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ARTICLE

The association between gestational diabetes and stillbirth: a systematic review and meta-analysis

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Abstract

Aims/hypothesis Controversy exists over whether gestational diabetes increases the risk of stillbirth. The aim of this review was to examine the association between gestational diabetes and stillbirth.

Methods We performed searches of the published literature to May 2021. Study selection and data extraction were performed in duplicate by independent reviewers. Meta-analyses of summary measures were conducted using random-effect models for cohort and case–control studies separately. The study protocol was registered in PROSPERO (registration ID CRD42020166939).

Results From 9981 citations, 419 were identified for full-text review and 73 met inclusion criteria (n = 70,292,090). There was no significant association between gestational diabetes and stillbirth in cohort studies (pooled OR 1.04 [95% CI 0.90, 1.21]; I^2 86.1%) or in case–control studies (pooled OR 1.57 [95% CI 0.83, 2.98]; I^2 94.8%). Gestational diabetes was associated with lower odds of stillbirth among cohort studies presenting with an adjusted OR (pooled OR 0.78 [95% CI 0.68, 0.88]; I^2 42.7%). Stratified analyses by stillbirth ≥28 weeks' gestation, studies published prior to 2013 and studies identified as low quality demonstrated a significantly higher odds of stillbirth in meta-regression (p = 0.016, 0.023 and 0.005, respectively). Egger's test for all included cohort studies (p = 0.018) suggests publication bias for the main meta-analysis.

Conclusions/interpretation Given the substantial heterogeneity across studies, there are insufficient data to define the relationship between stillbirth and gestational diabetes adequately. In the main analyes, gestational diabetes was not associated with an increased risk of stillbirth. However, heterogeneity across studies means this finding should be interpreted cautiously.

Keywords Diabetes · Fetal death · Gestational diabetes · Meta-analysis · Neonatal outcomes · Perinatal death · Pregnancy · Pregnancy outcomes · Screening · Stillbirth · Systematic review

Abbreviation

IADPSG International Association of Diabetes and Pregnancy Study Groups

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Research in context

What is already known about this subject?

- Pre-existing diabetes before pregnancy is a well-established risk factor for stillbirth
- The risk of stillbirth among women with contemporary definitions of gestational diabetes, excluding pre-existing diabetes, is not as well-understood

What is the key question?

- Is gestational diabetes associated with an increased risk of stillbirth?

What are the new findings?

- There was no significant association between gestational diabetes and stillbirth, although there was substantial heterogeneity in our findings
- Sensitivity analyses demonstrated that inclusion of late stillbirth only, publication before 2013, and studies of low quality produced findings of a significantly higher risk of stillbirth not seen in studies including early stillbirth, more recent studies and studies of higher quality, respectively
- Adjustment for known confounders demonstrated a significantly lower risk of stillbirth in women with gestational diabetes compared with women without this condition

How might this impact on clinical practice in the foreseeable future?

- A relationship between gestational diabetes on its own and stillbirth is not clearly evident; recommendations regarding delivery timing for the sole purpose of preventing stillbirth among pregnancies with gestational diabetes that lack risk factors for stillbirth may require reconsideration

Introduction

Gestational diabetes, defined as glucose intolerance with onset or first recognition during pregnancy, is one of the most common medical complications in pregnancy, affecting 6–25% of pregnant women depending on diagnostic criteria used [1–3]. The prevalence of gestational diabetes is rising worldwide, in parallel with the obesity epidemic [4]. Gestational diabetes confers an approximate 1.5-fold to threefold higher risk of some adverse neonatal or maternal outcomes, depending on the definition used, although complications such as hypertensive disorders of pregnancy, shoulder dystocia and macrosomia can be reduced by approximately 50% by appropriate treatment during pregnancy [5–11]. It is well-recognised that pregnancies among women with pre-existing diabetes carry a four- to fivefold increased risk of stillbirth compared with the general obstetric population [12, 13]. However, the literature examining the incidence of stillbirth in women with gestational diabetes has been inconsistent, and many of the previously published studies that suggested an association between gestational diabetes and stillbirth were performed at a time when women with suspected pre-existing overt diabetes were not excluded from the definition of gestational diabetes.

Based on the conflicting data currently available, it remains unclear whether gestational diabetes portends an increased risk of stillbirth. Some, but not all, observational studies have shown that individuals with gestational diabetes are more likely to experience a stillbirth, although this risk does not appear to be as pronounced as that for pregnancies with pre-existing diabetes [14–16]. This inconsistency may be influenced by the variability in gestational age cut-off chosen for stillbirth definition in the studies and the range of diagnostic criteria used for gestational diabetes diagnosis. Furthermore, several factors such as obesity, advanced maternal age, excessive gestational weight gain and unrecognised pre-existing diabetes are important confounders of any postulated relationship with gestational diabetes [17–20]. If present, risk of stillbirth in gestational diabetes might be mitigated by adequate glycaemic control in pregnancy, as well as induction of labour [21].

Despite the discordant evidence and heterogeneity of existing studies, some professional organisations recommend that all pregnant women with gestational diabetes be offered induction of labour between 38 and 40 weeks' gestation to potentially reduce the risk of stillbirth [22–26]. However, whether gestational diabetes is associated with an increased risk of stillbirth remains largely unknown. To address this knowledge gap, we conducted a systematic review and meta-analysis of observational studies examining the relationship between gestational diabetes and risk of stillbirth.

Methods

A systematic review and meta-analysis was performed as outlined in the registered protocol (PROSPERO registration ID CRD42020166939) [27]. The study was conducted and is reported in accordance with the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines [28].

Data sources and searches We developed a search strategy in collaboration with a medical librarian using keywords related to gestational diabetes and pregnancy outcomes, as outlined in electronic supplementary material (ESM) Methods. The search themes were combined using the Boolean term 'AND'. The search was modified and adapted according to search headings for each database. The search, limited to human studies, was performed in duplicate on 27 January 2020 and was updated on 1 May 2021. The following databases were searched systematically: MEDLINE; EMBASE; Cochrane Database of Systematic Reviews; and Cochrane Central Register of Controlled Trials. The reference lists of the included articles and relevant reviews were examined to identify additional relevant publications for inclusion. Local experts in the field were consulted to ensure no studies had been missed.

Study selection Studies needed to meet all of the following criteria to be eligible for inclusion in this review: (1) included pregnant individuals; (2) included those with gestational diabetes defined by the investigator-reported definition; (3) included a comparator group of pregnant women without gestational diabetes; (4) reported on the outcome of stillbirth; and (5) were either cohort studies or case–control studies reporting the association between gestational diabetes and the risk of stillbirth. Only studies reporting original data, written in English or French, published in full-text format were included. There was no restriction on time of publication or study setting. We included only languages that our study team was fluent in so we were able to directly evaluate all included studies.

Since stillbirth is a rare outcome and the absence of the event does not enable calculation of a risk estimate, studies reporting no stillbirth occurrence in either or both arms were excluded from this systematic review and meta-analysis [29]. Authors of studies only reporting perinatal mortality data were contacted by e-mail to inquire about stillbirth occurrence specifically, given it comprises part of perinatal mortality data. Studies were excluded if the information was not available.

