

Association between maternal dysglycaemia and adverse perinatal outcomes: A retrospective cohort study using a Japanese mother–infant-linked claims database

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Abstract: Claims-based perinatal studies in Japan are limited because normal pregnancies are not covered by health insurance. This study aimed to examine the association between maternal dysglycaemia and perinatal outcomes using a mother–infant-linked claims database. We conducted a retrospective cohort study using the JMDC Claims Database from April 2012 to March 2023. Singleton mother–infant pairs were presumed by family ID and categorised into six mutually exclusive claims-based categories: anti-diabetic prescriptions both before and during pregnancy with (Category 1) or without (Category 2) a pre-pregnancy type 1 diabetes code, prescriptions in prenatal period only (Category 3), prescriptions before pregnancy only (Category 4), a gestational diabetes (GDM) management-fee claim without anti-diabetic prescriptions (Category 5) and no identified claims-based indicator of dysglycaemia (Category 6). Outcomes included caesarean section, macrosomia, preterm birth, neonatal asphyxia, neonatal intensive care unit (NICU) admission and congenital malformations of the circulatory system. Among 115,113 presumed mother–infant pairs, 21.5% of mothers underwent caesarean section, with higher proportions in Categories 1 and 2 (40.6% and 48.3%). Highest point estimates were observed in Category 1 for most outcomes. Category 2 was associated with increased risks of caesarean section (adjusted risk ratio 2.04, 95% confidence interval 1.77–2.35), preterm birth (3.69, 2.57–5.28) and NICU admission (3.88, 3.02–4.99). Category 5 was positively associated with macrosomia (2.43, 1.64–3.62). Claims-based indicators of maternal dysglycaemia were associated with adverse perinatal outcomes. These findings suggest potential utility of mother–infant-linked claims data for Japanese perinatal monitoring, subject to further validation.

Keywords: gestational diabetes mellitus, diabetes in pregnancy, caesarean section, macrosomia, administrative health data

1. Introduction

Dysglycaemia during pregnancy, including pre-existing diabetes and gestational diabetes (GDM), is a well-established risk factor for adverse perinatal outcomes, including preterm birth, caesarean section and neonatal complications such as macrosomia (1,2). Globally, the prevalence of GDM has risen in parallel with increasing

maternal age and obesity and introduction of the International Association of Diabetes and Pregnancy Study Groups criteria has further increased the number of women diagnosed (3-5). Large studies in Asian countries have reported that even mild glucose intolerance is associated with adverse birth outcomes and nationwide claims-based studies in Korea have demonstrated recent increases in both GDM prevalence and caesarean section

rates (6,7). Collectively, these findings underscore importance of contemporary management of maternal dysglycaemia in the perinatal period in the context of changing epidemiology.

In Japan, as in many other countries, frequency of GDM has increased alongside advanced maternal age and lifestyle changes (8). Following the 2010 revision of diagnostic criteria, prevalence rose from approximately 2–3% to 7–13% and GDM is no longer a rare complication (9,10). Cohort studies from clinical institutions and government-led initiatives in Japan have provided important evidence on association between maternal dysglycaemia and perinatal outcomes (11,12); however, these studies are limited by potential selection bias and restricted generalisability (13). In contrast, health insurance claims databases provide large-scale, population-based data with high coverage, enabling epidemiological analyses at the population level. Studies from neighbouring countries such as Taiwan and Korea have demonstrated utility of such health insurance data to evaluate associations between GDM and perinatal outcomes, providing real-world evidence (6,7).

In Japan, normal pregnancy and delivery are not covered by public health insurance and are therefore not fully captured in claims data, making claims-based studies of maternal dysglycaemia and perinatal outcomes challenging (14). Nevertheless, a large mother–infant-linked claims database enables investigation of maternal and infant outcomes simultaneously using routinely collected healthcare data. Claims data can capture medically attended pregnancy complications, delivery-related interventions, and neonatal outcomes, and mother–infant linkage enables analysis of linked mother–infant pairs. Such approaches may complement existing cohort studies by providing large-scale real-world evidence to inform clinical practice and health policy in Japan.

Therefore, we applied a claims-based approach to perinatal epidemiology using a large Japanese mother–infant-linked claims database to examine association between maternal dysglycaemia and perinatal outcomes in both mothers and infants.

2. Materials and Methods

2.1. Study design and data source

This retrospective cohort study used the JMDC Claims Database (JMDC Inc., Tokyo, Japan) from April 2012 to March 2023. The JMDC Claims Database is a commercial database comprising health insurance data for approximately 17 million individuals. It primarily includes data from employment-based health insurance societies covering employees of large companies and their dependents. The database therefore mainly represents a working-age population and their families, with beneficiaries aged 0–74 years.

The JMDC Claims Database contains beneficiary information and health insurance claims. Claims data are categorised into diagnoses, procedures and prescriptions. Diagnoses are coded using the International Classification of Diseases, 10th Revision (ICD-10); drugs are coded using World Health Organization Anatomical Therapeutic Chemical classification; and procedures are coded using reimbursement points codes established by the Ministry of Health, Labour and Welfare. Detailed codes used to define study variables are listed in Supplementary Table S1 (<https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>).

In the JMDC Claims Database, beneficiaries covered under the same insurance contract share a family ID, which serves as a proxy for household information and enables identification of family relationships among insured individuals and their dependents. In this study, we used this family ID to identify presumed mother–infant pairs. A shared family ID indicates coverage under the same insurance contract and does not by itself confirm a mother–infant relationship; the linkage is therefore described as a presumed mother–infant linkage throughout.

This study was approved by the Ethics Committee of University of Tsukuba (approval number 1882-2). The study used de-identified data from the JMDC Claims Database and the investigators had no access to personal identifiers or contact information. Therefore, informed consent and opt-out procedures were not applicable. The study conformed to the provisions of the Declaration of Helsinki (as revised in 2013).

