

Comparison of Home Glucose Monitoring with the Oral Glucose Tolerance Test to Detect Gestational Glucose Intolerance

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Background. Recent evidence suggests that infant morbidity is increased among women who have abnormal prenatal glucose screening tests but who do not have gestational diabetes mellitus (GDM). These women fall into a diagnostic gray zone and historically have not been treated.

Methods. Forty-eight pregnant women with abnormal oral glucose challenge test results performed self-monitored blood glucose (SMBG) testing seven times per day for 1 week before undergoing a diagnostic 100-g oral glucose tolerance test (OGTT). At delivery, perinatal complications and birthweights were recorded. Results of SMBG tests for women with normal OGTTs were correlated with infant birthweights.

Results. Thirteen infants (37%) were found to be large for gestational age (LGA). Significant correlation was

found between increasing birthweight and increasing average fasting SMBG values ($P < .001$), increasing percentage of SMBG values above 120 mg/dL (6.7 mmol/L) ($P < .01$), and increasing average SMBG values ($P < .016$).

Conclusions. Maternal home glucose values at 28 weeks correlate with the risk of LGA infant births among women in the diagnostic gray zone. Women with average fasting SMBG values >95 mg/dL (5.3 mmol/L) are at increased risk for giving birth to LGA infants and may be more likely to exhibit complications usually associated with GDM.

Key words. Screening; diabetes, gestational; gestational age; infant, large for gestational age; fetal macrosomia. (*J Fam Pract* 1994; 39:558-563)

Gestational diabetes mellitus (GDM), a term that applies to hyperglycemia first discovered in pregnancy, is present in 3% to 12% of pregnancies, making its identification and treatment essential to the delivery of optimal obstetric care.¹ GDM is associated with an increased incidence of fetal macrosomia, neonatal hypoglycemia, hypocalcemia, polycythemia, and hyperbilirubinemia.² Diagnostic criteria for GDM using the 100-g oral glucose tolerance test (OGTT) have been defined by the National Diabetes

Data Group.³ These criteria are based on an interpretation of work performed by O'Sullivan and Mahan,⁴ who evaluated women with hyperglycemia in pregnancy for the purpose of identifying those at increased risk for subsequent development of non-insulin-dependent diabetes mellitus (NIDDM). Subsequently, a positive association was made between an abnormal OGTT and increased perinatal mortality.⁵ More recently, the primary purpose of diagnosis among patients with GDM has been to reduce adverse perinatal outcome⁶ in conjunction with evaluation of maternal risk for the subsequent development of NIDDM. For that reason, it is appropriate to reexamine the current diagnostic criteria.

The large-for-gestational-age (LGA) infant and macrosomic infant are among the most common adverse outcomes of GDM.⁷ LGA infants rank above the 90th per-

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centile in weight, and macrosomic infants weigh more than 4000 g at birth, regardless of gestational age. Mothers of macrosomic infants are at increased risk of protracted labor, fetopelvic disproportion, and shoulder dystocia.⁸ They have twice the normal risk of cesarean section, as well as an increased risk of postpartum hemorrhage.⁹ The infant is at increased risk for brachial plexus palsy, clavicle and humerus fracture, fetal asphyxia, hypoglycemia, hyperbilirubinemia, organomegaly, and low Apgar scores at the time of birth.^{10,11} Current literature also suggests that large infants are at increased risk of late diabetes-related sequelae, including obesity and possible developmental delays.¹² Previous attempts to find long-term measures of glucose control that could predict adverse perinatal outcomes have not been successful. Hemoglobin A_{1c} has been demonstrated to be an insensitive measure of abnormal glucose metabolism in pregnancy, identifying only 40% of women with an abnormal OGTT.^{13,14} Fructosamine and glycosylated serum protein have also been reported as insensitive screening tests in pregnancy for gestational diabetes.^{15,16}