At each stage, review and identification of studies were performed in duplicate by two independent reviewers (PL and JLB). After removal of duplicates, titles and abstracts of all references retrieved from the initial search were screened to assess eligibility. Next, full-text articles of potentially relevant publications were scrutinised in detail. Inclusion criteria were applied to select eligible articles and reasons for exclusion at the full-text review were documented. Agreement was recorded at each stage and reported as a κ statistic. Disagreements between reviewers were resolved through consensus or by discussion with a third independent reviewer (JMY). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram was used to summarise the search and study selection process [30]. If two studies reported data on the same cohort for stillbirth occurrence, only the study with the most complete data was included [31, 32].

Data extraction and quality assessment From each eligible study, two reviewers independently extracted relevant information, using a standardised data collection form (PL and NM). Any disagreement between reviewers was resolved as outlined above. Data from included studies were extracted for study characteristics including first author name, year of publication, study design, country where the study was conducted, quality of the methods, number of groups, total number of participants, diagnostic criteria used for gestational diabetes, timing of diagnosis and type of population screened. Extracted data elements also included outcomes measures such as stillbirth definition, stillbirth incidence based on the exposure, size of the association (OR or RR) with corresponding 95% CI and factors adjusted for. Individuals' characteristics, including BMI, age and parity, were extracted. Covidence (Veritas Health Information, Melbourne, VIC, Australia; 2020 and 2021 versions [current version v2655 bf7ee44c]) and Microsoft Excel (Version 16.30; Microsoft Corporation, Redmond, WA, USA) were used for data management.

The methodological quality and potential risk of bias of included studies was assessed by two independent reviewers using the validated Newcastle–Ottawa scale [33]. Studies with a total score of 5 or less were considered as low-quality studies. Studies were awarded full points for comparability if an adjusted estimate, controlling for at least two potential confounders, was specifically reported for stillbirth incidence and/or if cases and controls were matched for multiple factors, including BMI. Any discrepancies were resolved through discussion and if consensus could not be reached, the dispute was resolved with the help of a third reviewer (JMY).

Data synthesis and analysis Meta-analyses were conducted using random-effect models for cohort and case–control studies separately. Observational studies reporting OR and RR, adjusted or unadjusted or providing the incidence of stillbirth were included in the meta-analysis. Study effect estimates were included using the following hierarchy: (1) study-reported ORs were used when available; (2) we converted RR to OR or calculated the OR when outcome rates were

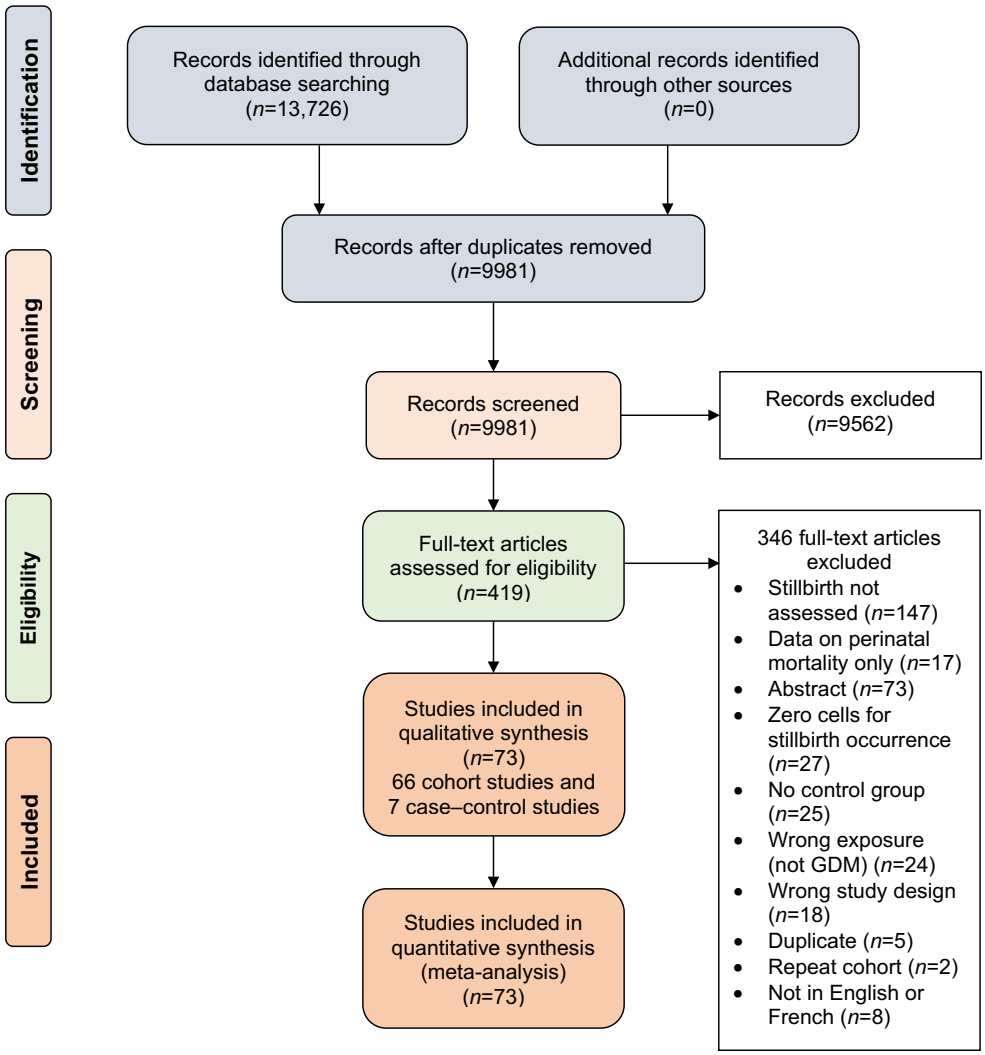


Fig. 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. Adapted from Moher D et al. [30]. GDM, gestational diabetes

available; (3) if neither of those were possible and an RR was reported, we used RR as equal to OR under the rare disease assumption [34].

The heterogeneity of the studies was quantified using I^2 statistics, where $I^2 > 50\%$ represents moderate and $I^2 > 75\%$ represents substantial heterogeneity across studies [35]. Publication bias was assessed by visual examination of the funnel plot and/or using Egger's test as appropriate.

To explore potential sources of heterogeneity, subgroup analyses were carried out according to relevant study characteristics previously extracted. Meta-regression analyses were performed based on our registered protocol and where the number of included studies reporting was high enough. Sensitivity analyses were conducted to evaluate the influence of individual studies on the overall effect by excluding studies one by one and comparing the results in the analysis. Sensitivity analyses were also conducted to assess the effect of adjusted and unadjusted estimates. All statistical analyses were performed using Stata (version 16.0; StataCorp LP, College Station, TX, USA).

Results

From the 9981 citations reviewed for title and abstract, 419 citations were identified for full-text review (Fig. 1). A total of 73 articles (66 cohort studies and seven case–control studies) involving 70,292,090 participants were included. Cohort studies included 69,697,806 participants (66,077,325 control participants and 3,620,481 with gestational diabetes) and case–control studies included 594,284 participants (588,991 live births [controls] and 5293 stillbirths). Of 20 cohort studies reporting perinatal mortality data, specific information about stillbirth occurrence was obtained for three studies [36–38], which were included in the analyses. The κ statistic for inter-rater agreement for the original search was 0.56 (95% CI 0.51, 0.60) for the title and abstract review and 0.87 (95% CI 0.82, 0.93) for the full-text review.