2.2. Study population

We identified presumed mother–infant pairs using the family identification number in the JMDC Claims Database. For each mother, we selected the first delivery during the study period and excluded pairs involving multiple births (Figure 1).

2.2.1. Inclusion criteria

Infants were defined as individuals whose insurance relationship was recorded as "child" and whose month of birth matched their month of insurance enrolment. Mothers were defined as female beneficiaries whose insurance relationship was recorded as "insured" or "dependent".

2.2.2. Exclusion criteria

Women whose insurance enrolment had ended before April 2012 were excluded. Infants born before April 2012 were excluded. When more than one adult woman shared the same family identification number, all such women were excluded because the mother could not be uniquely identified. Pairs in which mother and infant

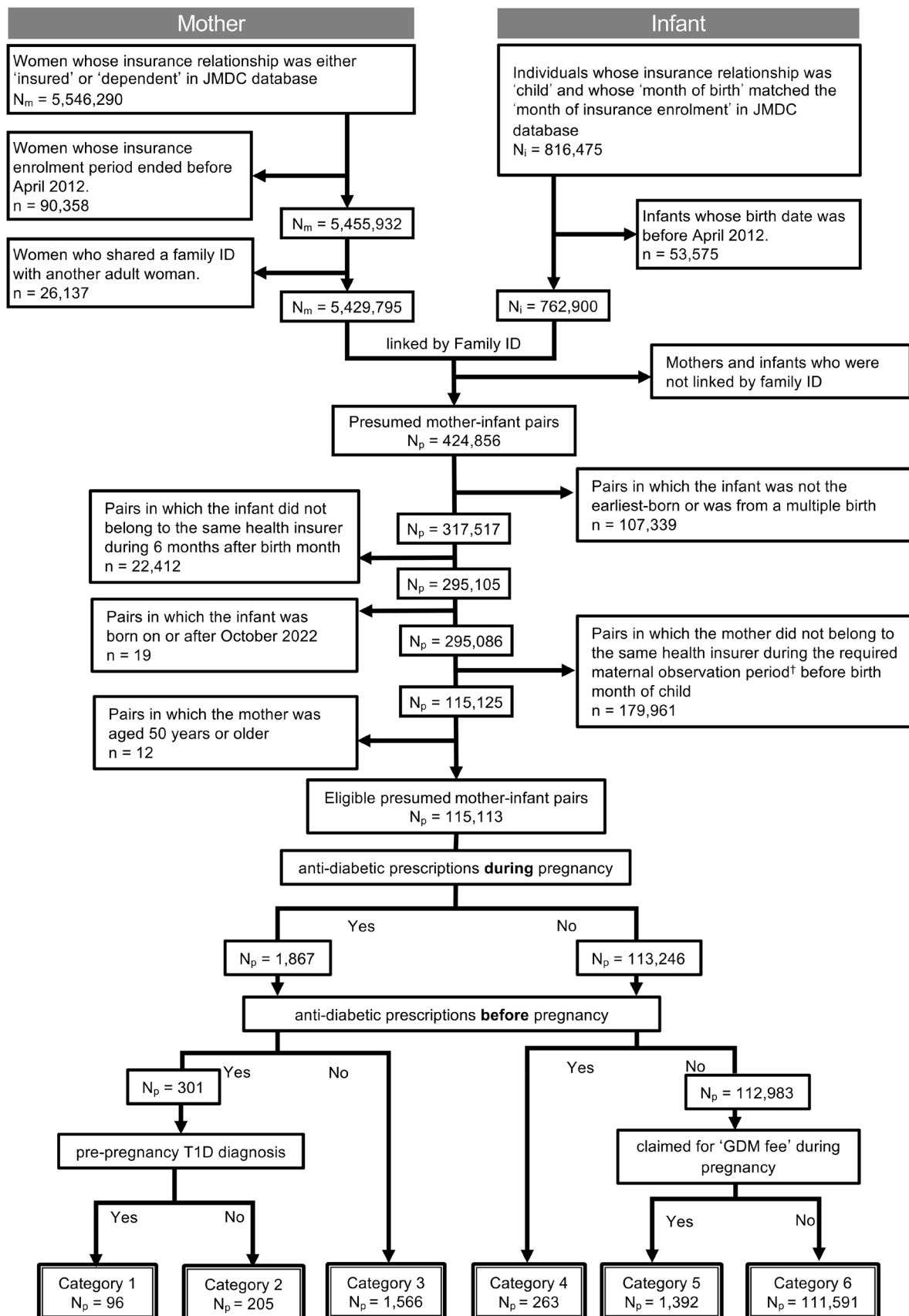


Figure 1. Flowchart of study population selection. The figure shows selection of eligible presumed mother–infant pairs from the JMDC Claims Database. Mothers and infants were linked using family IDs. Key exclusion criteria included discontinuous maternal insurance enrolment, infant disenrolment within 6 months after birth, non-earliest-born or multiple births, maternal age ≥ 50 years, and infant birth on or after October 2022. †: Observation period was defined as the operational pregnancy period (months -9 through 0 , with the infant's birth month defined as month 0) plus the preceding 6 months. For pregnancies ending in preterm birth, operational pregnancy period comprised months -8 through 0 . *Abbreviations:* GDM, gestational diabetes; N_i, number of infants; N_m, number of mothers; N_p, number of mother–infant pairs; T1D, type 1 diabetes.

could not be matched by family ID were excluded.

When a mother had more than one delivery recorded in the database, only the first was included. Multiple births were excluded, such that one singleton infant was analysed per mother. Infants who disenrolled from insurance within 6 months after birth were also excluded. To ensure that all included infants had the opportunity for complete 6-month follow-up, infants born on or after October 2022 (6 months prior to the end of the database period in March 2023) were excluded.