In GDM, maternal insulin resistance is exaggerated beyond the levels found in nonpregnant women.¹⁷ When maternal pancreatic β -cells fail to compensate, maternal hyperglycemia results in increased transplacental diffusion of glucose to the fetus. This, in turn, stimulates excessive fetal pancreatic β -cell production of insulin.¹⁸⁻²⁰ Fetal hyperinsulinemia fosters abnormal fat deposition. Clinical studies have shown that the risk of a large infant is five to nine times greater among women with glucose levels >105 mg/dL (5.8 mmol/L) fasting and 140 mg/dL (7.8 mmol/L) postprandial, as compared with women without diabetes and those with treated GDM whose glucose level is maintained between 60 and 120 mg/dL (3.3 and 6.7 mmol/L).^{21,22} Early intervention and strict glucose control in women with gestational diabetes has been demonstrated in several studies to decrease maternal and fetal complications and reduce the incidence of LGA infants.^{8,21}

Recent work has demonstrated that some women with an abnormal screening glucose challenge test (GCT) but a normal OGTT result remain at increased risk of adverse neonatal outcome.^{6,23,24} Langer and associates²⁵ have demonstrated that women with only one abnormal result on OGTT have a 35% risk of neonatal complications. Because these women frequently fall into a diagnostic gray zone where recommendations for treatment are unclear, some investigators have considered lowering both the screening and the diagnostic criteria.^{24,26}

With the advent of newer technologies for determination of blood glucose levels, other methods for identifying glucose intolerance in pregnancy can be evaluated. In gestational diabetes, frequent self-monitoring of blood

glucose allows for close assessment of metabolic control. The availability of the portable glucose reflectance meter with an internal memory chip has facilitated the collection of verifiable self-monitored blood glucose data.²⁷ This study prospectively examined the correlation between self-monitored blood glucose values and infant morbidity, measured in terms of occurrence of LGA infants in women with an abnormal 1-hour GCT and a normal 3-hour OGTT.

Methods

Women were recruited from family medicine and obstetric practices associated with a large metropolitan hospital center. A consecutive sample of pregnant women was identified: those who were between the 24th and 29th gestational week and had plasma glucose results >140 mg/dL (7.8 mmol/L) and <200 mg/dL (11.1 mmol/L), as determined 1 hour following ingestion of 50 g of a standard liquid glucose solution, regardless of prandial state.¹ Following informed consent, subjects were interviewed, and the following data were obtained: pregravid weight, maternal height, family history of diabetes, obstetrical history, medications, tobacco and drug use, and gestational age. Women were excluded from the study if they had a previous history of GDM or a hemoglobin of <10.0 g/dL (100 g/L) since reflectometer readings below this value were considered unreliable.

Subjects were instructed in blood glucose monitoring techniques by a nurse specialist in diabetes. A memory-based reflectance meter capable of storing 440 blood glucose values with the corresponding time and date of the test (Glucometer M, Miles Laboratories Inc, Ames Division, Elkhart, Ind) was provided. Subjects were asked to immediately begin measuring their capillary blood glucose seven times per day (fasting, preprandial, 2 hours after the beginning of each meal, and at bedtime) for 7 days. They remained on an unrestricted diet. At the end of 7 days, capillary blood glucose measurements were downloaded directly from the reflectance meter to a computer, and patients underwent a 3-hour oral glucose tolerance test (OGTT) using a standardized 100-g oral glucose load. Women were instructed to fast for at least 8 hours before the OGTT. Gestational diabetes was diagnosed in accordance with the criteria of the National Diabetes Data Group, which requires that at least two of the following blood glucose values are met: >105 mg/dL (5.8 mmol/L), >190 mg/dL (10.5 mmol/L), >165 mg/dL (9.2 mmol/L), and >145 mg/dL (8.0 mmol/L) at 0, 1, 2, and 3 hours, respectively.³

Following the OGTT, no further glucose testing was performed for patients who did not meet National Dia-

betes Data Group criteria for gestational diabetes. Patients diagnosed with GDM were treated with diet or insulin therapy, according to established protocols to obtain glycemic control.²⁸ After delivery, the following outcome data were obtained: infant birthweight, gestational age, method of delivery, maternal weight gain, and presence of maternal or infant complications during labor or delivery.