Table 1 Characteristics of included cohort studies

Study	Country	Study design	No. of participants		Gestational week for stillbirth definition (or inclusion criteria)	Universal vs risk-factor-based screening	Timing of GDM screening (gestational week)	Diagnostic criteria for GDM[b]
			Control group	GDM group[a]				
Aberg et al. (2001) [39]	Sweden	Retrospective	4256	116	25	Universal	25–30	Sweden criteria: 2 h BG post 75 g OGTT ≥9 mmol/l
Aberg et al. (1997) [40]	Sweden	Retrospective	7916	3958	28	Not reported	Not reported	Not reported
Abolfazl et al. (2008) [41]	Iran	Retrospective	350	70	Not reported	Not reported	Not reported	Not reported
Alfadhli et al. (2015) [32]	Saudi Arabia	Prospective	281	292	22	Universal	First antenatal visit and week 24–28	IADPSG
Aljohani et al. (2008) [42]	Canada	Retrospective	315,131	9474	20	Universal	Not reported	Canadian guidelines
Al Teheawt and Farida (1995) [43]	Egypt	Retrospective	9685	71	Not reported	Not reported	Not reported	Not reported
Barakat et al. (2010) [44]	Oman	Retrospective	245	213	Not reported	Universal	First antennal visit and week 24–28	WHO 1999
Bashir et al. (2020) [31]	Qatar	Retrospective	1420	801	Not reported	Universal	First antennal visit and week 24	WHO 2013
Bawah et al. (2019) [45]	Ghana	Retrospective	120	80	Not reported	Universal	24–28	ADA 2010
Berg et al. (2007) [46]	Sweden	Retrospective	30,823	719	Not reported	Universal	First antenatal visit and week 24	WHO 1998
Bhat et al. (2012) [36]	India	Retrospective	292	286	Not reported	Not reported	24–28	ADA 1997
Bogdanet et al. (2017) [37]	Ireland	Retrospective	2496	752	Not reported	Not reported	Not reported	IADPSG
Casey et al. (1997) [47]	USA	Retrospective	61,209	874	Not reported	Risk factors	24–28, earlier if risk factors	NDDG
Chirenje et al. (1992) [48]	Zimbabwe	Retrospective	34,362	70	Not reported	Risk factors	Not reported	WHO 1980
Chou et al. (2010) [49]	Taiwan	Retrospective	10,116	874	Not reported	Universal	24–28	Carpenter–Coustan
Djelmis et al. (1997) [50]	Croatia	Retrospective	46	43	Not reported	Not reported	20–28	WHO 1985
Donovan et al. (2017) [51]	Canada	Retrospective	165,439	13,088	29	Universal	28	HAPO 1.75
Dyck et al. (2020) [52]	Canada	Retrospective	399,871	10,514	Not reported	Not reported	Not reported	Not reported
El Mallah et al. (1997) [53]	Saudi Arabia	Retrospective	8904	972	Not reported	Universal	24–28, earlier if risk factors	O'Sullivan and Mahan (NDDG)
Ethridge et al. (2014) [54]	USA	Retrospective	7771	619	37	Not reported	>24	IADPSG
Fadl et al. (2010) [6]	Sweden	Retrospective	1,249,772	10,525	28	Risk factors	Not reported	Variable criteria
Feng et al. (2018) [55]	China	Retrospective	996	996	20–28	Not reported	24–28	ADA 2016
Hilden et al. (2019) [56]	Sweden	Retrospective	1,440,834	14,833	22–28	Risk factors	First trimester and week 24–28	Variable criteria
Hossein-Nezhad et al. (2007) [57]	Taiwan	Prospective	1862	114	Not reported	Universal	24–28, earlier if risk factors	Carpenter–Coustan
Hutcheon et al. (2013) [14]	USA	Retrospective	1,925,080	76,669	20–28	Not reported	Not reported	Not reported
Ijas et al. (2019) [38]	Finland	Retrospective	18,897	5680	22	Universal (except for very low risk)	24–28, earlier if risk factors	ADA 2000–2010

Table 1 (continued)

Study	Country	Study design	No. of participants		Gestational week for stillbirth definition (or inclusion criteria)	Universal vs risk-factor-based screening	Timing of GDM screening (gestational week)	Diagnostic criteria for GDM[b]
			Control group	GDM group[a]				
Jiang et al. (2017) [58]	Australia	Retrospective	896	3185	24	Universal	Not reported	ADIPS 1998 and IADPSG
Johnstone et al. (1990) [59]	Kuwait	Retrospective	731	246	Not reported	Risk factors	Not reported	FBG >5.8 mmol/l at least twice
Jovanovic et al. (2015) [60]	USA	Retrospective	773,751	54,780	Not reported	Not reported	Not reported	Not reported
Kalra et al. (2013) [61]	India	Prospective	467	33	Not reported	Universal	24–28	Modified version WHO 1999
Karmon et al. (2009) [62]	Israel	Retrospective	174,029	10,227	Not reported	Universal	24–28	Carpenter–Coustan
Keshavarz et al. (2005) [63]	Iran	Prospective	1247	63	Not reported	Universal	24–28, earlier if risk factors	Carpenter–Coustan
Khatun et al. (2005) [64]	Bangladesh	Prospective	40	40	24	Not reported	Not reported	Carpenter–Coustan
Koning et al. (2018) [65]	Netherlands	Retrospective	2851	1580	Not reported	Risk factors	Not reported	WHO 1999 and WHO 2013
Lai et al. (2016) [66]	Canada	Retrospective	306,576	18,137	20	Universal	24–28	HAPO 2.0
Lamminpaa et al. (2016) [67]	Finland	Retrospective	256,170	27,154	Not reported	Universal	24–28	ADA 2000–2010
Langer et al. (2005) [8]	USA	Retrospective	1110	1665	Not reported	Universal	Not reported	Carpenter–Coustan
Li et al. (2020) [68]	China	Retrospective	787	2367	28	Universal	24–28	IADPSG
Magee et al. (1993) [69]	USA	Prospective	521	101	Not reported	Universal	28	Carpenter–Coustan
Mahalakshmi et al. (2016) [70]	India	Retrospective	2843	799	Not reported	Not reported	24–28	Carpenter–Coustan then IADPSG
Morikawa et al. (2017) [71]	Japan	Retrospective	223,108	13,037	22	Universal	Not reported	IADPSG
Nayak et al. (2013) [72]	India	Prospective	221	83	Not reported	Universal	24–32	IADPSG
Nguyen et al. (2020) [73]	Vietnam	Prospective	604	1344	28	Universal	24–28	Multiple criteria
Odar et al. (2004) [74]	Uganda	Prospective	60	30	Not reported	Universal	24–32	WHO 1999
Ovesen et al. (2015) [75]	Denmark	Retrospective	389,609	9014	22	Risk factors	27–30, earlier if risk factors	National Danish guidelines, 2 h BG ≥9 mmol/l
Panigrahi et al. (2020) [76]	India	Prospective	188	30	22	Not reported	24–32	2 h BG post 75 g OGTT ≥7.8 mmol/l
Pan et al. (2015) [77]	China	Prospective	16,173	1635	Not reported	Universal	24–28	WHO 1999 and IADPSG
Peticca et al. (2009) [78]	Canada	Retrospective	115,996	3188	20	Universal	Not reported	Not reported
Pintaudi et al. (2015) [79]	Italy	Retrospective	11,553	3851	Not reported	Risk factors	24–28, earlier if risk factors	ADA 2000–2010
Ramachandran et al. (1998) [80]	India	Prospective	851	211	Not reported	Universal	24–28	O'Sullivan and Mahan (NDDG)
Riskin et al. (2020) [81]	Israel	Retrospective	526	479	Not reported	Not reported	Not reported	Not reported
Rosenstein et al. (2012) [15]	USA	Retrospective	3,997,925	193,028	36	Universal	Not reported	California Diabetes and Pregnancy Program

