immediately spun down.

The plasma was analyzed by the Dimension RXL. Manufacturers of this equipment state that sensitivity for this test is 1 mg/dL which is the lowest concentration of glucose that can be distinguished from zero. Specificity for this test can be affected by high levels of unconjugated bilirubin, cholesterol, and/or hemoglobin. To ensure the validity and reliability of this biochemical measurement, laboratory protocol for calibration of the device was followed. Standard protocol for this equipment entails a two
level control to be run by the laboratory director each morning. If the control fails, a second control is run and if that fails, the machine is calibrated. If the control is accurate, then the machine will deliver an automatic calibration notice every 90 days. The machine is also calibrated with every new reagent cartridge.

Participants were informed at the time of intake that if they had a one hour glucose test result greater than or equal to 140 mg/dL, they would be informed by their provider of the result and the need of additional testing. This entailed a three hour glucose tolerance test. To accomplish this testing, the participants were instructed to fast after midnight the night before the test. The next morning they arrived at the lab, had a fasting blood sugar drawn, and then drank a 100 gram glucola solution. They then had their blood drawn at the \( \frac{1}{2} \) hour, 1 hour, 2 hour, and 3 hour intervals. Urine specimens were also obtained at the time of the blood draws. As before, the participants stayed in the lab waiting area during the test. Results were entered onto the data collection sheet by the researcher.

Participants who were diagnosed with GDM were referred to the local Sweet Success program. Sweet Success provided services by a registered dietician for evaluation of dietary needs and diet planning. Through this program, the participants also met with a diabetic nurse educator for instructions on diabetic management, sugar testing, insulin administration and reviewed implications for long-term health issues. Providers also followed these women more closely. Weekly or biweekly visits to evaluate maternal weight, fetal growth, sugar levels, activity level, and medication management were scheduled upon diagnoses. Increased surveillance measures for detection of potential
adverse outcomes were monitored through non-stress testing, ultrasound, blood pressure measurements, and testing urine for sugar and protein.

Data Analysis

Before the data could be evaluated, the researcher excluded the identifiers for those who had withdrawn from the study or failed to report to the lab for testing by the end of the collection period. Next, the researcher reviewed the results to determine if the participants had reported to the lab during the 24 to 28 week testing period. The results of those who had reported to the lab after the 28-week cutoff were also excluded from the final data analysis. The remaining data were reviewed by the researcher to determine how many 1-hour tests were positive from each of the treatment groups. Once the study participants who had positive screening tests had completed their 3-hour GTT, the number of positive and negative 3-hour results were noted. Since the data were classified as positive or negative, a nominal-scale measurement applied. The two resulting proportions of positive results from each treatment group were compared by performing a Z confidence interval for the difference between the proportions at a 95% confidence level.

It was the hope of the researcher that this quasi-experimental study would give greater insight into how dietary factors influence the glucose screening test. By using two randomized treatment groups, the researcher was able to compare the influence of the fasting and fed state on screening test results. After the data were collected, the ratio of true positive test results from both groups were determined and compared by analyzing the difference between the proportions. Providers at the clinic plan to use this data to
counsel their patients prior to testing regarding the most optimal manner in which to get accurate results.
CHAPTER IV

RESULTS

Over the course of 4 months, 186 women were recruited to participate in this study. Prior to 24 weeks gestation, 1 participant had suffered a spontaneous abortion and 4 other participants withdrew from the study. The remaining 181 women were randomly assigned to the two treatment groups. By the end of the collection period, the researcher found that 15 participants had not reported to the lab for testing, and 18 had their testing performed after the 28-week cutoff. Only 1 participant, of those excluded from the data analysis, had a positive 1-hour screening test which subsequently was proven a false positive reading after the 3-hour GTT. The results from the final 148 participants were evaluated by the researcher and demonstrated a fasting treatment group and a fed treatment group each containing 74 women.

The data revealed that of the 148 participants, 31, or 20.94%, had 1 hour GCT results \( \geq 140 \) mg/dL. This percent was higher than the initial 16.6% seen after a cursory review of charts in the fall of 2006. Fifteen of these participants were in the fasting treatment group and 16 were in the fed treatment group. The characteristics of these study participants are found in Table 3.