Glucose metabolism, measured by SMBG testing, was characterized using Glucofacts (Miles Laboratories Inc, Diagnostics Division, Elkhart, Ind, 1989). This computer program downloads glucose meters and summarizes individual glucose data including ranges and averages. Statistical analysis was performed using SAS (SAS Institute Inc, Cary, NC). Women with an abnormal GCT but a normal OGTT were referred to as the "gray zone" group. A product-moment correlation coefficient was calculated for the gray zone group between infant birthweight and 18 study variables. The gray zone group was segmented into four subgroups based on the individual's average fasting SMBG level: group A, ≤ 85 mg/dL (4.7 mmol/L); group B, 86 to 94 mg/dL (4.8 to 5.2 mmol/L); group C, 95 to 104 mg/dL (5.3 to 5.8 mmol/L); and group D, ≥ 105 mg/dl (5.8 mmol/L). Relative risks of giving birth to an LGA infant for groups A through D were calculated using logit estimators, with group A as the reference to which others were compared.

Two-by-two tables were corrected for empty cells using .5 added to every cell.²⁹ Fisher's exact test was employed to detect significance of birthweight difference for each group as compared with group A. Trend analysis was performed using a Mantel-Haenszel statistic for trend. Univariate and bivariate regression were performed to evaluate possible confounding effects from the following factors known to influence birthweight: gestational age, multiparity, and maternal pregravid weight. Birthweight was the dependent variable and average fasting glucose the independent variable in the univariate (reduced) model. The full model included the confounding variable of interest. The change in the beta coefficient for average fasting glucose was examined to reflect degree of confounding. Any change in the beta coefficient of less than 10% was considered insignificant.

Birthweight percentiles of infants were obtained by using a standard of fetal growth in the United States (Brenner curve)³⁰ to correct for differences in gestational age. LGA infants were identified as those ranking at or above the 90th percentile. Twins and infants born before the 37th gestational week were excluded from these analyses because of inaccuracy in determining LGA.

Results

Of the 101 women with a GCT >140 mg/dL (7.8 mmol/L) who were contacted for participation in the study, 53 agreed to participate. The most common reasons given for refusal were lack of time and hesitation to undergo blood glucose testing seven times per day. There was no difference in insurance status or ethnicity between the groups. No significant difference was found in the average plasma glucose at the 1-hour GCT between women who agreed to be in the study (158 ± 14 mg/dL [8.8 ± 0.8 mmol/L]) and those who declined (157 ± 14 mg/dL [8.7 ± 0.8 mmol/L]). Forty-eight women (91%) completed the study. Of the five women who dropped out, four did not complete daily capillary blood glucose measurements, and one refused the 3-hour OGTT. There were no statistical differences for the GCT between those who remained in the study and those who dropped out.

Following the week of intensive self-monitoring, five subjects were diagnosed with gestational diabetes by OGTT, according to National Diabetes Data Group criteria. Although no significant difference was found between this group and the gray zone group with respect to pregravid weight, gravida, or weight gain during pregnancy, the women with gestational diabetes had a significantly greater BMI (body mass index) ($P = .032$), higher average screening values ($P < .003$), higher average fasting values ($P < .001$), and higher average overall SMBG values ($P < .001$) than the gray zone group. Of the women with GDM, two pregnancies resulted in LGA infants, one of whom experienced an episode of neonatal hypoglycemia.

Six women from the gray zone group had premature deliveries (less than 37 weeks' gestation), one of whom had twins. Two additional sets of twins were born. These were excluded from analysis because of inaccuracy in determining LGA. Thirteen infants from the remaining 35 (37%) born to the eligible participants were LGA. This is significantly greater than the 10% that would be expected from the distribution of birthweights from the Brenner curve ($P < .005$). Additional complications identified at the time of delivery in the gray zone group included one late intrauterine fetal death, one neonatal hypoglycemia, one mild shoulder dystocia, one cephalopelvic disproportion, and two fourth-degree lacerations.

