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Onset of T2DM after Gestational Diabetes: What the prevention paradox tells us about risk

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Abstract

This study investigates the effect of severity of gestational diabetes (GDM) on likelihood of post-delivery glucose testing and early onset Type 2 diabetes (T2DM). We asked if clinical focus on relative risk (RR), i.e. greater probability of T2DM onset in a higher-severity group, contributes to missed opportunities for prevention among women with lower-severity GDM. A sample of 12,622 continuously-insured women with GDM (2006-2015) was drawn from a large national dataset (OptumLabs® Data Warehouse) and followed for 3-years post-delivery. Higher-severity GDM was defined as addition of hypoglycemic therapy to standard of care for GDM. We found that women with higher-severity (n=2,627) were twice as likely as lower-severity women (n=9,995) to obtain glucose testing post-delivery. Moreover, 357 (13.6%) of the higher-severity women developed T2DM by year-3 vs. 600 (6.0%) lower-severity women. In an analysis of the population attributable fraction (PAF), defined as the contribution of excess risk to population prevalence, lower-severity women contributed more cases to diabetes rates than higher-risk women (PAF 79% vs. 21%), despite an increased RR in the higher-severity group (13.6% vs. 6.0%, RR 2.26, 95%CI 2.00, 2.56). Projecting out to the 327,950 U.S. deliveries in 2014, we estimate that 9,277 higher-severity women (13.6%) and 15,584 lower-severity women (6.0%), will have developed T2DM by 2018. These data demonstrate that lower-severity GDM contributes substantially to the diabetes epidemic. Greater awareness of clinical and cost implications of gaps in follow-up for lower-severity GDM may strengthen the likelihood of post-delivery testing and primary care referral, and thus reinforce the path to prevention.

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CONFLICT OF INTEREST

Authors report no conflicts of interest.

Keywords

gestational diabetes; prevention paradox; T2 diabetes onset

BACKGROUND

Gestational diabetes (GDM) offers an instructive window on women's health over the life course and their future risk of chronic illness, illuminating a 60% chance of developing type 2 diabetes (T2DM) within the following decade.¹ Nevertheless most women with GDM are not tested after delivery^{2, 3} and do not transition to primary care in time to prevent, delay, or treat T2DM.⁴⁻⁶ Both the American Diabetes Association and the American Congress of Obstetricians and Gynecologists have issued clear, population focused guidelines requiring postpartum glucose monitoring and referral to primary care for preventive measures.^{7,8} However these guidelines have not been widely adopted in clinical practice despite the national concern about the increasing prevalence and cost of diabetes,⁹ and availability of evidence-based measures for T2DM prevention.¹⁰ This gap in the bridge from obstetric complication to comprehensive prevention may be an example of a missed opportunity –a prevention paradox in action.

The prevention paradox argues that determinants of disease and prevention strategies differ according to whether the focus is on sick individuals rather than sick populations. If we focus narrowly on women with the most severe presentation (sick individuals), we will correctly identify the subset with the highest probability of developing disease later in life, but we are less likely to continue to monitor those who have a less severe presentation, and will thus miss those who make up the largest proportion of patients who go on to develop chronic illness.⁹ The number of lower-risk women with less severe GDM who are not followed, perhaps because they themselves and their clinicians think they are less likely to develop disease, as documented in interviews with both patients and physicians⁶ may contribute significantly to the diabetes epidemic in the U.S.⁴

The potential effects of this prevention paradox have been worked out for the link from obesity to diabetes,¹⁰ but not yet for the link between GDM and T2DM. For example, people who are overweight are estimated to contribute 712,000 new cases of diabetes, compared to those who are obese (456,000 cases) or very obese (247,000 cases), even though the risk of diabetes for the very obese is three times the risk for those who are overweight. In the case of GDM, testing after delivery is known to be a hard sell for women with a new baby and competing responsibilities.

Risk can be calculated in two very different ways. Clinical risk is usually assessed as relative risk (RR), the ratio of the probability of an event occurring in an exposed group (higher severity women) compared to the probability of the event occurring in a comparison group (lower-severity women). Population risk is usually analyzed by determining the population attributable fraction (PAF), the proportional reduction in population disease that would occur if exposure to a risk factor among higher-severity women were reduced to an alternative ideal exposure.