Mothers were excluded if they had any gap in insurance enrolment from 6 months before start of the operational pregnancy period through the infant's birth month (months -15 through 0, or -14 through 0 for preterm birth). Pairs in which the woman was aged 50 years or older were excluded because a mother–infant relationship is implausible at the upper extreme.

2.3. Pregnancy period

The infant's birth month was defined as month 0. The operational pregnancy period comprised the 10 calendar months from month -9 through the infant's birth. However, if the mother or infant met the claims-based definition of preterm birth shown in Supplementary Table S1 (<https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>) (maternal ICD-10 O60.1/O60.3 or infant ICD-10 P07.2/P07.3), the operational pregnancy period comprised the 9 calendar months from month -8 through infant's birth. For classification of medication use, prescriptions recorded in months -7 through 0 were classified as occurring "during pregnancy", whereas those recorded in months -15 through -8 were classified as occurring "before pregnancy". For pregnancies ending in preterm birth, corresponding windows were months -6 through 0 and -14 through -7, respectively. This cutoff was selected to reflect timing of pregnancy recognition in clinical practice.

2.4. Measurements

All variables were extracted from the JMDC Claims Database using diagnostic, procedure and prescription claims, as well as beneficiary registry data. Data sources and claims codes used to define all variables are presented in Supplementary Table S1 (<https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>), and assessment windows for key study variables are illustrated in the study design diagram (Supplementary Figure S1, <https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>).

2.4.1. Exposure

The exposure was maternal dysglycaemia. Mothers were classified according to prescriptions for anti-diabetic

medications before and during pregnancy, diagnoses of type 1 diabetes (T1D) before pregnancy and claims for the home management fee for gestational diabetes (GDM fee) during pregnancy. The GDM fee is a reimbursement code unique to Japan that applies to pregnant women with high-risk GDM, overt diabetes in pregnancy or pre-existing diabetes; further details are provided in Supplementary Method S1 (<https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>).

Mothers were classified into six mutually exclusive categories (Supplementary Figure S2 and Supplementary Table S6, <https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>). First, they were divided according to whether they had prescriptions for anti-diabetic medications before and/or during pregnancy. Mothers with prescriptions in both periods were further stratified by presence of a pre-pregnancy T1D diagnosis: those with such a diagnosis were classified as Category 1 (Anti-diabetic prescriptions before and during pregnancy, with a pre-pregnancy T1D diagnosis; Both-periods prescription, T1D-coded) and those without as Category 2 (Anti-diabetic prescriptions before and during pregnancy, without a pre-pregnancy T1D diagnosis; Both-periods prescription, no T1D code). Mothers with prescriptions only during pregnancy were classified as Category 3 (Anti-diabetic prescriptions in prenatal period only; Prenatal-only prescription), and those with prescriptions only before pregnancy as Category 4 (Anti-diabetic prescriptions before pregnancy only; Pre-pregnancy-only prescription). Among mothers with no prescriptions in either period, those with claims for the GDM fee during pregnancy were classified as Category 5 (GDM fee claim without anti-diabetic prescriptions; GDM fee only, no prescription) and those without such claims as Category 6 (No identified claims-based indicator of dysglycaemia; No identified indicator of dysglycaemia). These categories are claims-based proxies rather than confirmed clinical phenotypes and do not represent a gradient of clinical severity.

2.4.2. Outcomes

We assessed six perinatal outcomes: one maternal outcome (caesarean section) and five neonatal outcomes (macrosomia, preterm birth, neonatal asphyxia, admission to the neonatal intensive care unit [NICU] and congenital malformations of the circulatory system) (1,15).

A single qualifying claim within the outcome-specific assessment window was sufficient to meet a diagnosis-based criterion. When diagnoses were used in the definition, records flagged as suspected diagnoses were excluded.

2.4.3. Covariates

Insurance status (insured vs. dependent) and infant sex were extracted as baseline characteristics. Maternal age

group was selected a priori as a confounder. Hypertensive disorders of pregnancy (HDP) were identified as a factor that could potentially act as either a confounder or a mediator.

Because some women prescribed anti-diabetic medications before pregnancy may have received metformin for polycystic ovary syndrome (PCOS) rather than diabetes, a diagnosis of PCOS was also extracted for descriptive purposes.

2.5. Statistical analyses

Maternal characteristics, including insurance status, age group (< 30, 30–34 and $\geq$ 35 years) and the prevalence of hypertensive disorders of pregnancy, were summarised by maternal dysglycaemia category. Infant sex was also described.

Proportions of caesarean section, macrosomia, preterm birth, neonatal asphyxia, NICU admission and congenital malformations of the circulatory system were reported by maternal dysglycaemia category. Differences across categories were assessed using chi-square tests.

We examined associations between maternal dysglycaemia categories and perinatal outcomes using multivariable modified Poisson regression models with robust variance estimators. The primary estimate was the maternal-age-group-adjusted risk ratio; the primary model was therefore adjusted for maternal age group only. Given that HDP was considered to have characteristics more consistent with a mediator than with a confounder, the model additionally adjusted for HDP was treated as a secondary model. Estimates are reported as adjusted risk ratios (aRRs) with 95% confidence intervals (CIs) based on robust variance (vce(robust) in Stata); no additional clustering specification was used because each mother contributed only one mother–infant pair. Category 6 was used as reference category in all models, and no direct contrasts between Categories 1–5 were performed. There were no missing values for variables used in these analyses in the final analytic cohort.