The relationship between birthweight and 18 study variables was examined for the gray zone group patients. Table 1 contains the correlation coefficient and significance for each study variable in estimating birthweight. Examination of the OGTT resulted in no single value or combination of values achieving a correlation with birthweight percentile at the 95% confidence interval (CI) in the gray zone group. On the other hand, several SMBG values significantly correlated with birthweight.

Table 1. Pearson Correlation Coefficients for Gray Zone Group Variables on Birthweight (excluding gestational age <37 weeks)

Variable	r Value	P Value (2-tailed)
Pregravid weight	.406	.017
Gravida	.356	.039
Weight gain	.116	.541
Family history	.019	.918
Gestational age	.385	.024
Oral glucose tolerance test		
Fasting	.316	.074
1 hour	.314	.074
2 hour	.318	.071
3 hour	.048	.792
Self-monitored blood glucose test		
Average glucose	.409	.016
% above 120	.435	.010
Highest glucose	.161	.364
Lowest glucose	.262	.134
Average fasting	.552	.001

NOTE: Gray zone group is defined as women with an abnormal glucose challenge test but a normal oral glucose tolerance test.

The strongest correlate, fasting SMBG, was used to determine whether the SMBG association with infant birthweight was being confounded by other factors known to affect birthweight (pregravid weight, multiparity, or gestational age at delivery). A statistical model was used to determine the change in correlation that occurred when the data were adjusted for these factors (Table 2). Increased gravida and gestational age did not affect the relationship between birthweight and fasting SMBG values. Pregravid weight mildly confounded the relationship: the beta coefficient of the full model was 15% less than that of the reduced model.

When the gray zone group was segmented according to average SMBG, the average infant birthweight percent-

Table 2. Contribution of Potential Confounding Factors to Average Fasting Self-monitored Blood Glucose (SMBG) Correlation with Birthweight

Variables	Beta Coefficient	Standard Deviation
Average fasting SMBG	22.697	6.067
Average fasting SMBG + gravida	20.666 92.919	5.976 51.795
Average fasting SMBG + gestational age	20.502 124.327	5.876 60.138
Average fasting SMBG + pregravid weight	19.226 3.464	6.307 2.160

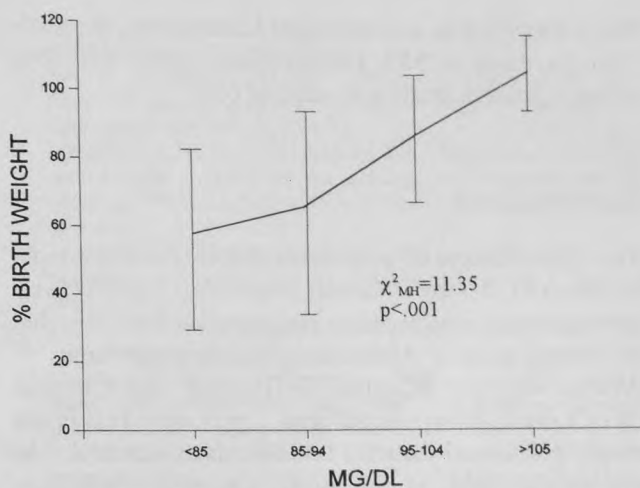


Figure. Average infant birthweight percentile vs maternal average fasting glucose at 28 weeks for groups A through D. Bars represent standard deviation; χ^2_{MH} denotes Mantel-Haenszel statistic.

tile in groups A through D rose significantly ($P<.001$), with average birthweight percentile increasing from 58% to 106% (Figure). The relative risk of producing an LGA infant was approximately 13 times greater in women with a fasting SMBG value >105 mg/dL (5.8 mmol/L) than that of women with a fasting SMBG value \leq 85 mg/dL (4.7 mmol/L) (Table 3). Four women in the gray zone group had one abnormal value on the OGTT. Three of these women were in group B, and one was in group D.

