Initial detection and management of gestational diabetes through primary health care services

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Abstract

Introduction: Timely detection of gestational diabetes and initiation of treatment is important for fetal development.

Objective: to evaluate the effect of the intervention on birth weight.

Method: an intervention study was carried out on a specific population of pregnant women, using a cluster randomized controlled trial design.

Results: A total of 215 (73.4%) women were included in the trial, 120 (77.4%) women at the intervention sites and 95 (68.8%) women at the control sites.

Conclusions: the prevalence of GDM in pregnant women is high and would require a detection and management approach that allows early interventions through a primary level of care.

Keywords: gestational diabetes mellitus, treatment, primary care Source: DeCS

Resumen

Introducción: La detección oportuna de la diabetes gestacional y el inicio del tratamiento son importantes para el desarrollo fetal.

Objetivo: evaluar el efecto de la intervención sobre el peso al nacer.

Método: se realizó un estudio de intervención sobre las gestantes una población específica, utilizando un diseño de ensayo controlado aleatorio por conglomerados.

Resultados: Se incluyeron en el ensayo un total de 215 (73,4%) mujeres, 120 (77,4%) mujeres en los sitios de intervención y 95 (68,8%) mujeres en las instalaciones de control.

Conclusiones: la prevalencia de DMG en mujeres embarazadas de es alta y requeriría de un enfoque de detección y manejo que permita intervenciones tempranas a través de un nivel primario de atención.

Palabras clave: diabetes mellitus gestacional, tratamiento, atención primaria Fuente: DeCS

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Introduction

Worldwide, every sixth woman is affected by hyperglycemia during pregnancy and low- and middle-income countries bear more than 90% of the global burden. Prevalence is highest in Southeast Asia (24.2%), and the Middle East and North Africa region already rank second, with prevalence rates reaching 21.8%, while in North America and Europe, prevalence ranges from 14.6% to 16.2%[1–8].

Timely detection of gestational diabetes (GDM) and initiation of treatment is important to interrupt the impact of maternal hyperglycemia on fetal development and to reduce the immediate and lifelong negative consequences of fetal hyperinsulinemia. In addition, screening during pregnancy provides an additional opportunity to prevent the development of future diabetes in mothers and their children, particularly in settings where prenatal care (PNC) often remains women's only contact with the health sector[9–17].

In Ambato, screening for GDM has not yet been widely adopted, and situation analysis in two districts revealed that laboratory testing, diagnosis and treatment of GDM was often associated with long delays resulting in undiagnosed cases or delayed diagnosis after the onset of a complication. To reduce delays and increase women's access to screening and treatment, the authors devised an intervention targeting frontline healthcare providers who offer PNC in primary care[12].

To test the hypothesis that initial screening and management of GDM at the primary level of care would reduce the incidence of macrosomia and result in lower birth weight of newborns, and to assess its potential for future scale-up, the study conceived this hybrid effectiveness and implementation research using a cluster randomized controlled trial design.

Method

An efficacy implementation study conducted a cluster randomized controlled trial in Ambato. Two districts were chosen for this implementation trial, the first being mainly urban and the second a predominantly rural district.

To select health facilities for the study, the participants extracted from the list of health centers provided by the district directorates all those performing at least 30 prenatal care consultations per month (new cases). They were then numbered continuously in each district, and a random number generator was used to select ten health centers per district, the first five serving as intervention centers and the remaining five as control facilities. At the selected facilities, all pregnant women of the age of consent attending primary care and newly diagnosed with GDM were eligible to participate in the trial. Pregnant women with known type 1 or 2 diabetes were excluded.

Prenatal care providers at the intervention centers (two providers per site) received a 1-day training on GDM screening and management. The training focused on implementing new GDM algorithms for screening and management based on the latest FIGO consensus recommendations[13], preparation and performance of a 75g oral glucose tolerance test (OGTT), and provision of nutrition and exercise counseling. All PNC services in the intervention sites received the necessary equipment for GDM screening, including glucometers, test strips, 75g OGTT solutions, brochures, and guidelines on nutrition for women affected by GDM. Applying the WHO criteria adopted by FIGO in its latest consensus recommendations for the diagnosis of GDM, women tested positive for GDM at the intervention sites either by a fasting blood glucose test before 24 weeks or by a 75g PTGO in the second trimester.