Table 1 (continued)

Study	Country	Study design	No. of participants		Gestational week for stillbirth definition (or inclusion criteria)	Universal vs risk-factor-based screening	Timing of GDM screening (gestational week)	Diagnostic criteria for GDM[b]
			Control group	GDM group[a]				
Schmidt et al. (2001) [7]	Brazil	Prospective	4598	379	28	Universal	24–28	WHO 1999 and ADA 2000–2010
Shand et al. (2008) [82]	Australia	Retrospective	349,933	16,727	30	Universal	26–28	ADIPS
Shen et al. (2020) [83]	China	Retrospective	13,379	1718	20	Universal	26–28	IADPSG
Shindo et al. (2020) [84]	Japan	Retrospective	2789	503	22	Universal	24–28, earlier if risk factors	FBG 5.1–5.5 mmol/l
Soliman et al. (2018) [85]	Qatar	Retrospective	8995	3027	Not reported	Not reported	Not reported	IADPSG
Srichumchit et al. (2015) [86]	Thailand	Retrospective	20,421	1350	Not reported	Risk factors	24–28, earlier if risk factors	NDDG
Stone et al. (2002) [87]	Australia	Retrospective	58,231	2169	Not reported	Universal	Not reported	ADIPS and others
Svare et al. (2001) [88]	Denmark	Prospective	295	327	28	Risk factors	Booking and week 30–32	Danish criteria
Tavera et al. (2021) [89]	USA	Retrospective	53,521,875	3,088,231	Not reported	Not reported	Not reported	Not reported
Vivet-Lefebure et al. (2007) [90]	France	Retrospective	1172	1172	22	Universal	24–28	Carpenter–Coustan
Wahabi et al. (2013) [91]	Saudi Arabia	Retrospective	2472	569	24	Risk factors	28–32	Carpenter–Coustan
Wahabi et al. (2017) [92]	Saudi Arabia	Prospective	6951	2354	24	Universal	24–34	IADPSG
Xiong et al. (2001) [93]	Canada	Retrospective	108,664	2755	Not reported	Universal	24–28	NDDG
Young et al. (2020) [94]	China	Retrospective	543	190	24	Risk factors	24–28, earlier if risk factors	IADPSG

[a] This number represents the total number of participants with gestational diabetes if multiple GDM groups were included in a study

[b] If multiple GDM groups were included in a study, the most inclusive criteria used to diagnose gestational diabetes is outlined in this table

ADIPS, Australasian Diabetes in Pregnancy Society; BG, blood glucose; FBG, fasting blood glucose; GDM, gestational diabetes; HAPO, Hyperglycemia and Adverse Pregnancy Outcome; NDDG, National Diabetes Data Group

Table 2 Characteristics of included case–control studies

Study	Country	No. of participants		Gestational week for stillbirth definition	Universal vs risk-factor-based screening	Timing of GDM screening (gestational week)	Diagnostic criteria for GDM
		Control (livebirths)	Cases (stillbirths)				
Challis et al. (2002) [95]	Mozambique	110	109	28	Not reported	Not reported	WHO, 2 h BG≥ 9 mmol/l
Gwako et al. (2021) [96]	Kenya	428	214	28	Not reported	Not reported	Not reported
Ibiebele et al. (2016) [97]	Australia	359,435	1552	20	Not reported	Not reported	Not reported
Maleki et al. (2021) [98]	Iran	516	172	28	Not reported	Not reported	Not reported
Ohana et al. (2011) [99]	Israel	226,599	1694	22	Not reported	Not reported	Not reported
Stacey et al. (2019) [21]	UK	277	94	28	Based on risk factors	Not reported	Variable criteria
Tabatabaee et al. (2020) [100]	Iran	1626	1458	Not reported	Not reported	Not reported	Not reported

BG, blood glucose; GDM, gestational diabetes

Study characteristics Study characteristics are summarised in Table 1 [6–8, 14, 15, 31, 32, 36–94], Table 2 [21, 95–100] and ESM Table 1. Study year ranged from 1990 to 2021, and sample size ranged from 80 to 56,610,106 participants. Multiple criteria were used to diagnose gestational diabetes, the most common being the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria and Carpenter–Coustan criteria [101, 102].

Quality assessment Study quality assessment, using the Newcastle–Ottawa scale, is presented in ESM Tables 2 and 3. Most of the studies were rated as low risk of bias for participant selection. Only a small number of studies obtained full points for comparability. The adequacy of follow-up was reported inconsistently, and most cohort studies were thus awarded full points for ascertainment of outcome, presuming participants were followed until delivery, by which time a stillbirth would have occurred. A total of 11 cohort studies obtained a total score of 5 or less and were classified as low quality.

Assessment of publication bias A funnel plot for the main analysis is presented in ESM Fig. 1. On visual inspection, there was asymmetry in which there is a relative absence of small negative studies. The result of Egger's test was statistically significant for the main analysis ($p = 0.018$); this is consistent with the funnel plot and would suggest publication bias.

Association between stillbirth and gestational diabetes The 66 cohort studies were pooled to evaluate the risk of stillbirth. One study presented stillbirth risk stratified by stillbirth definition (20 vs 28 weeks) [14]. The main meta-analysis was performed, including the 28 weeks' cohort, and a sensitivity analysis substituting the 20 weeks definition was conducted. The pooled unadjusted weighted OR was 1.04 (95% CI 0.90, 1.21; I^2 86.1%), suggesting no significant association between gestational diabetes and stillbirth. The analysis performed including the 20 weeks' cohort similarly found no association (OR 1.02 [95% CI 0.88, 1.17]; I^2 84.7%). These meta-analyses were performed using OR as the effect size, combining OR for 65 studies and RR for one study [15]. A sensitivity analysis was performed excluding the study reporting the RR and showed similar results (OR 1.00 [95% CI 0.87, 1.15]; I^2 81.0%). An additional analysis restricted to the 12 cohort studies reporting an adjusted OR or RR was performed and found that gestational diabetes was associated with a lower risk of stillbirth (OR 0.78 [95% CI 0.68, 0.88]; I^2 42.7%) (Fig. 3).

A meta-analysis was performed for stillbirth odds using data for the seven case–control studies. The pooled OR was 1.57 (95% CI 0.83, 2.98); I^2 94.8%, suggesting that gestational diabetes was not associated with stillbirth (Fig. 4).