Clinical decision-making driven by relative risk rather than by attributable fraction may also add to the diabetes prevalence, but this possibility has not yet been investigated among women with GDM.

OBJECTIVE

We investigated the influence of GDM severity on outcomes of postpartum glucose testing and glucose testing of any type by one year and three years, to determine the risk of early T2DM onset and the volume of early T2DM cases by severity of GDM presentation, and estimate what results of different methods of risk calculation (RR vs. PAF) might suggest for the contribution of GDM to U.S. diabetes prevalence.

METHODS

Sample

This analysis is a secondary inquiry from a larger investigation of predictors of follow-up after GDM,¹¹ using national data from OptumLabs® Data Warehouse (OLDW), a comprehensive, longitudinal, de-identified datasytem derived from insurance claims, electronic medical record data assigned both encounter and enrollment codes, survey results and enrollment assessments. This multi-source national data set is available as a package to academic researchers through academic partnerships. Coding allows all data points to be assigned to unique individuals across episodes of care. Claims data are available for all of these episodes; electronic medical information is much less complete. The details of sample selection are available from the original publication in print and in online supplementary material.

First we identified all unique women with delivery of a livebirth between 1/31/06–9/30/12, as represented by single or multiple claims for pregnancy, delivery and/or postpartum care, using the International Classification of Diseases, 9th revision (ICD-9). We then characterized the first GDM-affected livebirth in the system (ICD-9 GDM code 648.8x), excluding women who had an ICD-9 code or history of standard hypoglycemic therapy suggestive of pre-existing T2DM, either prior to the 28th week of the index pregnancy or immediately postpartum. We also excluded women who did not have continuous insurance coverage from 1-year pre-pregnancy to 3-years post-delivery, because our unit of analysis was adequacy of follow-up after GDM in women who had limited financial barriers to seeking care.

We also excluded women who lacked comprehensive validated demographic data or information about service providers and delivery institutions, because demographic and institutional factors have been shown to affect adequacy of follow-up care. These exclusions were large (see Figure 1), but necessary to achieve analytic goals. We assessed generalizability of the reduced sample through comparisons of excluded with included women, and proceeded with analyses only after comparability was determined. Included and excluded samples were similar on all key variables listed in Table 1. Findings from these comparability analyses are summarized in the Results section, and available in online supplementary material associated with the original publication.¹¹

Protection of human subjects

This study was determined to be “not human research” by the Boston University Institutional Review Board because extensive, regularly monitored de-identification processes are in place.

Variable construction

We defined a GDM diagnosis conservatively as either one inpatient or two outpatient ICD-9 codes of 648.8, excluding cases with evidence for pre-existing T2DM as described above. Outcome variables include: glucose testing within the recommended period of 56-84 days post-delivery by fasting blood glucose, oral glucose tolerance test, or hemoglobin A1C within six months of delivery, and any of these tests at one year and three years post-delivery. These time periods were additive—e.g. any postpartum test counted as testing at one year and also at three years. Women who had any second pregnancy within the three year follow-up period were excluded, because their opportunity for follow-up was limited by that pregnancy, and glucose testing during a second pregnancy would confound the outcome of follow-up testing. Diagnosis of T2DM in the period from 12 weeks postpartum to three years after an index GDM delivery was based on the same combination of claims history and medication records that was used to identify pre-existing T2DM.

Analytic Measures

We conducted descriptive analyses to determine the prevalence of 1) higher severity (defined as use of hypoglycemic medication for GDM) vs. lower severity (standard of care, usually consisting of diet and counseling only during a GDM pregnancy), 2) rates of glucose testing during the postpartum period and by one and three years following delivery, 3) the proportion in each category with onset of T2DM within three years after delivery, 4) the relative risk (RR) and 95%CI for T2DM onset by level of severity, and 5) analysis of the population attributable fraction (PAF) to determine the comparative contributions of lower and higher severity groups to the prevalence of T2DM. SAS 9.4 (Cary, NC) was used for these analyses. PAFs and their 95% confidence intervals were calculated using proc stdrate in SAS. Calculation of national estimates of early T2DM onset were based on a GDM rate of 9.2%.¹²

RESULTS

Our sampling method yielded an analytic sample of 12, 622 continuously insured women who had no prior evidence of T2DM on claims history or record of medications prescribed (see Figure 1: Strobe Diagram). The GDM rate of 8.2% that we found in our sample is roughly comparable to the national rate of 9.2% estimated by DeSisto et al. at the CDC, based on 2014 prevalence.¹²

Continuity of enrollment

Women with continuity of enrollment (n=280,933) were generally similar to those excluded for enrollment gaps (1,004,376), although statistical differences were present (p<.001), magnified due to large sample size. For example, those with continuous coverage were on average 31.6 years old (s.d. 5.3) compared to 30.0 (s.d. 5.7) for non-continuous enrollees.