In additional analyses, we described distribution of anti-diabetic medications prescribed before and during pregnancy. We also reported proportion of mothers who were prescribed metformin before pregnancy and had a diagnosis of PCOS. Furthermore, we evaluated association between maternal dysglycaemia and caesarean section within maternal age groups. As a sensitivity analysis, we reconstructed exposure categories using a common 10-calendar-month operational pregnancy period (months –9 through 0) for all pregnancies, irrespective of preterm-birth status, with prescriptions in months –7 through 0 classified as occurring "during pregnancy" and those in months –15 through –8 classified as occurring "before pregnancy" (Supplementary Table S5, <https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>).

For this sensitivity analysis, maternal continuous-enrolment criterion was also re-evaluated using months –15 through 0 for all pregnancies; no additional pairs were excluded.

All analyses were conducted using Stata version 17.0 (StataCorp, College Station, TX, USA). A two-sided *p* value of less than 0.05 was considered statistically significant.

3. Results

3.1. Maternal and infant characteristics

A total of 115,113 presumed mother–infant pairs were included in the analysis. Mothers were categorised into six groups according to dysglycaemia (Categories 1–5) or no identified claims-based indicator of dysglycaemia (Category 6) (Figure 1).

Overall, 38.0% of mothers were aged 35 years or over, with the highest proportion in Category 2 (62.4%). Hypertensive disorders of pregnancy were present in 4.7% of mothers overall and were most prevalent in Category 2 (30.2%). Female infants accounted for 48.6% of the cohort (Table 1).

3.2. Perinatal outcomes by maternal dysglycaemia category

Overall, 21.5% of mothers underwent caesarean section; the proportion was higher in Categories 1 and 2 (40.6% and 48.3%, respectively). Macrosomia occurred in 0.8% of infants overall and was most common in Category 1 (6.3%). Preterm birth occurred in 3.3% overall, with higher proportions in Categories 1 and 2 (14.6% and 12.7%, respectively). Neonatal asphyxia occurred in 3.2% of infants and NICU admission in 5.7%, with both outcomes more frequent in Categories 1–4. Congenital malformations of the circulatory system were recorded in 2.3% of infants overall. Differences across categories were statistically significant for all outcomes (*p* < 0.001) (Table 2).

3.3. Associations between maternal dysglycaemia and perinatal outcomes

In the primary model adjusted for maternal age group, Category 1 was associated with increased risks of several outcomes, including caesarean section (aRR 1.89, 95% CI 1.49–2.40), macrosomia (aRR 8.69, 95% CI 4.00–18.91), preterm birth (aRR 4.54, 95% CI 2.78–7.40), neonatal asphyxia (aRR 3.65, 95% CI 2.09–6.38), and NICU admission (aRR 6.26, 95% CI 4.73–8.28). Category 2 was also associated with increased risks of caesarean section (aRR 2.04, 95% CI 1.77–2.35), preterm birth (aRR 3.69, 95% CI 2.57–5.28), neonatal asphyxia (aRR 3.66, 95% CI 2.53–5.30), and NICU admission (aRR 3.88, 95% CI 3.02–4.99).

Table 1. Maternal and infant characteristics by maternal dysglycaemia category

Variables	Total	Anti-diabetic drug prescription						p value
		Before & during pregnancy		During pregnancy		Before pregnancy		
		T1D coded	No T1D code	Prenatal-only	Pre-pregnancy-only	GDM fee only	No prescription	
		Category 1	Category 2	Category 3	Category 4	Category 5	Category 6	
Total, n	115,113	96	205	1,566	263	1,392	111,591	
Insurance status, n (%)								
Insured	12,249 (10.6)	8 (8.3)	20 (9.8)	187 (11.9)	8 (3.0)	186 (13.4)	11,840 (10.6)	< 0.001
Dependent	102,864 (89.4)	88 (91.7)	185 (90.2)	1,379 (88.1)	255 (97.0)	1,206 (86.6)	99,751 (89.4)	
Age category, n (%)								
< 30 years	27,141 (23.6)	19 (19.8)	26 (12.7)	163 (10.4)	65 (24.7)	196 (14.1)	26,672 (23.9)	< 0.001
30–34 years	44,237 (38.4)	38 (39.6)	51 (24.9)	476 (30.4)	103 (39.2)	461 (33.1)	43,108 (38.6)	
≥ 35 years	43,735 (38.0)	39 (40.6)	128 (62.4)	927 (59.2)	95 (36.1)	735 (52.8)	41,811 (37.5)	
Hypertensive disorders of pregnancy, n (%)								
Yes	5,407 (4.7)	19 (19.8)	62 (30.2)	157 (10.0)	25 (9.5)	113 (8.1)	5,031 (4.5)	< 0.001
No	109,706 (95.3)	77 (80.2)	143 (69.8)	1,409 (90.0)	238 (90.5)	1,279 (91.9)	106,560 (95.5)	
Infant sex, n (%)								
Female	55,918 (48.6)	54 (56.3)	90 (43.9)	743 (47.4)	118 (44.9)	700 (50.3)	54,213 (48.6)	0.160
Male	59,195 (51.4)	42 (43.8)	115 (56.1)	823 (52.6)	145 (55.1)	692 (49.7)	57,378 (51.4)	

Note: Maternal and infant characteristics are summarised by maternal dysglycaemia category. Differences across categories were assessed using chi-square tests. Exposure categories were claims-based proxies and were defined as follows: Category 1, anti-diabetic prescriptions before and during pregnancy with a pre-pregnancy T1D diagnosis; Category 2, anti-diabetic prescriptions before and during pregnancy without a pre-pregnancy T1D diagnosis; Category 3, anti-diabetic prescriptions in prenatal period only; Category 4, anti-diabetic prescriptions before pregnancy only; Category 5, GDM fee claim without anti-diabetic prescriptions; and Category 6, no identified claims-based indicator of dysglycaemia. Abbreviations: GDM, gestational diabetes; T1D, type 1 diabetes.