Stratified analyses A stratified analysis was conducted using studies reporting a stillbirth definition by gestational age: the early stillbirth group included studies using a threshold of <28 weeks' gestation; and the late stillbirth group included studies defining stillbirths using a threshold of 28 weeks' gestation or beyond (cut-offs 28–37 weeks) (Fig. 5). No significant association was found in the pooled analysis restricted to the 21 studies that included early stillbirth in their definition (OR 0.86 [95% CI 0.69, 1.06]; I^2 74.5%). However, when the analysis was restricted to the 11 studies that only

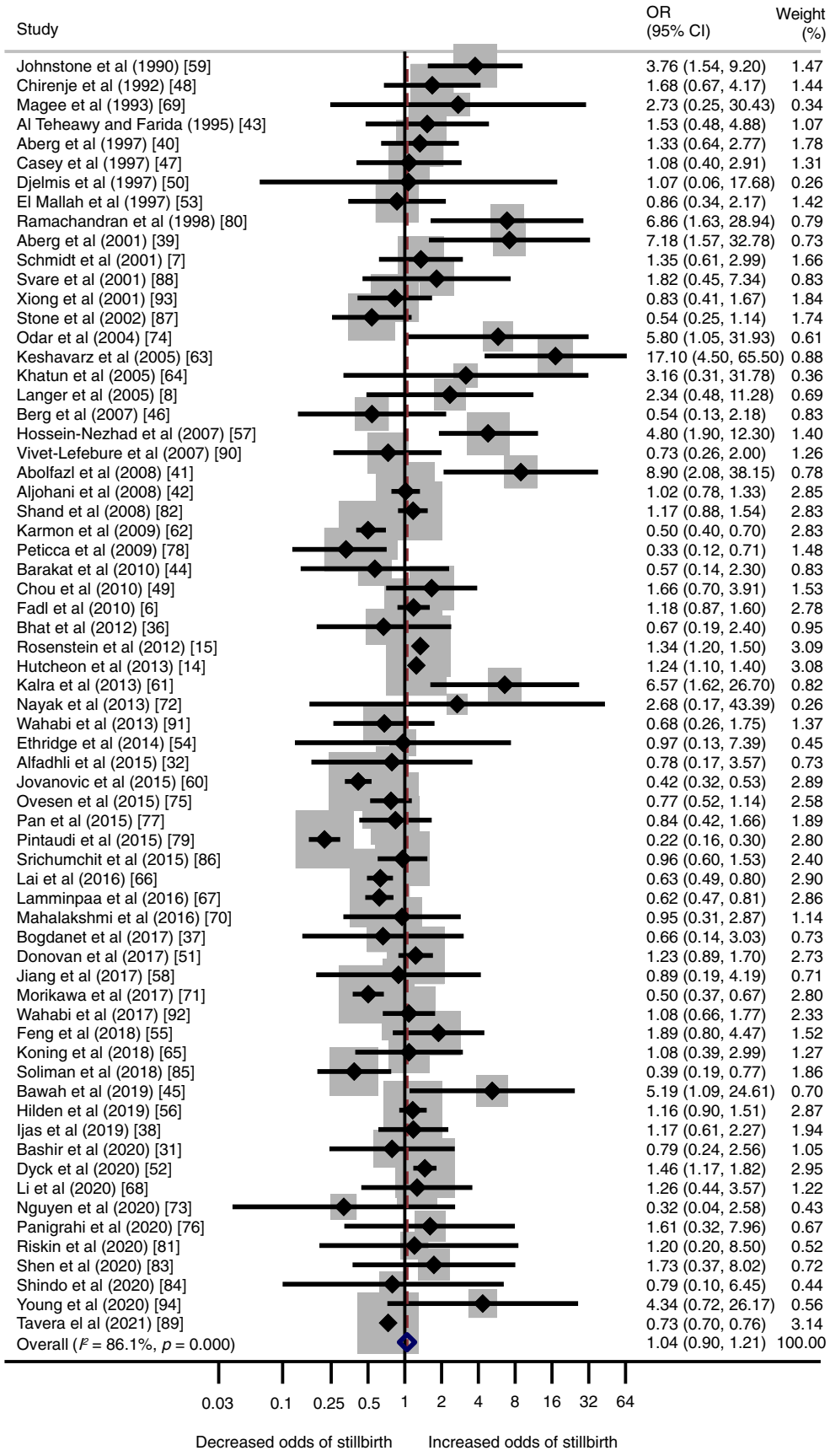
included late stillbirths, gestational diabetes was significantly associated with an increased risk of stillbirth (OR 1.27 [95% CI 1.18, 1.37]; I^2 0%; meta-regression $p = 0.016$) (Fig. 2, Table 3). Funnel plots for these analyses are displayed in ESM Figs 2, 3. Visual inspection of the funnel plot for publications using only late stillbirth in the definition ($n = 11$) reveal there may be evidence of publication bias, although this was not supported by Egger's test ($p = 0.25$).

Cohort studies were also analysed according to their year of publication using the median as the threshold: 31 studies published before 2013; and 35 studies published in 2013 or later (ESM Fig. 4). Risk of stillbirth was significantly higher in studies published before 2013 (OR 1.35 [95% CI 1.06, 1.71]; I^2 74.1%) compared with 2013 or later (OR 0.86 [95% CI 0.72, 1.04]; I^2 86.7%; meta-regression $p = 0.023$) (Table 3). The funnel plots for these analyses are displayed in ESM Figs 5, 6. Egger's test was not statistically significant in studies published prior to 2013 ($p = 0.34$) or after 2013 ($p = 0.32$).

A total of 14 studies were performed in North America, 18 in Asia, 13 in the Middle East, 14 in Europe, three in Africa, three in Australia and one in Brazil (ESM Fig. 7). With a

Table 3 Stratified analyses and meta-regression

Covariate	No. of cohorts	OR (95% CI)	I^2 (%)	p value for meta-regression
Year of publication				
2013 onwards	35	0.86 (0.72, 1.04)	86.7	0.023
Before 2013	31	1.35 (1.06, 1.71)	74.1	
Region				
North America	14	0.92 (0.72, 1.18)	94.2	Reference
Europe	14	0.90 (0.59, 1.36)	87.3	0.82
Asia	18	1.48 (0.96, 2.27)	69.2	0.092
Middle East	13	1.23 (0.72, 2.09)	80.1	0.45
Africa	3	2.87 (1.24, 6.63)	19.8	0.026
Australia	3	0.90 (0.52, 1.56)	45.8	0.89
Brazil	1	1.35 (0.61, 2.99)	–	0.52
Stillbirth definition				
Included late only stillbirth	11	1.27 (1.18, 1.37)	0	0.016
Included early and late stillbirth	21	0.86 (0.69, 1.06)	74.5	
Diagnostic criteria				
IADPSG	13	0.95 (0.65, 1.38)	62.0	Reference
ADA 2000–2010	5	0.85 (0.38, 1.88)	92.4	0.58
National Diabetes Data Group	6	1.05 (0.68, 1.62)	34.9	0.68
Carpenter–Coustan	9	1.85 (0.80, 4.26)	84.6	0.21
Timing of screening				
Includes screening before 24 weeks	7	1.10 (0.87, 1.39)	0	Reference
Screening after 24 weeks	29	1.11 (0.89, 1.38)	66.4	0.62
Screening after 24 weeks but earlier if risk factors	10	1.34 (0.65, 2.76)	91.3	0.50
Universal vs risk-factor-based screening				
Risk-factor based	12	1.07 (0.66, 1.74)	89.8	0.70
Universal	37	1.10 (0.89, 1.37)	79.4	
Study quality				
Low quality	11	2.57 (1.13, 5.82)	82.9	0.005
Moderate to high quality	55	0.96 (0.82, 1.11)	86.8	
Retrospective vs prospective design				
Prospective	15	2.27 (1.35, 3.84)	62.2	0.001
Retrospective	51	0.93 (0.79, 1.08)	87.6	
Hospital-based vs registry-based				
Hospital-based	42	1.44 (1.10, 1.89)	68.1	0.006
Registry-based	24	0.83 (0.69, 1.01)	93.2	