Finally, we determined the sensitivity and specificity of prediction of LGA infants by average fasting SMBG values obtained during the study. Only two infants of mothers diagnosed with GDM were LGA; however, since all mothers with GDM were aggressively treated, all five of these infants were considered at risk for LGA and were counted as LGA in this calculation. Eight of nine infants with an average fasting SMBG value >105 mg/dL (5.8 mmol/L) were large for gestational age (specificity, 95%; sensitivity, 44%; positive predictive value, 89%). Fifteen of 24 infants with an average fasting SMBG value >95 mg/dL (5.3 mmol/L) were large for gestational age.

Table 3. Relative Risk of Large-for-Gestational-Age Infants Among Women with High Screen and Normal Oral Glucose Tolerance Tests Grouped by Fasting Self-monitored Blood Glucose (SMBG) Levels

Group	Fasting SMBG (mg/dL)	No.	Birthweight Percentile	Standard Deviation	Relative Risk	P Value
A	\leq 85	6	57.8	26.4	1	—
B	86-94	13	65.7	29.4	3.7	NS
C	95-104	12	87	20.6	7.5	.05
D	\geq 105	4	105.5	10.1	13.6	.005

NOTE: Twin and premature infants are excluded from analysis.

Using this value as a predictor of LGA infants, the sensitivity increased to 83%, but specificity declined to 59%, giving a positive predictive value of 63%.

Conclusions

The identification of gestational diabetes and the rapid initiation of therapy to restore euglycemia can effectively prevent the adverse perinatal and maternal outcomes that are directly associated with underlying hyperglycemia.^{8,31} Women with an abnormal GCT result and a normal OGTT result, however, fall into a gray zone that is not clearly gestational diabetes but for which maternal risks may be increased. In this study, a significantly higher-than-expected proportion of LGA infants were born to women with an abnormal GCT and normal OGTT (the gray zone group). The women who gave birth to large infants could be distinguished from other women in the gray zone by SMBG testing at 28 weeks' gestation. Almost all the LGA infants were born to women who had persistent fasting hyperglycemia >95 mg/dL (5.3 mmol/L) over 7 days undetected by standard diagnostic procedures. Three women had average fasting SMBG values >105 mg/dL (5.8 mmol/L) but had four normal values on the OGTT. All these women gave birth to infants who ranked higher than the 90th percentile in weight. These women probably represent unrecognized cases of GDM.

It has been suggested that the values of the National Diabetes Data Group criteria for the diagnosis of GDM should be lowered.^{15,17} In this study, OGTT values below the standard criteria correlated poorly with birthweight. Lowering the OGTT criteria would be expected to identify more women at risk for giving birth to LGA infants (increased sensitivity), but at the expense of a higher false-identification rate (decreased specificity). Even assuming that all women in this study who were diagnosed with GDM would have given birth to LGA infants if the women had not been treated (surely an overestimation), current criteria would have anticipated only 28% of the infants who were born large for gestational age. When the criteria of the OGTT were lowered to 95, 180, 155, and 140 mg/dL (5.3, 10.0, 8.6, and 7.8 mmol/L), the sensitivity increased to 39%, resulting in the identification of four more women, two of whom gave birth to LGA infants. The poor predictive value of the OGTT was in contrast to the better predictive value of self-monitoring.

Significant correlation was found to exist between infant birthweight and several SMBG values. In addition to the average fasting blood glucose, the average overall blood glucose and the percentage of values >120 mg/dL (6.7 mmol/L) were also correlated with infant weight.

These values remained significant when corrected for the correlation also seen between prenatal maternal weight, multiparity, and variation of gestational age.

It is notable that no significant correlation was found between the fasting value of the OGTT and the birth-weight percentile. It appears that each patient continued her regular lifestyle and meal habits during the period of self-monitoring. Since patient behavior is altered during or preceding a physician visit, fasting blood glucose measurements performed at a single clinic visit might give misleading results. Patients have substantial daily variability in blood glucose. The validity of SMBG is significantly increased by having multiple measures during the week. The fasting blood glucose measurements made during the 3-hour OGTT correlated only moderately at $r=.58$ ($P<.001$) with the average fasting SMBG values. The average of seven tests was a better predictor of LGA and seemed to be more representative of the subject's overall carbohydrate metabolism.