Table 2. Perinatal outcomes by maternal dysglycaemia category

Variables	Total	Anti-diabetic drug prescription						p value						
		Before & during pregnancy		During pregnancy		Before pregnancy			No prescription					
		T1D coded		No T1D code		Prenatal-only			Pre-pregnancy-only		GDM free only		No identified indicator of dysglycaemia	
		Category 1		Category 2		Category 3			Category 4		Category 5		Category 6	
Total, n	115,113	96	205	1,566	263	1,392	111,591							
Maternal outcome														
Caesarean section, n (%)	24,702 (21.5)	39 (40.6)	99 (48.3)	592 (37.8)	82 (31.2)	399 (28.7)	23,491 (21.1)							
Neonatal outcomes														
Macrosomia, n (%)	875 (0.8)	6 (6.3)	5 (2.4)	41 (2.6)	3 (1.1)	25 (1.8)	795 (0.7)							
Preterm birth, n (%)	3,788 (3.3)	14 (14.6)	26 (12.7)	145 (9.3)	8 (3.0)	52 (3.7)	3,543 (3.2)							
Neonatal asphyxia, n (%)	3,700 (3.2)	11 (11.5)	25 (12.2)	123 (7.9)	24 (9.1)	58 (4.2)	3,459 (3.1)							
Admission to NICU, n (%)	6,568 (5.7)	33 (34.4)	47 (22.9)	278 (17.8)	27 (10.3)	142 (10.2)	6,041 (5.4)							
Congenital circulatory malformations, n (%)	2,662 (2.3)	7 (7.3)	10 (4.9)	54 (3.4)	11 (4.2)	35 (2.5)	2,545 (2.3)							

Note: Proportions of perinatal outcomes are summarised by maternal dysglycaemia category. Exposure categories were claims-based proxies and were defined as follows: Category 1, anti-diabetic prescriptions before and during pregnancy with a pre-pregnancy T1D diagnosis; Category 2, anti-diabetic prescriptions before and during pregnancy without a pre-pregnancy T1D diagnosis; Category 3, anti-diabetic prescriptions in prenatal period only; Category 4, anti-diabetic prescriptions before pregnancy only; Category 5, GDM fee claim without anti-diabetic prescriptions; and Category 6, no identified claims-based indicator of dysglycaemia. Differences across categories were assessed using chi-square tests. Macrosomia: maternal ICD-10 O66.2 or infant ICD-10 P08.0/P08.1. Congenital circulatory malformations: ICD-10 Q20–Q28. Abbreviations: GDM, gestational diabetes; NICU, neonatal intensive care unit; T1D, type 1 diabetes.

Category 3 was also associated with increased risks of several outcomes, including preterm birth (aRR 2.71, 95% CI 2.31–3.18) and NICU admission (aRR 3.03, 95% CI 2.71–3.38). Category 4 was not associated with preterm birth (aRR 0.96, 95% CI 0.49–1.90), whereas increased risks were observed for caesarean section (aRR 1.49, 95% CI 1.25–1.79), neonatal asphyxia (aRR 2.96, 95% CI 2.02–4.33) and NICU admission (aRR 1.91, 95% CI 1.33–2.73). Category 5 was associated with an increased risk of caesarean section (aRR 1.26, 95% CI 1.16–1.37), macrosomia (aRR 2.43, 95% CI 1.64–3.62) and NICU admission (aRR 1.78, 95% CI 1.52–2.08). For congenital malformations of the circulatory system, the point estimate was highest for Category 1 (aRR 3.17), with more modest elevations in Categories 2–4; however, several confidence intervals were wide, with lower bounds close to unity. Estimates from the secondary model additionally adjusted for HDP were attenuated for several outcomes, but the directions of the principal associations were unchanged (Table 3).

3.4. Additional analyses

The distribution of anti-diabetic medications prescribed before and during pregnancy is shown in Supplementary Table S2 (<https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>). Before pregnancy, insulin and metformin were the most frequently prescribed medications, particularly in Categories 2 and 4. During pregnancy, insulin was the most commonly prescribed medication in Categories 1–3, whereas oral agents were infrequently prescribed.

Supplementary Table S3 (<https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>) summarises analyses of metformin use before pregnancy. A total of 336 mothers were prescribed metformin before pregnancy, most commonly in Category 4 ($n = 221$) and Category 2 ($n = 108$). Among these mothers, 85 had a diagnosis of PCOS. The prevalence of PCOS among mothers prescribed metformin before pregnancy was 10.2% in Category 2 and 33.5% in Category 4.

Age-stratified analyses of caesarean section are shown in Supplementary Table S4 (<https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>). Maternal dysglycaemia was associated with an increased risk of caesarean section in most categories. Point estimates varied numerically across age groups. No formal test of interaction was performed.

In the sensitivity analysis using a common 10-month operational pregnancy window for all pregnancies, exposure distribution changed only slightly: number of women in Category 2 increased from 205 to 206 and number in Category 6 decreased from 111,591 to 111,590, whereas numbers of women in Categories 1, 3, 4 and 5 were unchanged. The corresponding risk ratios were materially unchanged (Supplementary

Table S5, <https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>).

4. Discussion

4.1. Main findings of this study

Using a Japanese mother–infant-linked claims database, we found that several claims-based categories of maternal dysglycaemia were associated with adverse perinatal outcomes. Relative to Category 6, Category 1 showed highest point estimates for four of the six outcomes in the primary model, whereas Category 2 showed highest point estimate for caesarean section. For neonatal asphyxia, elevated point estimates were observed in both Categories 1 and 2. Associations with adverse perinatal outcomes were also observed across Categories 2–5, although specific outcomes and magnitudes of association differed by category. Categories 1–5 were not directly compared with one another. In the secondary model additionally adjusted for HDP, estimates were attenuated for several outcomes, but directions of the principal associations were unchanged. The highest point estimate for macrosomia was observed in Category 1, although Category 5 was also associated with more than a two-fold increased risk compared with Category 6. For congenital malformations of the circulatory system, point estimate was highest in Category 1, with more modest elevations in Categories 2–4, although confidence intervals were wide.