Study
OR (95% CI)
Weight (%)
Johnstone et al (1990) [59] 3.76 (1.54, 9.20) 1.47
Chirenje et al (1992) [48] 1.68 (0.67, 4.17) 1.44
Magee et al (1993) [69] 2.73 (0.25, 30.43) 0.34
Al Teheawy and Farida (1995) [43] 1.53 (0.48, 4.88) 1.07
Aberg et al (1997) [40] 1.33 (0.64, 2.77) 1.78
Casey et al (1997) [47] 1.08 (0.40, 2.91) 1.31
Djelmis et al (1997) [50] 1.07 (0.06, 17.68) 0.26
El Mallah et al (1997) [53] 0.86 (0.34, 2.17) 1.42
Ramachandran et al (1998) [80] 6.86 (1.63, 28.94) 0.79
Aberg et al (2001) [39] 7.18 (1.57, 32.78) 0.73
Schmidt et al (2001) [7] 1.35 (0.61, 2.99) 1.66
Svare et al (2001) [88] 1.82 (0.45, 7.34) 0.83
Xiong et al (2001) [93] 0.83 (0.41, 1.67) 1.84
Stone et al (2002) [87] 0.54 (0.25, 1.14) 1.74
Odar et al (2004) [74] 5.80 (1.05, 31.93) 0.61
Keshavarz et al (2005) [63] 17.10 (4.50, 65.50) 0.88
Khatun et al (2005) [64] 3.16 (0.31, 31.78) 0.36
Langer et al (2005) [8] 2.34 (0.48, 11.28) 0.69
Berg et al (2007) [46] 0.54 (0.13, 2.18) 0.83
Hossein-Nezhad et al (2007) [57] 4.80 (1.90, 12.30) 1.40
Vivet-Lefebure et al (2007) [90] 0.73 (0.26, 2.00) 1.26
Abolfazl et al (2008) [41] 8.90 (2.08, 38.15) 0.78
Aljohani et al (2008) [42] 1.02 (0.78, 1.33) 2.85
Shand et al (2008) [82] 1.17 (0.88, 1.54) 2.83
Karmon et al (2009) [62] 0.50 (0.40, 0.70) 2.83
Peticca et al (2009) [78] 0.33 (0.12, 0.71) 1.48
Barakat et al (2010) [44] 0.57 (0.14, 2.30) 0.83
Chou et al (2010) [49] 1.66 (0.70, 3.91) 1.53
Fadl et al (2010) [6] 1.18 (0.87, 1.60) 2.78
Bhat et al (2012) [36] 0.67 (0.19, 2.40) 0.95
Rosenstein et al (2012) [15] 1.34 (1.20, 1.50) 3.09
Hutcheon et al (2013) [14] 1.24 (1.10, 1.40) 3.08
Kalra et al (2013) [61] 6.57 (1.62, 26.70) 0.82
Nayak et al (2013) [72] 2.68 (0.17, 43.39) 0.26
Wahabi et al (2013) [91] 0.68 (0.26, 1.75) 1.37
Ethridge et al (2014) [54] 0.97 (0.13, 7.39) 0.45
Alfadhli et al (2015) [32] 0.78 (0.17, 3.57) 0.73
Jovanovic et al (2015) [60] 0.42 (0.32, 0.53) 2.89
Ovesen et al (2015) [75] 0.77 (0.52, 1.14) 2.58
Pan et al (2015) [77] 0.84 (0.42, 1.66) 1.89
Pintaudi et al (2015) [79] 0.22 (0.16, 0.30) 2.80
Srichumchit et al (2015) [86] 0.96 (0.60, 1.53) 2.40
Lai et al (2016) [66] 0.63 (0.49, 0.80) 2.90
Lamminpaa et al (2016) [67] 0.62 (0.47, 0.81) 2.86
Mahalakshmi et al (2016) [70] 0.95 (0.31, 2.87) 1.14
Bogdanet et al (2017) [37] 0.66 (0.14, 3.03) 0.73
Donovan et al (2017) [51] 1.23 (0.89, 1.70) 2.73
Jiang et al (2017) [58] 0.89 (0.19, 4.19) 0.71
Morikawa et al (2017) [71] 0.50 (0.37, 0.67) 2.80
Wahabi et al (2017) [92] 1.08 (0.66, 1.77) 2.33
Feng et al (2018) [55] 1.89 (0.80, 4.47) 1.52
Koning et al (2018) [65] 1.08 (0.39, 2.99) 1.27
Soliman et al (2018) [85] 0.39 (0.19, 0.77) 1.86
Bawah et al (2019) [45] 5.19 (1.09, 24.61) 0.70
Hilden et al (2019) [56] 1.16 (0.90, 1.51) 2.87
Ijas et al (2019) [38] 1.17 (0.61, 2.27) 1.94
Bashir et al (2020) [31] 0.79 (0.24, 2.56) 1.05
Dyck et al (2020) [52] 1.46 (1.17, 1.82) 2.95
Li et al (2020) [68] 1.26 (0.44, 3.57) 1.22
Nguyen et al (2020) [73] 0.32 (0.04, 2.58) 0.43
Panigrahi et al (2020) [76] 1.61 (0.32, 7.96) 0.67
Riskin et al (2020) [81] 1.20 (0.20, 8.50) 0.52
Shen et al (2020) [83] 1.73 (0.37, 8.02) 0.72
Shindo et al (2020) [84] 0.79 (0.10, 6.45) 0.44
Young et al (2020) [94] 4.34 (0.72, 26.17) 0.56
Tavera el al (2021) [89] 0.73 (0.70, 0.76) 3.14
Overall (I^2 = 86.1%, p = 0.000) 1.04 (0.90, 1.21) 100.00
0.03 0.1 0.25 0.5 1 2 4 8 16 32 64
Decreased odds of stillbirth
Increased odds of stillbirth

◀ **Fig. 2** Forest plot of ORs (95% CIs) for stillbirth in gestational diabetes compared with controls in cohort studies. The size of the grey squares represents the weight of the study in the pooled analysis. The vertical red dashed line represents the pooled OR

higher baseline rate of stillbirth in the population [103, 104], a pooled analysis restricted to studies from Africa was conducted and found that gestational diabetes was associated with an increased risk of stillbirth (OR 2.87 [95% CI 1.24, 6.63]; I^2 19.8%; meta-regression $p = 0.026$) (Table 3). No significant association was found for the other study regions.

A stratified analysis by study quality found that there was no increased risk of stillbirth in moderate- to high-quality studies (OR 0.96 [95% CI 0.82, 1.11]; I^2 86.8%), but there was an association in low-quality cohort studies (OR 2.57 [95% CI 1.13, 5.82]; I^2 82.9%; meta-regression $p = 0.005$) (Table 3 and ESM Fig. 8). The funnel plots for these analyses are displayed in ESM Figs 9, 10. Egger's test was not statistically significant for moderate- to high-quality studies ($p = 0.10$) but did indicate possible publication bias in studies that were scored as low quality ($p = 0.002$).