Their race was equally likely to be listed as White (50%) with some small differences (<2%) in the racial distributions between Blacks and Asians. Continuously enrolled women were more likely to reside in the Northwest or Midwest and were slightly less likely to be covered under restrictive health insurance plans.

Known vs. 'unknown' demographic characteristics

Women with validated demographics were similar to the original group of 23,181 GDM women with continuous coverage from which they were drawn. Those who met inclusion criteria for a complete set of data for age, race/ethnicity, education, net worth of income, provider and hospital characteristics, were similar to those who lacked survey data in age and race, co-existing chronic illness, prevention-related behaviors prior to pregnancy, almost all pregnancy related conditions and all outcomes of interest, but differed slightly in the distribution of type of insurance coverage and geographic location. In the primary investigation, these differences had no impact on outcomes.

Differences based on severity of GDM

In Table 1, women with higher severity are compared with lower severity women on co-morbidities, pregnancy and delivery outcomes, demographic characteristics, provider type and health care systems attributes. Higher-severity women in this sample were more likely to have a variety of expected co-existing conditions and pregnancy and delivery complications, except for preterm birth, which did not differ between groups. Higher severity women were also more likely to visit an endocrinologist and/or nutritionist during the GDM-affected pregnancy. They were slightly older, and the proportion with a high school degree or less was a few percentage points higher, but they resembled lower-severity women in racial distribution and four out of five categories of income distribution. They were also similar in the type of provider present at delivery, and in the size of the hospitals where they delivered. The distribution of type of delivery setting was significantly different, but only by 1.5 percentage points.

Analytic outcomes are presented in Table 2. Using prescription of hypoglycemic medication vs. standard of care for a GDM-affected pregnancy as an indicator of GDM severity, women with more severe GDM (n=2,627) are much more likely than those with less severe GDM (n=9,995) to obtain: 1) Oral glucose tolerance test (OGTT) in the recommended postpartum interval (5.5%, 3.0%, RR 1.83, 95%CI 1.87 (1.50, 2.22); 2) glucose testing by 1-year post-delivery (32.9% vs.18.8%, RR 1.75, 95%CI 1.63, 1.87); 3) glucose testing by 3-years post-delivery (61.6% vs. 48.2%, RR 4.34, 95%CI 4.10, 4.60).

A larger proportion of women in the higher severity group were diagnosed with T2DM in the three years after delivery (13.6% vs. 6.0% of the women in the lower severity category, RR 2.26, 95%CI 2.00, 2.56). However the number of higher severity women who developed T2DM by 3 years post-delivery (n=357) is much smaller than the number of lower severity women who developed early onset T2DM (n=600).

For the population of women with gestational diabetes (all women in the sample), we calculated the attributable fraction due to severity of gestational diabetes on early onset T2DM. Higher risk severity had an attributable fraction of 21% (95% CI 17%, 24%), while

lower severity had an attributable fraction of 79% to T2DM onset during the three years of post-delivery follow-up.

Projection of results to U.S. delivery statistics

In terms of sheer numbers, if we use the 2014 figure of 3,999,386 U.S. births as an estimate, 327,950 deliveries may have been affected by GDM.¹² Based on our findings for the distribution of risk, we estimate that 68,214 of them (20.8%) would have required hypoglycemic medication and could thus be considered to be more severe and at higher risk, compared to 259,736 women at more moderate risk (79.2%). Projecting out to the larger population from rates of T2DM onset established in this study, 9,277 women in the higher-risk category (13.6%) and 15,584 lower-risk women (6.0%), would develop T2DM in the next three years. Women in the lower-risk category are less likely to be monitored after delivery, according to our findings, but the actual number of lower-risk women with early onset of T2DM is greater than the number of higher-risk women with early onset because of the sheer volume of lower-risk cases.