4.2. Comparison with previous studies

Overall caesarean rate in our cohort (21.5%) was similar to that reported in Japan's 2020 Survey of Medical Institutions (21.6%) (16). Condition-specific rates by dysglycaemia were also broadly consistent with those reported in a national birth cohort study by Yokomichi *et al.* (T1D, 37.9%; type 2 diabetes, 46.5%; GDM, 26.2–30.7%) (17). Caesarean rate in Category 5 was also similar to that reported in a single-centre retrospective study by Shindo *et al.* (28.6%) (18). Overall prevalence of macrosomia (0.8%) was comparable to previous estimates in the general population (19). However, rate of macrosomia among infants in Category 1 was higher than that reported by Yokomichi *et al.* (17), which may reflect differences in case numbers and exposure definitions.

Overall preterm birth rate (3.3%) was lower than national estimates (4.8–5.6%) (20), possibly because multiple births were excluded from our study population. Among mothers in Category 5, prevalence of preterm birth (3.7%) was substantially lower than that reported in a previous Japanese GDM registry study (21). This difference may reflect our narrower definition of Category 5, which was restricted to women with a GDM fee claim who did not receive anti-diabetic medication.

Table 3. Risk ratios for perinatal outcomes by maternal dysglycaemia category, primary and secondary models

Variables	Unadjusted	Primary model (adjusted for maternal age group)	Secondary model (adjusted for maternal age group and HDP)
Caesarean section (<i>n</i> = 24,702)	RR (95% CI)	RR (95% CI)	RR (95% CI)
Category 6	ref.	ref.	ref.
Category 1	1.93 (1.51–2.46)	1.89 (1.49–2.40)	1.59 (1.27–2.00)
Category 2	2.29 (1.99–2.64)	2.04 (1.77–2.35)	1.54 (1.34–1.78)
Category 3	1.80 (1.68–1.92)	1.61 (1.51–1.72)	1.52 (1.43–1.62)
Category 4	1.48 (1.24–1.77)	1.49 (1.25–1.79)	1.40 (1.17–1.68)
Category 5	1.36 (1.25–1.48)	1.26 (1.16–1.37)	1.21 (1.11–1.31)
Macrosomia (<i>n</i> = 875)	RR (95% CI)	RR (95% CI)	RR (95% CI)
Category 6	ref.	ref.	ref.
Category 1	8.77 (4.03–19.10)	8.69 (4.00–18.91)	8.67 (3.99–18.85)
Category 2	3.42 (1.44–8.16)	3.24 (1.36–7.76)	3.23 (1.35–7.73)
Category 3	3.67 (2.70–5.01)	3.50 (2.56–4.78)	3.49 (2.56–4.77)
Category 4	1.60 (0.52–4.94)	1.61 (0.52–4.96)	1.60 (0.52–4.95)
Category 5	2.52 (1.70–3.74)	2.43 (1.64–3.62)	2.43 (1.63–3.62)
Preterm birth (<i>n</i> = 3,788)	RR (95% CI)	RR (95% CI)	RR (95% CI)
Category 6	ref.	ref.	ref.
Category 1	4.59 (2.83–7.46)	4.54 (2.78–7.40)	3.18 (1.94–5.23)
Category 2	3.99 (2.79–5.73)	3.69 (2.57–5.28)	2.16 (1.52–3.07)
Category 3	2.92 (2.49–3.42)	2.71 (2.31–3.18)	2.40 (2.04–2.82)
Category 4	0.96 (0.48–1.90)	0.96 (0.49–1.90)	0.84 (0.43–1.65)
Category 5	1.18 (0.90–1.54)	1.12 (0.85–1.46)	1.03 (0.79–1.34)
Neonatal asphyxia (<i>n</i> = 3,700)	RR (95% CI)	RR (95% CI)	RR (95% CI)
Category 6	ref.	ref.	ref.
Category 1	3.70 (2.12–6.45)	3.65 (2.09–6.38)	2.92 (1.69–5.04)
Category 2	3.93 (2.72–5.69)	3.66 (2.53–5.30)	2.57 (1.76–3.76)
Category 3	2.53 (2.13–3.01)	2.37 (1.99–2.82)	2.20 (1.85–2.62)
Category 4	2.94 (2.01–4.32)	2.96 (2.02–4.33)	2.72 (1.86–4.00)
Category 5	1.34 (1.04–1.73)	1.28 (0.99–1.65)	1.22 (0.95–1.57)
Admission to NICU (<i>n</i> = 6,568)	RR (95% CI)	RR (95% CI)	RR (95% CI)
Category 6	ref.	ref.	ref.
Category 1	6.35 (4.81–8.38)	6.26 (4.73–8.28)	4.96 (3.71–6.63)
Category 2	4.24 (3.29–5.45)	3.88 (3.02–4.99)	2.69 (2.10–3.46)
Category 3	3.28 (2.94–3.66)	3.03 (2.71–3.38)	2.80 (2.51–3.13)
Category 4	1.90 (1.33–2.71)	1.91 (1.33–2.73)	1.75 (1.22–2.51)
Category 5	1.88 (1.61–2.21)	1.78 (1.52–2.08)	1.69 (1.44–1.97)
Congenital circulatory malformations (<i>n</i> = 2,662)	RR (95% CI)	RR (95% CI)	RR (95% CI)
Category 6	ref.	ref.	ref.
Category 1	3.20 (1.57–6.53)	3.17 (1.55–6.47)	2.77 (1.36–5.63)
Category 2	2.14 (1.17–3.92)	2.02 (1.10–3.70)	1.63 (0.89–2.98)
Category 3	1.51 (1.16–1.97)	1.43 (1.10–1.87)	1.37 (1.05–1.79)
Category 4	1.83 (1.03–3.27)	1.84 (1.03–3.29)	1.76 (0.98–3.14)
Category 5	1.10 (0.79–1.53)	1.06 (0.76–1.47)	1.03 (0.74–1.43)