Can we realistically expect SMBG testing from women with an abnormal GCT? Frequent SMBG testing requires training as well as a high degree of patient motivation. In general, pregnant women are highly motivated concerning the welfare of their infants, and training with new, simplified meters is fairly easy. Additionally, since fasting SMBG values were most highly correlated with LGA, it may not be necessary to monitor as frequently as was done in this study. It should be noted, however, that SMBG monitoring may not be available to all patients. Pregnancy is accompanied by a lowered hematocrit, which may prevent use of standard capillary monitors in some patients.

Since this study examined only women who already had an abnormal 1-hour GCT, all women in this study would have a higher likelihood of having gestational diabetes than would those with normal GCTs. As a result, the estimates of sensitivity, specificity, and predictive value would be expected to be overstated if applied to women without a positive screening test. In addition, it should be noted that several ($n=18$) variables were used in the examination of patients in this study. Because several variables were used, the associations found may appear more impressive than they may prove to be on confirmatory investigation, and clinical implementation should await further study.

SMBG testing appears to allow characterization of the risk of LGA infants among women in the gray zone. This may be accomplished by a short period of daily monitoring with a glucose reflectance meter. Women with an average fasting capillary glucose >95 mg/dL (5.3 mmol/L) seem to be at increased risk for LGA infants, and women with fasting capillary glucose levels >105 mg/dL (5.8 mmol/L) are certainly at risk and may rep-

resent cases of GDM missed by the OGTT. Further studies are needed to determine the cost of such follow-up, to determine the extent to which adverse outcomes other than LGA infants are identified by SMBG values, and to compare the SMBG level with modified criteria for the OGTT in determining risk of adverse neonatal outcome.

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PREDICTING LARGE-FOR-GESTATIONAL-AGE INFANTS

TITLE: Comparison of home glucose monitoring with the oral glucose tolerance test to detect gestational glucose intolerance

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Background. Gestational diabetes mellitus (GDM), which is glucose intolerance first recognized during pregnancy, occurs in 2% to 3% of pregnancies.¹ GDM has been associated with an increased risk of perinatal complications. Concern exists regarding similar risks for pregnant women with an abnormal 1-hour screening glucose challenge test (GCT) but a normal 3-hour oral glucose tolerance test (OGTT).

Clinical question. Can self-monitored blood glucose levels predict infant morbidity, as measured by the occurrence of large-for-gestational-age (LGA) infants, among women with an abnormal GCT but a normal OGTT?

Population studied. Pregnant women were recruited from family medicine and obstetric practices associated with a large metropolitan hospital center. Potential study subjects were identified after an abnormal GCT was obtained between the 24th and 29th gestational week. Exclusion criteria included a history of GDM or a hemoglobin less than 10.0 g/dL (100 g/L). No information was given regarding age, race, or ethnicity.

Study design and validity. Consenting women with an abnormal GCT measured capillary blood glucose with a home glucometer seven times daily for 1 week while remaining on an unrestricted diet. They then underwent a standard 3-hour OGTT. Women diagnosed with GDM were treated with either diet or insulin therapy, according to standard protocols. Following the OGTT, no further glucose testing was performed for patients who did not meet the standard diagnostic criteria for GDM.

Outcomes measured. Statistical correlations were made between self-monitored blood glucose levels and infant

birthweights. Large for gestational age was defined as above the 90th percentile birthweight. Regression analysis was performed to control for the following confounding variables: gestational age, multiparity, and maternal pregravid weight. Similar analysis was not reported for other potential confounders, including maternal age, weight gain, history of giving birth to an LGA infant, family history of diabetes, or previous stillbirth or congenital malformations.