DISCUSSION

The total burden of diabetes compels us to reconsider the importance of follow-up for the group of women with less severe GDM from which the majority of post-GDM T2DM cases arise. Identification of higher-risk individuals is important, but our finding of almost four times the number of lower-risk women with early onset T2DM suggests that it is necessary to widen the net for prevention after GDM if we are going to have a real effect on the U.S. diabetes epidemic. Accountable care strategies also demand that we go beyond individual high risk and associated clinical outcomes to consider overall population outcomes and the opportunity costs of gaps in prevention.¹³

The women in this sample were diverse in socioeconomic circumstances, but had a relatively high mean for educational and economic attainment, and may thus represent a health literacy status that is above the national average. Higher educational attainment and continuous insurance coverage do mirror the best potential for being able to engage in preventive activities after a GDM delivery, but the rates of glucose testing and contact with primary care were quite low, even among this sample. A population-based approach of universal screening and referral thus makes sense for these women, but even more so for the women who were not represented in our sample, those who lack comprehensive insurance and socio-economic advantage associated with comprehensive insurance coverage, and thus might be presumed to have reduced access to followup care.

Qualitative studies of physician and patient barriers to follow-up suggest many challenges.⁶ Clinicians experience systems barriers in setting up an OGTT in the postpartum period, and can be more focused on immediate concerns than on prevention of chronic illness later in life.⁵ In a previous qualitative study, Bernstein et al. found that patients want to toss the experience of GDM behind them and focus on life with a new baby, and may not return for follow-up unless they understand the importance of prevention.⁶ Solving this problem requires awareness of the clinical and cost implications of not following large numbers of lower-severity women who will develop early-onset T2DM. Innovative strategies such as

home glucose testing and patient navigation need to be tested for effectiveness and cost implications. Referral from obstetrics to primary care as part of the ‘meaningful discharge’ at delivery may increase the rate of contact for monitoring. Preventive measures may add cost in the initial stages, but reduce the burden of chronic illness and its associated costs in the longer term. Addressing this prevention paradox could enhance women’s health across the life course, and reduce the contribution of GDM to the U.S. diabetes epidemic.

This study has several limitations. First, the sample was intentionally restricted to continuously insured women. This exclusion gave us power to evaluate key predictors of follow-up holding major financial barriers constant. However the loss of approximately 80,000 women with GDM (8.2% of the 1,004,376 who were excluded for episodic insurance) may have limited generalizability, but many of the excluded women would have had only a few months of coverage because of post-pregnancy changes in enrollment, and in this sense they would have differed from the homogenous group we chose to study. In this trade-off, the study gained internal validity at the cost of external validity. While this sample does not purport to be representative of all US women, the prevalence of GDM among the women we studied was comparable to the national average, and the clinical profile shown in Table 1 does not differ markedly from national reports in variables related to GDM prevalence and pregnancy and delivery complications.¹⁴

A second limitation was the lack of information about two important variables: parity and hyperlipidemia prior to pregnancy. This factor is important because both GDM and T2DM incidence vary with parity and obesity, and differences in these two attributes could act as confounders. This type of information is usually available only in smaller datasets from an individual institution, garnered from medical records. However, we were able to measure excess weight gain in pregnancy, and while we did not have parity, we did have age as a rough indicator that is separate from but often travels with parity. We were also able to compare lower and higher risk groups on demographic characteristics, pre-existing conditions and pregnancy and delivery complications; the differences that we found between these groups were representative of known conditions that accompany greater GDM severity.

Finally, this set of findings comes from a secondary analysis, and as such is limited by construction of the sample to meet the primary aims of the original study. Information derived from secondary analysis generally requires a follow-on study to assess generalizability.

CONCLUSION

Women with substantial but lower risk early T2DM onset after a delivery complicated by GDM represent the bulk of the contribution of GDM to the T2DM epidemic. Severity-based follow-up practices for glucose testing and referral to primary care address highest risk, but appear to overlook the largest number of women who will develop diabetes in the years immediately following delivery. Greater adherence to the population-based approach for screening and continued monitoring that is recommended by ADA and ACOG guidelines will reduce these lost opportunities for prevention.