The 31 women with positive screening tests were notified by their provider of the need for further testing with a 3-hour GTT. One of the study participants in the fed treatment group however, had a GCT result of 242 mg/dL and was deemed GDM by her
TABLE 3

*Characteristics of Mothers with Positive GCT*

<table>
<thead>
<tr>
<th></th>
<th>Fed</th>
<th>Fasting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-19</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>20-29</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>30-34</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td><strong>Pregnancy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primipara</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Multipara</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>20-25</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>26-29</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>&gt;30</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>East Indian</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Hmong</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>+Family Hx (1st degree)</td>
<td>9</td>
<td>4</td>
</tr>
</tbody>
</table>
provider and immediately referred to the Sweet Success program. By the conclusion of the data collection process, 1 participant (from the fasting group) had not completed the recommended GTT. The remaining 29 women, 14 from the fasting group and 15 from the fed group, did report for further testing. Figure 1 demonstrates the breakdown of the results obtained from the complete testing process.

![Figure 1. Glucose screening results of two treatments.](image-url)
As noted in Figure 1, only two participants satisfied the criteria for the diagnoses of GDM by the standards set from the NDDG. Both of these participants had been randomized into the fed group. The ratio therefore of true positive results in the fed treatment group was 2/15. In the fasting group, none of the participants met criteria for GDM and the resulting ratio of true positive results was 0/14. The Z confidence interval for the difference between the proportions for this data at a 95% confidence level was found to be (-.0387, .30536). The results did not prove to be statistically significant and therefore indicated that preparatory diet instructions would not help to decrease the false positive results of the test. However, the data did reveal a significant trend which was applicable to patient management and prevention of possible adverse perinatal outcomes.

As contentious as the issue of screening has been, so too have the recommendations regarding management of markedly high screening results. At the clinic where this study was conducted, six of the seven providers recognize women with GCT results $\geq 200$ mg/dL as having impaired glucose tolerance and thus manage these women as having GDM. The decision to manage patients in this manner is based on recommendations of the regional Perinatologist group, the World Health Organization’s recommendation that women with IGT be classified as having GDM, and on studies which have shown a correlation between markedly high GCT results and GDM.

Friedman, Khoury-Collado, Dalloul, Sherer, and Abulafia (2006) found that in a population of black obstetrical patients, a GCT result of $\geq 200$ mg/dL was diagnostic for GDM in 100% of the cases. In this study, the rate of GDM in women with an abnormal GCT result between 180 mg/dL and 199 mg/dL was 72%. The authors therefore recommended the 3-hour GTT for abnormal screening test results up to and including
199mg/dL, but found it unnecessary to proceed to the 3-hour GTT when screening test results reached ≥200 mg/dL. Recently, Wong, Garden, and Jalaludin (2009) also confirmed a positive predictive value (PPV) of 85.3% in patients with GCT results of ≥198 mg/dL and 95.3% in patients with GCT of ≥216 mg/dL. These researchers also noted that if the GCT was performed before midday, the PPV for GDM rose to 90.7% and 97.3% respectfully.

Since it is well established that IGT can lead to adverse perinatal outcomes and a higher risk for type 2 diabetes in later years, the clinicians involved in this study believe it is prudent to follow mothers with screening results ≥200 mg/dL as GDM. For that reason, the researcher reexamined the data to include those participants with results ≥200 mg/dL and found 3 additional participants from the fed group that were classified and managed by their providers as GDM. Thus, in determining a management protocol for women undergoing the GCT, 5 of the 16 women in the fed group actually benefitted from closer surveillance and diabetic education during their prenatal care. None of the women in the fasting group reached this threshold on their screening test. The researcher recalculated the Z confidence interval for the difference between these new proportions (5/16 in the fed group and 0/14 in the fasting group) at a 95% confidence level and found it to be (.08538, .53962). Thus statistical significance was reached when the diagnostic criteria for GDM included not only a positive 3-hour GTT, but a screening result of ≥200mg/dL. This would indicate that it is beneficial to advise patients to have the GCT after consuming a meal.

The results of this study showed the rate of GDM detected using criteria from the NDDG was 6.45%. This percent falls within the national average. When results from
the women with IGT (as defined by a screening result $\geq 200 \text{ mg/dL}$) were added to the positive results, the percentage of women managed as GDM rose to 16%. Of the women with GCT results $\geq 140 \text{ mg/dL}$, nearly 42% had first degree relatives with diabetes mellitus and came from racial groups at high risk for GDM. Also, 61% of the women needing retesting with the 3-hour GTT had a BMI of $\geq 26$ and all 5 of the participants managed for GDM had a BMI of $\geq 30$. These data confirm previously identified risks factors for GDM.
CHAPTER V

DISCUSSION

Reflecting on Study Results

Researchers have long been engaged in conducting studies that seek to improve the diagnostic process for GDM. Still, a gold standard for testing has not been realized. Leading health organizations have yet to come together with one accepted standard, and providers are left to interpret a plethora of medical research which still does not provide a consensus for diagnosis. This study sought to expand on the earlier research by Coustan et al. (1986) and Lewis et al. in addressing the nutritional status of mothers prior to the glucose screening test.