Results. Of the 48 consenting women with an abnormal GCT who completed the study, five met the diagnostic criteria for having GDM. Infants born to two of these women were LGA. One of these infants experienced neonatal hypoglycemia. No information was provided regarding the severity of this event. Thirteen of the 43 women not meeting the diagnostic criteria for GDM gave birth to LGA infants. Complications of these deliveries included one intrauterine fetal demise, one neonatal hypoglycemia, one mild shoulder dystocia, one cephalopelvic disproportion, and two 4th-degree lacerations. The strongest predictor for increased birthweight among the women not diagnosed with GDM was the average fasting self-monitored blood glucose level. This relationship was confounded by pregravid weight but not by parity or gestational age. The risk for a woman giving birth to an LGA infant increased proportionally with an increase in her average fasting self-monitored blood glucose.

Recommendations for clinical practice. In this trial of pregnant women with an abnormal GCT, intensive home blood glucose monitoring was more effective than the standard OGTT in predicting which women will deliver LGA infants. The authors have taken advantage of sophisticated technology to record and analyze 49 blood glucose determinations for each patient.

The difficulties inherent in the intensive glucose monitoring may, however, have affected the results of the study. Only one half of the women who were eligible agreed to participate in this study. These women may have been more willing to undergo the frequent blood glucose determinations because they were at an increased risk of either glucose intolerance or giving birth to an LGA infant, or both, thus potentially increasing the statistical correlation between these two outcomes. Unlike the current study, previous reports show that any association between blood glucose levels and birthweight is lost when adjusted for maternal weight and age.¹

A second difficulty with applying the results of this study to clinical practice is that the expense and discomfort associated with the diagnostic procedure—almost 50

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capillary blood glucose determinations—may not be acceptable to many pregnant patients. In addition, the computer support to evaluate the results may not be available to most clinicians. It is unknown whether less extensive monitoring is as useful.

A third, broader concern is that no consensus exists regarding the need for universal screening of pregnant women for glucose intolerance.¹⁻⁴ This study suggests that 1 week of intense self-monitored blood glucose levels will identify more pregnant women who will deliver LGA infants. It does not help us determine whether this identification benefits either the mother or the infant. Pregnant women falsely identified with glucose intolerance may be considered at “high risk” and subject to extensive and expensive testing and interventions. Women at risk for delivering LGA infants with no evidence of glucose intolerance may be falsely reassured and not treated. Evidence from randomized controlled trials showing an overall benefit from screening for glucose intolerance in pregnancy is clearly needed.

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GUIDELINES FOR MANAGING ANKLE INJURIES: The Ottawa Ankle Rules

TITLE: Implementation of the Ottawa Ankle Rules
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Background. Although acute ankle injuries are one of the most common chief complaints of patients presenting for care in emergency departments (EDs), there are no well-validated guidelines to assist physicians in deciding when radiographic evaluation of the injured extremity is necessary. As a result, patients are usually referred for a radiograph to rule out treatable fracture. Previous studies by

this group developed a set of decision rules that were refined and validated through prospective evaluation.^{1,2}

Clinical question. Does the instruction of physicians in the implementation of the Ottawa ankle rules have the potential to change clinical behavior and result in a decrease in the number of patients referred for ankle and foot radiographic series?

Population studied. All adult patients presenting to either of two emergency departments with acute ankle pain resulting from blunt trauma, including twisting, falls, and direct blows, were enrolled in the study. A community hospital facility with no house staff, which served as the control facility, enrolled patients during two 5-month blocks (February through June) in 1991 and 1992. The intervention hospital was a teaching institution and enrolled patients during the same 5-month block in 1990 (before-intervention) and 1992 (after-intervention). Exclusion criteria included age less than 18 years, pregnancy, presence of isolated injuries of the skin, referrals from outside hospitals with radiographs, more than a 10-day interval since injury, and reassessment of an earlier injury.

Study design and validity. The study was a nonrandomized controlled trial comparing rates of ankle and foot radiographic series before and after intervention. Attending physicians and house staff at the intervention institution were instructed in the use of the ankle rules through lectures, handouts, pocket cards, and two posters mounted in the ED. Data forms were attached to patient charts reminding physicians to evaluate for specific areas of tenderness and the ability of the injured ankle to bear weight. The decision to refer for radiography was left to the treating physicians. All radiographs were evaluated by a radiologist and final reports were reviewed for all cases.