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HIGHLIGHTS

- Women with gestational diabetes (GDM) are at high risk for Type 2 diabetes (T2DM).
- Follow-up based solely on severity misses the majority of early onset T2DM.
- Follow-up guidelines apply to all GDM, not just greatest GDM severity.
- Effective prevention includes diet, exercise, and medications.
- Adherence to guidelines would help avert lost opportunities for prevention.

Figure 1.
Strobe diagram

Table 1

Demographic, health and systems characteristics of insured women with GDM

VARIABLE	TOTAL N=12,622 (%)	Higher severity N=2,627 (%)	Lower severity N=9,995 (%)
Demographics			
* Age (mean, s.d.)	33.3 (4.8)	33.8 (4.7)	33.2 (4.9)
Race/ethnicity:			
Asian	12.3	12.8	12.2
African American	7.4	7.7	7.3
Hispanic	12.9	13.4	12.8
White	67.4	66.2	67.7
* Education:	33.0	35.5	32.3%
12 th grade			
* Net worth of assets: (missing=333)			
<\$25k	29.3	30.2	29.1
25K-\$149k	34.3	34.0	34.4
\$150k-\$249k	14.6	13.2	14.9
\$250k-\$499k	15.2	15.9	15.1
\$500+	6.5	6.6	6.5
Geographic region: (missing =3)			
New England	3.3	3.5	3.3
Mid Atlantic	7.5	6.5	7.7
East North Central	14.1	13.6	14.2
West North Central	13.1	14.1	12.8
South Atlantic	25.9	37.2	25.6
East South Central	2.9	3.3	2.7
West South Central	15.4	12.9	16.0
Mountain	7.9	7.9	7.9
Pacific	10.0	11.0	9.7
Co-existing conditions			
* Charlson Comorbidity Index >0	14.5	16.7	13.9
* Any substance use disorder pre-delivery	1.0	1.9	0.8
* Any non-SUD mental health disorder	9.3	11.0	8.9

VARIABLE	TOTAL N=12,622 (%)	Higher severity N=2,627 (%)	Lower severity N=9,995 (%)
* Polycystic ovary syndrome	6.6	8.5	6.1
Pregnancy and delivery conditions			
Preterm birth	9.4	10.0	9.2
* Cesarean delivery	13.2	15.2	12.7
* Gestational hypertension	8.2	10.2	7.7
* Pre- or eclampsia	7.4	8.9	7.0
* Excess gestational weight gain	2.7	3.8	2.4
* Obstructed labor	3.9	4.8	3.6
Postpartum depression (incident case)	1.2	1.4	1.1
Provider characteristics			
Obstetrician	93.7	94.1	93.6
Nurse-midwife family practitioner, other	6.3	5.9	6.4
* Endocrinology visit in pregnancy	19.9	29.4	17.3
* Nutritionist visit in pregnancy	3.3	4.4	3.1
Health care system characteristics			
* Type:			
Government	6.6	7.7	6.3
Not for profit, Church operated	14.0	13.1	14.3
Not for profit, Secular	63.4	63.7	63.4
For profit, Partnership or corporation	15.9	15.5	16.1
Hospital size			
1-199 beds	20.7	21.5	20.5
200-399 beds	36.5	36.0	36.7
400+beds	42.7	42.5	42.8

* indicates statistically significant difference between lower and higher severity groups

Table 2

Post-delivery surveillance rates and T2DM outcomes categorized by GDM severity, 2006-2015 (n=12,622): A secondary analysis of data from OptumLabs Data Warehouse (OLDW)

OUTCOME PARAMETER	HIGHER SEVERITY* (n=2,627) n %	LOWER SEVERITY (n=9,995) n %	RR	95%CI
Oral Glucose Tolerance Test 56-84 days post-delivery	144 (5.5)	300 (3.0)	1.83	1.50, 2.22
Glucose testing by 1-year post-delivery	864 (32.9)	1880 (18.8)	1.75	1.63, 1.87
Glucose testing by 3-years post-delivery	1618 (61.6)	1418 (48.2)	4.34	4.10, 4.60
Diagnosis of Type 2 Diabetes within 3 years after delivery	357 (13.6)	600 (6.0)	2.26	2.00, 2.56

* using prescription of hypoglycemic medication vs. the standard of diet and exercise counseling during pregnancy as an indicator of increased GDM severity