The results from this study mirrored those of Coustan et al. (1986) which indicated there was not a statistical difference in performing the GCT in the fasting or fed state. However, it is important to point out that both of the study participants who had a true positive result, as well as those with markedly high screening tests, had been randomized into the fed group. Furthermore, all the participants in the fasting group proved to have normal GTT results, strengthening the conclusion of Takizawa et al. that carbohydrate depletion may incorrectly suggest a diagnosis of impaired glucose intolerance. Results from this study also suggest that the Staub-Traugott Effect described by Lewis et al. may be responsible for the falsely higher glucose concentrations seen when the screening test is done in the fasting state.
More current research by Wong et al. (2009) and Friedman et al. (2006) suggest that women with markedly high GCT results should be managed as GDM. This trend has been adopted by the providers at the clinic where this study took place and the local Sweet Success Program does accept patients with GCT results of ≥200 mg/dL without further testing. The results of this study did show statistical significance in support of performing the GCT in the fed state when management of patients considered GDM includes those with markedly high GCT results.

Reducing false positive results of the GCT by performing the test in the fed state will reduce medical costs for the mother, decrease her exposure to unnecessary tests, and help providers more precisely assess the risk profile of their patients. More accurate results ensure that providers will have the tools to plan for better management of their patients, thus reducing the risks of perinatal complications.

Limitations of the Study

Several limitations were encountered during this study. The time allotted for data collection spanned over just 4 months which limited the number of participants that could be recruited. Although 181 women were recruited, over 30 either did not report for testing or tested after the prescribed testing cutoff. This resulted in total number of 148 from which only 31 met criteria for GTT testing. The resulting small sample size reflected the prevalence of patients with positive screening tests and suggested that further research should be planned over a longer collection period.

The researcher also encountered difficulties in recruiting the study participants. Despite attempts to identify potential study participants for the other
providers within the department, the researcher relied on these providers to provide information about the study and send their patients to the researcher for further details. Selection bias on the part of the providers could have limited the referrals to the researcher.

Lastly, patient compliance with the dietary instructions could have affected results. Although the preparatory requirements for the test were emphasized both verbally and in writing, participants were not strictly monitored to ensure that they reported for their test in the prescribed state. Laboratory personnel did verify the fasting or fed state per the participant’s report, but dietary intake was not observed.

Implications for Nursing Practice

As cited earlier in the study by Stamilio et al. false positive 1-hr. screening tests may be associated with higher mean birth weights and delivery complications. With this in mind, the researcher proposes that nurses consider the opportunity to promote optimal health behaviors during pregnancy with all patients who have a positive screening test regardless of the outcome of the GTT. This can be accomplished by reviewing dietary requirements in pregnancy, ways to eliminate extra fat from the diet, appropriate weight gain for the individual’s BMI, and by discussing safe and appropriate ways to incorporate exercise into a daily routine.

In keeping with the theoretical framework of this study, the researcher advises all nurses to assess the individual’s influencing factors as guided by Pender et al.’s HPM. This will enable the nurse to individualize recommendations to the pregnant woman diagnosed as GDM or IGT and help the mother develop a plan of action to decrease her
risk of diabetes as she ages. Women who have had GDM need glucose levels checked post-partum and if normal, they should be reassessed for glycemia at yearly intervals.

Women who are found to have impaired glucose tolerance should also be screened on a yearly basis. Counseling on diet and exercise should also be stressed for all women who have had GDM.

Implications for Nursing Research

As stated earlier, this study was limited by the small sample size and would be strengthened if reproduced over a longer data collection period to ensure a greater number of participants. This study also revealed the strong association between increased BMI and GDM and indicates that there is a need to investigate and develop better educational and health care programs directed at nutritional and lifestyle practices of childbearing women. The increased risk to women with GDM to develop overt diabetes has been well documented (ACOG, 2006). Therefore, it is this researcher’s opinion that further research should also be conducted to ascertain if women who have had GDM are receiving adequate postpartum and long term follow up.