All patients in the after-intervention group were followed up by telephone to assess progress of healing, impact of the injury on lifestyle, and patient satisfaction with their emergency care. Patients who were not studied radiographically were contacted by phone a second time 10 days after their ED visit and asked to return for reevaluation if they remained symptomatic.

Inclusion of the data form with the patient's chart during the intervention period may have falsely elevated compliance with the rules. Use of radiography was monitored for an additional 12 months after the intervention period when data collection sheets were no longer used. The use of radiographic studies remained unchanged during this period.

The inclusion of house officers as physicians in the intervention hospital may have made this study particularly susceptible to the Hawthorne effect. House officers' behavior may have been significantly more likely to

change because they were being observed, and this behavioral change might not have continued after the period of observation. The lack of change in rates of radiography during the 12-month follow-up period suggests that observation alone did not account for the decline in radiography use.

Outcomes measured. The primary outcome measured for all patients was the proportion referred for ankle or foot radiographic series. Additional outcomes measured were the direct cost of medical care, time spent in the ED, persistence of symptoms, ability to walk and return to work, and subsequent physician visits and radiographs.

Results. A total of 2342 patients were seen during the before- and after-intervention periods. A relative reduction of 28% of patients referred for ankle radiographs was seen at the intervention hospital between the two study periods ($P<.001$). During the same interval, there was a 2% relative increase in the use of the same studies at the control hospital ($P=NS$). Twenty-four percent of patients at the intervention hospital had no radiographic study during the postintervention period, compared with 4% of patients during the preintervention period.

Patients discharged from the ED without radiographs spent significantly less time in the ED (80 minutes vs 116 minutes, $P<.001$). Ninety-five percent of the non-radiograph group reported being satisfied with their care, compared with 96% of patients who were x-rayed. The nonradiograph group had fewer follow-up visits (7% vs 20%, $P<.001$) and a significantly lower total cost of care (\$62 vs \$173, $P<.001$). None of the patients discharged from the ED without radiographs were subsequently found to have fractures.

Recommendations for clinical practice. This study's investigators have identified a group of easily applied decision rules that have demonstrated a 30% reduction in the number of radiographs ordered with no reduction in the ability to properly and promptly diagnose clinically significant fractures of the ankle or midfoot.

The authors offer several caveats regarding appropriate application of the rules. Because patients less than 18 years old were excluded from the study, the rules cannot be generalized to the pediatric population. Physicians

should use caution when applying the rules to patients who may be difficult to reliably evaluate, such as those who are intoxicated, have a head injury, have multiple painful injuries, or have diminished sensation related to neurological deficits. Patients discharged with radiographic evaluation should be instructed to return for further evaluation if pain and ability to bear weight have not improved in 5 to 7 days.

The investigators suggest a stepwise evaluation of the injured ankle, which begins with asking the patient about the circumstance of the injury and the patient's ability to bear weight within the first hour after injury. The examiner then proceeds with palpation of the ankle, concentrating on the posterior edge of both malleoli (from proximal to tip including the entire distal 6 cm of the fibula), the base of the fifth metatarsal, and the navicular. Concentrating the examination on the posterior edge of the malleoli avoids producing pain secondary only to ligamentous tenderness from the anterior edge. Patients with localized tenderness of the posterior malleoli or fibula are referred for ankle radiography. Patients with tenderness of the fifth metatarsal or navicular are referred for a foot radiographic series. Patients with no localized tenderness are then asked to walk two steps on each lower extremity without assistance. If they can accomplish this task, they are considered "able to bear weight," regardless of how much they limp. Patients who are unable to bear weight both immediately and in the ED but who have no localized tenderness are referred for both ankle and foot radiographic series. Patients with no localized tenderness and who retain their ability to bear weight are discharged without radiography.

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