There was no significant association between diagnostic criteria used to diagnose gestational diabetes, timing of gestational diabetes screening or screening strategy (population vs risk-factor-based screening) and stillbirth risk (Table 3 and ESM Figs 11–13).

Finally, stratified analyses performed by study design (prospective vs retrospective and hospital-based vs registry-based cohort) found that prospective studies and hospital-based cohort studies were significantly associated with an increased risk of stillbirth (OR 2.27 [95% CI 1.35, 3.84]; I^2 62.2% and OR 1.44 [95% CI 1.10, 1.89]; I^2 68.1%, respectively [ESM Figs 14, 15]; meta-regression $p = 0.001$ and $p = 0.006$, respectively [Table 3]). The funnel plots for these analyses are displayed in ESM Figs 16–19. Egger's tests for retrospective cohorts ($p = 0.17$) and prospective cohorts ($p = 0.10$) were not significant. However, Egger's test for studies including hospital-based data was significant ($p < 0.001$), indicating publication bias, but was non-significant for studies using registry-based data ($p = 0.58$).

Discussion

This meta-analysis found that gestational diabetes was not associated with an increased risk of stillbirth, when pooling 66 cohort studies of more than 69 million participants; however, there was substantial heterogeneity across studies. The sensitivity analyses indicated potential sources of this heterogeneity, including year of publication, definition of stillbirth and study quality. Specifically, we found an increased risk of stillbirth in women with gestational diabetes in studies that limited their definition of stillbirth to those occurring at ≥28 weeks' gestation, cohort studies published prior to 2013, and low-quality studies. Furthermore, the meta-analysis of seven case–control studies showed no significant association between gestational diabetes and stillbirth; however, given the small number of studies included and substantial heterogeneity, this finding requires cautious interpretation.

Notably, when including only cohort studies that reported estimates adjusted for potential confounders, there was a significantly lower risk of stillbirth in women exposed to gestational diabetes compared with control women. Medical comorbidities, including obesity, and advanced maternal age are not only associated with development of gestational diabetes but are also independent risk factors for stillbirth and may potentially overestimate the association between gestational diabetes and fetal mortality if not accounted for [19, 105]. Another possible explanation for these findings is that gestational diabetes itself is associated with an increased risk of stillbirth but that the true effect is attenuated in the pooled estimate after adjustments for advanced maternal age and obesity due to confounding by indication (i.e. earlier induction of labour for advanced maternal age and/or obesity before the occurrence of stillbirth from gestational diabetes actually underestimate the influence of diabetes on fetal loss). Since many of the studies included in our meta-analysis were not primarily designed to examine stillbirth occurrence, most did not report adjusted estimates for this outcome and limited our pooled analysis. The results of this review require validation in larger prospective studies but if replicated by future research may warrant further reflection about current guidelines recommending delivery of pregnancies complicated by gestational diabetes.

A subgroup analysis restricted to studies that defined stillbirth using a gestational cut-off of 28 weeks or later found that gestational diabetes was associated with an increased risk of stillbirth with absence of statistical heterogeneity ($I^2 = 0$). In contrast, there was no significant association after pooling studies that defined stillbirth using a threshold of less than 28 weeks' gestation. This sensitivity analysis demonstrates an important potential source of bias in the literature examining the association between gestational diabetes and stillbirth. It reinforces the concept of immortal time bias described by Hutcheon et al. [14], as pregnancies must reach 24–28 weeks' gestation to be screened for gestational diabetes: the time period between the start of the cohort follow-up, if prior to 24–28 weeks' gestation and the time at which gestational diabetes is diagnosed is referred to as 'immortal'. Stillbirths occurring in that time period are not attributable to gestational diabetes since by the nature of its pathophysiology, this type of diabetes is not usually diagnosed until after 24 weeks' gestation. Including those stillbirths could potentially attenuate the association between gestational diabetes and stillbirth. Including only fetal deaths occurring after the screening window for gestational diabetes allows for more accurate determination

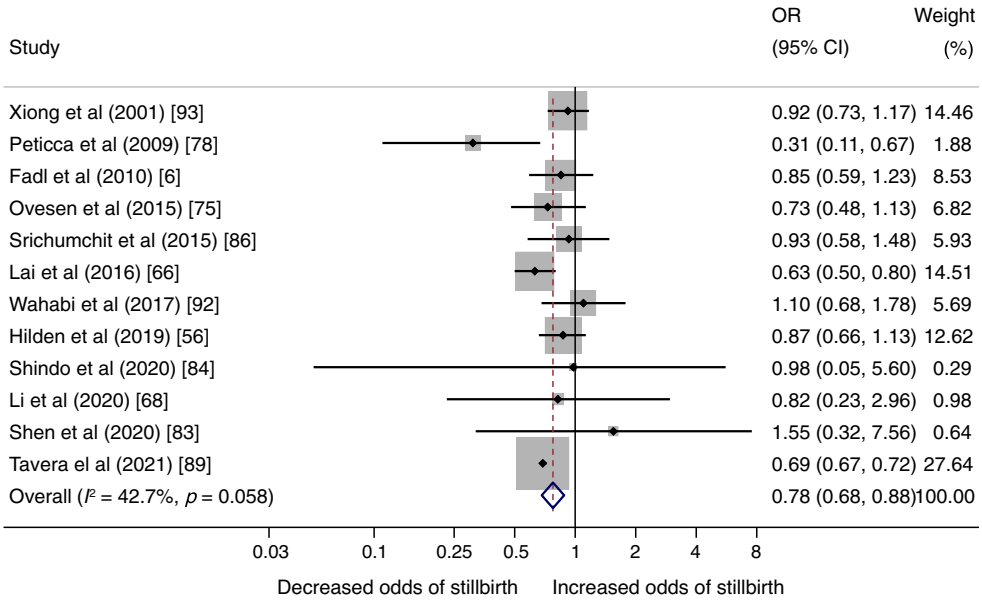


Fig. 3 Forest plot of adjusted ORs (95% CIs) for stillbirth in gestational diabetes compared with controls in cohort studies. The size of the grey squares represents the weight of the study in the pooled analysis. The vertical red dashed line represents the pooled OR

of the associated risk of stillbirth. Our study suggests that women with gestational diabetes are more likely to experience a stillbirth after 28 weeks' gestation than women without this condition. This finding must be interpreted with caution for two reasons. First, the funnel plot for studies including only definitions of late stillbirth indicated possible publication bias. While Egger's test was not statistically significant, it was likely underpowered for this stratified analysis of only 11 studies. Second, most studies reported unadjusted estimates, and the only two studies that reported an adjusted estimate did not find a significant association [6, 68].