Implications of Nursing Education

In order to coordinate the care of a woman with GDM, nurses need to have an education that includes a proficient background in nutrition as well as disease management. The results from this study confirm that the majority of the patients with an elevated GCT were overweight and all of the women managed for GDM were obese. Nurses therefore must have the knowledge to educate clients in healthy habits including sound nutrition, exercise, and stress management. The nutritional requirements of
pregnancy, as well as modifications for complications such as GDM, should be included in standard curriculum. Nurses must be aware of ethnic groups who are at high risk to develop diabetes or impaired glucose intolerance and be trained to be culturally sensitive in their approach to patients with recommendations or modifications. Finally, nursing students should become exposed to the theoretical perspectives of respected nurse theorists, such as Dr. Nola Pender, to help guide their nursing practice relevant to promoting a healthy lifestyle.

Conclusion and Recommendations

This study sought to determine if false positive results of the 1 hour glucose challenge test would improve with dietary modifications implemented prior to the test. The results of this study did not support the use of dietary intervention to lower the false positive rate of the screening test in diagnosing GDM by the criteria set forth by the NDDG. This study did suggest however, that performing the screening test in a fed state may assist in reducing the false positive rate of the GCT when the goal of screening and management also includes identifying those women with impaired glucose tolerance. Therefore, it is recommended that providers who manage patients with a threshold of \( \geq 200 \) mg/dL as GDM consider instructing their patients to perform the GCT in a fed state.
REFERENCES
REFERENCES


RISK CRITERIA FOR GESTATIONAL DIABETES

LOW RISK:
- Age < 25 years
- Normal prepregnancy BMI (≤ 25)
- No history of previous IGT or GDM
- No history of diabetes in first degree relatives
- Low risk ethnic group
- No history of poor fetal outcomes associated with GDM

AVERAGE RISK:
- Risks fall between low and high risk profile

HIGH RISK:
- Age >35
- Prepregnancy BMI ≥ 27
- History of previous GDM or IGT
- First degree relative with diabetes
- Belonging to ethnic group with increased prevalence of diabetes (includes: African American, Arabic, Hispanic, Native American, Pacific Islander, or South-east Asian)
- History of adverse outcome (i.e., macrosomia, shoulder dystocia, or birth trauma)

References


RESEARCH CONSENT FORM

STUDY TITLE: Is There a Way to Improve the Glucose Screening Test in Pregnant Women?
INVESTIGATOR: Karen Callahan RNPN

STUDY PURPOSE
The purpose of this research study is to find a way to make the usual sugar testing in pregnancy more accurate and reduce the number of repeat tests. At this time, there is no clear manner for preparing for this test. The researchers will ask participants to have their usual sugar test done either on an empty stomach or after breakfast.

RISKS AND BENEFITS
If you participate in this study you may be able to avoid having to repeat a sugar test that has come back abnormal. We do not expect participating in this study will expose you or your baby to any extra risks. If you have the test done on an empty stomach, you may have some slight discomfort from being hungry. Participation in this study may require an extra hour of your time.

VOLUNTARY CONSENT AND YOUR OPTION TO WITHDRAW
Participating in this study is your choice. You do not have to participate if you do not want to. You will receive the same quality care no matter what you decide. If you choose to participate, you have the right to pull out of the study at any time. If you do, your care and relationship with your doctor will not change in any way.

PROTECTING YOUR PRIVACY AND CONFIDENTIALITY
Your personal and medical information will remain private. The test results will be given a code so that your name will remain anonymous. Your doctor will continue to get all of your information. The information will be kept in a safe and locked area. Your information will not be given to anyone without your permission.

FOR QUESTIONS ABOUT THE STUDY
This study has been approved by the Institutional Review Board at California State University, Chico. If you have any questions about this study or about participating in it; you can call Karen Callahan at (530)749-3361 or Dr. Irene Morgan at (530) 898-6207.

I have read and understand the information in this consent and do agree to participate of my own free will in the proposed study.

__________________________              ______________________________
PARTICIPANT’S SIGNATURE      DATE

I have reviewed this consent with the participant and verify the participant’s understanding of the conditions.