Note: Risk ratios (RRs) and 95% confidence intervals (CIs) were estimated using multivariable modified Poisson regression models. Primary model was adjusted for maternal age group; secondary model was adjusted for maternal age group and hypertensive disorders of pregnancy. Because HDP may lie on the causal pathway between maternal dysglycaemia and some perinatal outcomes, the model without HDP adjustment was designated primary model. *n* denotes number of events for each outcome; all models included all 115,113 presumed mother–infant pairs; there were no missing data. Exposure categories were claims-based proxies and were defined as follows: Category 1, anti-diabetic prescriptions before and during pregnancy with a pre-pregnancy T1D diagnosis; Category 2, anti-diabetic prescriptions before and during pregnancy without a pre-pregnancy T1D diagnosis; Category 3, anti-diabetic prescriptions in prenatal period only; Category 4, anti-diabetic prescriptions before pregnancy only; Category 5, GDM fee claim without anti-diabetic prescriptions; and Category 6, no identified claims-based indicator of dysglycaemia. *Abbreviations:* CI, confidence interval; GDM, gestational diabetes; HDP, hypertensive disorders of pregnancy; NICU, neonatal intensive care unit; ref, reference; RR, risk ratio; T1D, type 1 diabetes.

NICU admission among infants born to mothers in Category 5 (10.2%) was broadly comparable to that reported for the GDM group in a previous single-centre retrospective study (8.2%) (18), although differences in study populations and disease definitions should

be considered when interpreting this comparison. The proportion of congenital malformations of the circulatory system was higher in our study than in previous reports across all dysglycaemia categories. A plausible explanation is that these malformations were

identified from claims recorded during the first 6 months after birth, whereas previous studies primarily assessed diagnoses at delivery and in the neonatal unit (17).

4.3. Clinical implications

Pregnancies with anti-diabetic prescriptions both before and during pregnancy (Categories 1 and 2) were associated with increased risks of multiple adverse perinatal outcomes. Among women in Category 2, higher prevalence of advanced maternal age and hypertensive disorders of pregnancy, together with possibility of a higher body mass index (BMI), suggests that these risks may be influenced by multiple coexisting factors. Although this study did not evaluate effectiveness of specific interventions, previous studies have shown that management of dysglycaemia can improve perinatal outcomes (22,23). Our findings are consistent with the classification of pregnancies complicated by diabetes as high risk and with the existing emphasis on preconception glycaemic assessment and optimisation, comprehensive complication screening and individualised delivery planning. Further interventional research is needed to evaluate these strategies in contemporary clinical practice.

Among women in Category 3, risks of several outcomes, including preterm birth, NICU admission and neonatal asphyxia, were higher than in Category 6. These findings are consistent with current clinical priorities, including timely screening, treatment when clinically indicated and glycaemic management during pregnancy (24). The contribution of specific management strategies, including continuous glucose monitoring and insulin pump therapy, warrants further investigation.

Even among women in Category 5, risks of caesarean section, macrosomia and NICU admission were elevated compared with Category 6. These findings suggest that pregnancies identified by a GDM fee claim without anti-diabetic prescriptions may remain at increased risk of adverse outcomes. Further studies are needed to determine whether non-pharmacological management approaches, including nutritional counselling and self-monitoring of blood glucose, modify these risks.

4.4. Feasibility of claims-based perinatal assessment

By combining family IDs (mother–infant linkage) with prescription records, diagnoses and a Japan-specific reimbursement code (GDM fee), we can characterise perinatal risk profiles according to claims-based categories of maternal dysglycaemia. A key strength of this approach is availability of information on prescriptions and diagnoses before pregnancy, which is not subject to recall bias and can be used to classify maternal clinical characteristics.

This study also demonstrates feasibility of assessing perinatal outcomes using administrative claims data

in Japan. In particular, caesarean section rates, which are known to vary across regions and facilities, could be evaluated using population-based claims data (25). Furthermore, use of broader outcome definitions, including neonatal asphyxia, preterm birth, and NICU admission, enabled meaningful comparisons despite limited numbers of individual neonatal conditions. These findings suggest the potential utility of claims-based mother–infant linkage as a complementary approach for monitoring perinatal indicators, subject to further validation.

Although mother–infant linkage is currently unavailable in many large healthcare databases, implementing such linkage in national administrative data sources could extend this approach to rarer outcomes. Examples include the National Database of Health Insurance Claims (NDB), a nationwide Ministry of Health, Labour and Welfare database containing health insurance claims and specific health check-up data (26), and Diagnosis Procedure Combination data, which include discharge abstracts and administrative claims from acute-care inpatient hospitals (27). If linkage is feasible, national perinatal monitoring and regional or facility-level benchmarking, as well as real-world evaluation of perinatal care, could become potential future applications of such data, subject to further validation.

4.5. Limitations

This study has several limitations. First, miscarriages and stillbirths were not captured and were therefore excluded from the analysis, potentially leading to underestimation of the full burden of adverse outcomes associated with maternal dysglycaemia. In addition, important potential confounders, including BMI, smoking, socioeconomic status, and use of assisted reproductive technology, were unavailable. Although maternal age was included as an adjustment variable, residual confounding may remain because age was analysed in categories. Hypertensive disorders of pregnancy may act not only as a confounder but also as a mediator between maternal dysglycaemia and perinatal outcomes; therefore, adjustment for HDP in the secondary model may constitute overadjustment. Future studies using complementary data sources with more detailed clinical and social information are needed to address these limitations.