Cut-off values for the diagnosis of DM were 0.92-1.25g/l (5.1-6.9mmol/l) for fasting glucose, or 1.8g/l (10mmol/l) and more than one hour, or between 1.53 and 1.99 g/l (8.5-11.0mmol/l). Two hours after ingestion of 75g of glucose. If glucose values exceeded internationally recommended targets for fasting or postprandial values during follow-up, women were referred for consultation to the diabetes referral center. At the monitoring facilities, screening and initial management of GDM followed standard practice using national recommendations. According to the latest national guidelines, pregnant women with a fasting glucose value of 0.92g/l in the first trimester or at their first prenatal care visit should be diagnosed with GDM without a repeat diagnostic test.

The primary outcome measure was the difference in mean birth weight between the two arms. In contrast, secondary outcomes were maternal weight gain and glucose levels during follow-up, pregnancy-related outcomes, including type of delivery, the presence or absence of obstetric delivery (prolonged labor, pre/eclampsia), shoulder dystocia and other complications) of the newborn (respiratory distress, hypoglycemia and others) and prevalence of GDM in the health centers using as numerator the number of women with positive GDM and as denominator the number of pregnant women with GDM.

Information on maternal and neonatal outcomes (birth weight, complications during delivery, Apgar) was based on information provided by prenatal care nurses and was verified for 91%(n=191) of the women in the respective hospital records. Birth weight was estimated by two independent investigators using the 50th percentile of the weight change nomograms developed by Paul et al. [17]

The hypothesis is that the primary outcome, mean birth weight, differs in the two groups. Using previous studies on differences in birth weight of newborns born to GDM-affected mothers who received different treatment schemes, it was assumed that the mean birth weight of newborns in the intervention group would be 300 grams lower than the mean birth weight in the control group (3400 versus 3700 grams) with a standard deviation of 500 grams), due to earlier detection and treatment of GDM. For our sample size calculation, an intraclass correlation coefficient of 0.1 was applied and assumed 20 clusters of equal size. With a power of 80% and an alpha of 5%, this yielded a sample size of 75 GDM-affected women per treatment arm, or 7.5 per health center, which was rounded to 8.

Individual patient data including age, gestation, parity, presence of previous obstetric risk factors, last menstrual period, weight and height, GDM test results and date of diagnosis, treatment, referral and follow-up information (glucose test results, weight, treatment), as well as routine monthly facility data, were collected by the antenatal nurse at the health center and reported on preformatted data collection forms. Database and statistical processing of the data were performed and analyzed in SPSS 26 statistical software (SPSS Inc., Chicago, IL, USA), and descriptive statistics were used for the collection, presentation and interpretation of the results.

Results

Of 846 women screened at intervention sites, 155 (18.3%) were eligible to participate in the trial. At the control sites, 138 of 1034 (13.3%) women who presented with a glucose test result at prenatal care were eligible to participate in the study. Across all study sites, a total of 215 (73.4%) women were included in the trial, 120 (77.4%) women at intervention sites and 95 (68.8%) women at control facilities. However, five women did not return to their health centers after the first encounter (loss to follow-up).

More women in the control sites already had a history of gestational diabetes, a macrosomic or premature infant delivery, and a medical history of hypertension. In the intervention group, more women were primigravid compared with the control group. Although most women in both arms were from rural areas, their proportion was higher in the control group. Women in the intervention facilities had a higher educational level than women in the control health centers.

Table 1. Average differences in birth weight between the intervention and control groups.

	Intervention group grams (standard deviation)	Control group grams (standard deviation)	Intervention effect	Adjusted p-value
Birth weight	3286 (115)	3430 (87)	-147,07	0,080
By gestational age at diagnosis				
Less than 24 weeks	3275 (37)	3479 (34)	-227,96	0,192
24-28 weeks	3321 (48)	3457 (21)	-373	0,249
More than 28 weeks	3243 (30)	3359 (32)	-126,39	0,361
By % of fasting glucose within the norm to follow				
Less than 1/3	3678(9)	3525 (28)	32,45	0,907
1/3-2/3	3342 (19)	3421 (29)	-109,48	0,567
More than 2/3	3233 (87)	3350 (30)	-277,9	0,210
By treatment				
Diet only	3270	3427	-155,38	0,072
Insulin	3415	3500	-26,88	0,960

Discussion

The findings of this research show lower birth weights in women who were detected and managed in the intervention health centers, although the evidence was inconclusive. However, there was a higher incidence of macrosomia in the control arm, which may be considered a protective effect of the intervention. The impact of treatment on reducing macrosomia has been described in other studies. A high prevalence of gestational diabetes was found, although the prevalence in rural areas was lower compared to urban areas. However, the prevalence of GDM is much higher than the reported prevalence of 21.8%[13].