__________________________              ______________________________
RESEARCHER’S SIGNATURE    DATE
| Pt. ID# | AGE | G/P/A/L | Wks. | Gest. | Fasting/Fed | 1 Hr. | 3 Hr. | 1 Hr. | 2 Hr. | 3 Hr. | Ht. | Wt. | BMI | Prev. Macro | Ethnic Group | Fm. Hx. | |-------|-----|--------|------|------|-----------|------|------|------|------|------|-----|-----|----------|-------------|---------|--------|
|       |     |        |      |      |            |      |      |      |      |      |     |     |    |           |              |         |        |
| 1     | 31  | 3/2/0/2| 24   | 24   | Fasting    | 128  | 5'5" | 132  | 22   | no   | Cau | neg |
| 2     | 19  | 1/0/0/0| 25   | 25   | Fasting    | 132  | 5'4" | 110  | 19   | no   | Cau | neg |
| 3     | 21  | 2/0/1/0| 26   | 26   | Fed        | 116  | 5'1" | 165  | 31   | no   | Hisp| father |
| 4     | 22  | 1/0/0/0| 25   | 25   | Fasting    | 110  | 5'7" | 142  | 22   | no   | E. I.| neg |
| 5     | 18  | 2/1/0/1| 24   | 24   | Fed        | 127  | 5'3" | 98   | 17   | no   | Cau | neg |
| 6     | 28  | 4/2/1/2| 28   | 28   | Fed        | 133  | 5'6" | 198  | 32   | no   | E. I.| neg |
| 7     | 26  | 3/2/0/2| 28   | 28   | Fasting    | 185  | 99   | 220  | 160  | 155  | 5'5"| 220 | 37   | no   | E. I. mother |
| 8     | 30  | 5/3/1/3| 27   | 27   | Fed        | 129  | 5'7" | 152  | 24   | 9'14"| Hisp| neg |
| 9     | 32  | 2/1/0/1| 25   | 25   | Fed        | 105  | 5'4" | 145  | 25   | no   | Hisp| neg |
| 10    | 27  | 5/1/3/1| 27   | 27   | Fasting    | 142  | 97   | 170  | 156  | 147  | 5'6"| 172 | 28   | no   | Hisp | neg |

G/P/A/L = gravida/para/abortions/living children
BMI = body mass index
Prev. Macro = Previous Macrosomia (>4500 grams or 9.9 lbs.)
Fm Hx. = family history
# Preparatory Breakfast for Glucose Screening Test

<table>
<thead>
<tr>
<th>Choice A</th>
<th>Choice B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food</strong></td>
<td><strong>Food</strong></td>
</tr>
<tr>
<td>3 – 4” pancakes</td>
<td>1 – 7” waffle</td>
</tr>
<tr>
<td>2 Tablespoons (1oz.) syrup</td>
<td>2 Tablespoons (1oz.) syrup</td>
</tr>
<tr>
<td>2 pats (1 Tbsp) butter or margarine</td>
<td>2 pats (1 Tbsp) butter or margarine</td>
</tr>
<tr>
<td>2 pieces bacon or sausage links</td>
<td>2 pieces bacon or sausage links</td>
</tr>
</tbody>
</table>

**Total Calories:** 510  
**Total Carbohydrates:** 50-56 grams

<table>
<thead>
<tr>
<th>Choice C</th>
<th>Choice D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food</strong></td>
<td><strong>Food</strong></td>
</tr>
<tr>
<td>2 pieces of French toast</td>
<td>2 pieces of buttered toast</td>
</tr>
<tr>
<td>2 Tablespoons (1oz.) syrup</td>
<td>1 cup hash browns (large portion)</td>
</tr>
<tr>
<td>2 pats (1 Tbsp) butter or margarine</td>
<td>1 Tbsps of jelly/jam</td>
</tr>
<tr>
<td>2 pieces bacon or sausage links</td>
<td>1 fried or scrambled egg</td>
</tr>
</tbody>
</table>

**Total Calories:** 510  
**Total Carbohydrates:** 55 grams

<table>
<thead>
<tr>
<th>Choice D</th>
<th>Choice D</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food</strong></td>
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<td>1 fried or scrambled egg</td>
</tr>
</tbody>
</table>

**Total Calories:** 570  
**Total Carbohydrates:** 65 grams

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APPENDIX E
We Need Your Help

Our providers are conducting a study to see if there is a way to improve one of your pregnancy screening tests.

All mothers are checked for diabetes when they reach 24 to 28 weeks in their pregnancy. If this test comes back positive, you will need an additional glucose test. Many times this second test comes back negative, meaning that you are not diabetic. In our effort to avoid having to do unnecessary tests, we are currently organizing a study with our mothers-to-be to see if the manner in which we do this test will give more accurate results. Participation is strictly voluntary and confidential. Your provider will give you more information on this study later in your pregnancy. If you would like further information, you can call our Nurse Practitioner, Karen Callahan, anytime at 749-3361.