Second, the study population consisted of employees of large companies and their dependents. Our eligibility criteria also required continuous insurance enrolment for mothers throughout the operationally defined pregnancy period and preceding observation period, and for infants throughout the 6-month post-birth assessment window, which further selects families with stable employment-based coverage. Self-employed individuals, people covered by National Health Insurance, and families with frequent changes in health insurer are therefore likely to

be underrepresented, and large size of the database should not be taken to indicate national representativeness of all births in Japan. In addition, infants who disenrolled from insurance within 6 months after birth were excluded. If disenrolment is related to maternal dysglycaemia or to infant health status, this restriction could introduce selection bias.

Third, exposure definitions were based on insurance claims and may not fully correspond to clinical diagnoses or events. Laboratory data, including glucose values and HbA1c, were unavailable, and exposure categories were therefore defined using diagnoses, prescriptions and reimbursement codes as claims-based proxies for maternal dysglycaemia. Ascertainment of pre-pregnancy T1D diagnoses depended on length of available pre-pregnancy observation, although at least 6 months of observation was required; this may have resulted in misclassification between Categories 1 and 2. Categories 1–5 should not be interpreted as representing an ordered gradient of clinical severity. Category 3 may include clinically heterogeneous conditions that cannot be distinguished using this classification. The pre-pregnancy-only prescription group (Category 4) was also heterogeneous. Metformin accounted for most prescriptions in this group (221 of 263 mothers), and 74 of these mothers had a diagnosis of PCOS (Supplementary Table S3, <https://www.globalhealthmedicine.com/site/supplementaldata.html?ID=131>), suggesting that some women were treated for PCOS during infertility treatment rather than for diabetes; this would be expected to attenuate observed associations towards Category 6. Conversely, Category 5 was defined by claims for the GDM home management fee, which is restricted to high-risk GDM, overt diabetes in pregnancy or pre-existing diabetes. Categories 3 and 5 together accounted for only 2.6% of the cohort, far below the reported prevalence of GDM in Japan (7–13%), so Category 6 almost certainly contained a substantial number of women with diet-controlled or unbilled GDM and represents absence of an identified claims-based indicator rather than confirmed normoglycaemia. If women with uncaptured dysglycaemia had higher outcome risks than truly normoglycaemic women, their inclusion in Category 6 would tend to attenuate elevated aRRs towards the null. However, because the extent and pattern of misclassification across the categories are unknown, the overall direction and magnitude of bias cannot be determined. In addition, the operational pregnancy period — and therefore both prescription-classification window and required maternal observation period — differed according to preterm-birth status in the primary analysis. In the sensitivity analysis, applying a common 10-month window and re-evaluating the maternal continuous-enrolment criterion resulted in no additional exclusions, only minimal changes in exposure classification, and no material changes in estimates. Nevertheless, this structural dependence remains a limitation of the primary analysis.

Fourth, outcome definitions were also based on insurance claims and may not fully correspond to clinically confirmed events or conditions. In particular, because measured birthweight was unavailable, maternal ICD-10 code O66.2 and infant codes P08.0 and P08.1 were used as claims-based proxies for excessive birthweight or heavy-for-gestational-age status and should not be interpreted as macrosomia confirmed using measured birthweight. Similarly, Q20–Q28 identified congenital malformations of the circulatory system recorded in claims and did not permit more detailed clinical confirmation. Differential ascertainment also cannot be excluded: women with recognised dysglycaemia and their infants may undergo more intensive fetal and neonatal surveillance, including ultrasonography, postnatal monitoring and echocardiography, which could increase likelihood that conditions are detected and recorded in claims and may have contributed to the observed associations.

Fifth, the mother–infant linkage was presumed rather than verified. A shared family identification number indicates coverage under the same insurance contract and does not by itself confirm a mother–infant relationship. The internal plausibility checks applied in this study — requiring an insurance relationship recorded as "child" with a month of birth matching the month of insurance enrolment, excluding family identification numbers shared by more than one adult woman, and excluding pairs in which the woman was aged 50 years or older — reduce ambiguity but do not independently establish relationship. Because normal pregnancy and delivery are not routinely covered by public health insurance in Japan, maternal delivery-related claims are not consistently captured and could not be used as a uniform concordance check across the cohort. Linkage errors may therefore remain in the retained cohort, and accuracy of the presumed mother–infant linkage has not been established.

Finally, despite the large cohort of more than 115,000 presumed mother–infant pairs, some paediatric outcomes remained uncommon and statistical precision was limited. Larger linked administrative databases may enable more robust evaluation of rare outcomes.

5. Conclusions

Using a Japanese mother–infant-linked claims database, we found that claims-based categories indicating maternal dysglycaemia were associated with adverse perinatal outcomes in real-world clinical practice. Highest point estimates relative to Category 6 were observed in Category 1 for most outcomes, while associations with adverse perinatal outcomes were also observed across Categories 2–5 with specific outcomes differing by category. These findings indicate that several claims-based categories were associated with adverse perinatal outcomes relative to Category 6, without

establishing differences between Categories 1–5 or effects of specific clinical management strategies.

This study also suggests potential utility of mother–infant-linked claims data to evaluate perinatal outcomes in Japan, where normal pregnancy and delivery are not routinely captured in health insurance claims. Subject to further validation, extension of this approach to larger administrative databases could facilitate national perinatal monitoring and benchmarking and support future epidemiological research on pregnancy complications and infant outcomes.

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