Two-thirds of patients evaluated at the intervention sites were diagnosed with GDM based on elevated fasting blood sugar, while one-third of women were diagnosed with tolerance testing. This has implications for planning, as most pregnant women attending prenatal care could already benefit from a fasting capillary PTG at their health center. In addition, this could reduce the costs of screening programs, as not all women would have to undergo a PTG [1,18–20].

Testing in intervention health centers allowed earlier diagnosis of GDM, and the mean difference between control and intervention settings in our study was 10 days. Rinkin et al. demonstrated that early pregnancy hyperglycemia affects neonatal outcomes[10,11]. While outcomes are related to the level of hyperglycemia, earlier detection and treatment reduce the time of fetal exposure to intrauterine infection. Our data demonstrated that early diagnosis and management of GDM causes the greatest differences in birth weight between the control and intervention arms, underscoring the difference in early active management of GDM. [20]

Women in the intervention sites had an average of seven follow-up visits to their health center, compared to women in the control sites. Frequent contacts could have contributed to the intervention effects of lower birth weights, lower maternal weight gain, and better glucose control in the intervention group(1). In addition, given that referral compliance was lower in women in the intervention facilities, this may indicate that women perceived a referral that added value to their health facility's services. Although the hypothesis of a birth weight difference of 300 grams between the control and intervention groups was too ambitious, the mean difference between 147 grams is in line with a treatment effect of 145 grams shown by Crother et al. in the ACHOIS trial(15).

Recommendations advise an average weekly weight gain during pregnancy of 400 grams for women with a normal pre-pregnancy weight and 300 grams for women who are overweight(5). The average weekly weight gain in both groups in our study population was below these recommended levels. Considering the growing obesity problem, where 48 % of women of reproductive age are overweight or obese, the weight recommendations should be reconsidered. Freig et al. critically pointed out the risks of the high current thresholds and suggested an average weekly weight gain of 170-285 grams throughout a pregnancy. Other studies suggest moderate weight loss in overweight and obese pregnant women to reduce adverse maternal and neonatal outcomes(4,5).

A higher proportion of women from intervention sites gave birth regionally or in hospitals compared to women from control sites, of whom almost 36% gave birth in health center maternity hospitals. Although the proportion of delivery complications reported in the control arm was twice as high as in the intervention arm, more neonatal complications occurred in newborns born to women in intervention facilities. The findings indicate the need to revise the referral system for GDM, which would also require a more tailored qualification for its management. While women with well-balanced GDM and no obstetric indications do not require delivery at higher levels of care, a referral could be limited to women on insulin schedules with unbalanced GDM and obstetric indications. This requires good integration of the three levels of care (21).

This study explores the prevalence of GDM and the effect of a GDM screening test and management intervention on maternal and neonatal outcomes at the first level of care. The advantage of this implementation study is its integration into the daily routine of prenatal health care providers, and as such, the findings relate to reality in a primary health care setting. In addition, despite the existing challenges for data collection and regular supervisory visits, sufficient information could be collected on a topic that has so far not received sufficient attention(7,22).

However, the study has some limitations, so the trial results should be interpreted cautiously. Women in the trial arms differed in some baseline characteristics, with a higher proportion of women with a history of GDM in the control arm. This could have been avoided by excluding these patients. While the study considered factors such as gestational age at inclusion, age and gestation at the analysis stage, there are other contextual factors such as family and spousal support, motivation to adhere to treatment and access issues that may have an on measured outcomes(4).

For the primary outcome, birth weight, one of the main limitations is the lack of comparable data on newborns born to mothers who were not affected by GDM at the respective facilities. Birth weight measurements were not directly observed and did not rely on reported data. Scales at the various facilities differed, and measurement errors were due to calibration problems or human errors that may have gone unnoticed(13–16). Pre-pregnancy weights of women are not available, and weighing was performed during the follow-up visit, although measurements were not always taken at each visit.

Future research should evaluate the individual components of the intervention and look at their impact separately on maternal and neonatal indicators. As the trial evaluated immediate health outcomes, future cohort studies could examine the longer-term recurrence of GDM and the incidence of type 2 DM in these women. In addition, there is a need to examine the outcomes of newborns of mothers in the two groups in terms of the impact of the intervention on their metabolic status.

Conclusions

The detection of GDM and its management at the primary level of care may have had a positive impact on birth weight and maternal weight gain, but the results are inconclusive. The results of this study indicate that the prevalence of GDM in pregnant women is high and would require a screening and management approach that allows early interventions through the primary level of care.

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