Our meta-analysis found that publication year was associated with stillbirth occurrence, as studies published before 2013 indicated a significantly higher risk of fetal death compared with studies published in or after 2013. One explanation might reside in the improvement of diabetes and prenatal care over the decades, including enhanced recognition of gestational diabetes, more stringent monitoring of glucose levels and increased fetal monitoring [106–110]. Another explanation is that, given older definitions used to diagnose gestational diabetes, earlier studies were more likely to include women with pre-existing diabetes who were undiagnosed prior to pregnancy. Therefore, including these women in analyses of gestational diabetes would inflate the risk of fetal loss because pre-existing diabetes is a strong risk factor for stillbirth. Additionally, diagnostic criteria for gestational diabetes have changed throughout the years and the adoption by many countries of the IADPSG criteria has led to an increase in the prevalence of gestational diabetes and the inclusion of less-severe hyperglycaemia [111, 112]. It is therefore possible that older studies have included women with more-severe dysglycaemia and, subsequently, women truly at higher risk of stillbirth: however, those historical case-definitions of gestational diabetes may no longer represent the contemporary population of pregnant women with this diagnosis [111–114]. Subgroup analyses stratified by diagnostic criteria, including subgroups of women diagnosed using IADPSG criteria, found no significant association

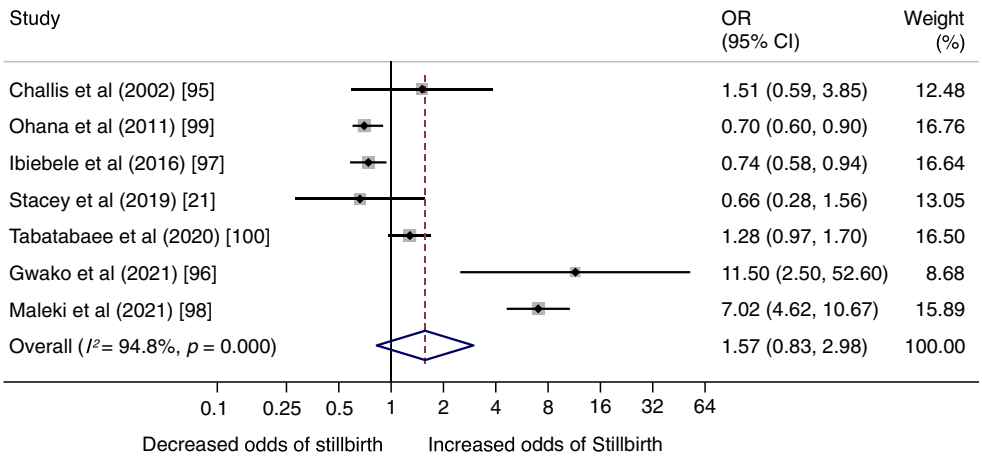


Fig. 4 Forest plot of ORs (95% CIs) for stillbirth in gestational diabetes compared with controls in case–control studies. The size of the grey squares represents the weight of the study in the pooled analysis. The vertical red dashed line represents the pooled OR

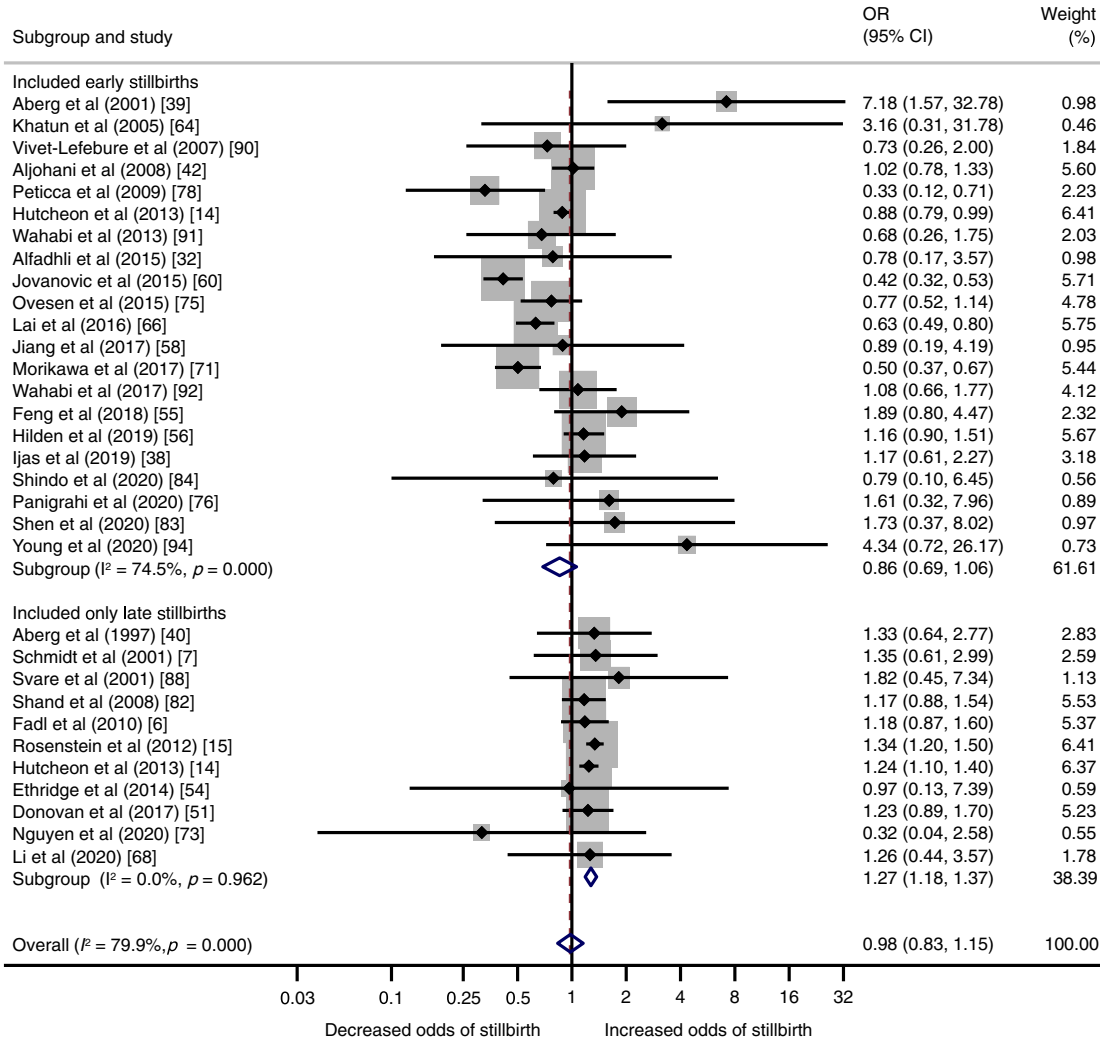


Fig. 5 Forest plot of ORs (95% CIs) for stillbirth in gestational diabetes compared with controls stratified by timing of stillbirth (defined as early [<28 weeks' gestation] or late [≥28 weeks' gestation]). The size of the grey squares represents the weight of the study in the pooled analysis. The vertical red dashed line represents the pooled OR

between gestational diabetes and stillbirth. Furthermore, there was no significant between-group difference regarding stillbirth incidence by diagnostic criteria, though we may have been underpowered in the meta-regression to demonstrate significance as approximately half of the studies did not report or use criteria that are widely accepted for the diagnosis of gestational diabetes. These studies were not included in this analysis.

To our knowledge, this study is the first meta-analysis to examine and quantify the relationship between gestational diabetes and stillbirth. With 9981 citations screened for eligibility and a sample size of >70 million women, it provides a comprehensive review of the existing literature and includes studies using contemporary diagnostic criteria for gestational diabetes. Our study is further strengthened by use of a registered protocol and rigorous methodology. However, limitations include the presence of heterogeneity across the published studies, potentially preventing robust conclusions to be drawn. Most studies reported unadjusted data for stillbirth occurrence, which may introduce bias as many important confounders can interfere in the relationship between stillbirth and gestational diabetes. Though we included a large number of studies and women, we still may have lacked power to demonstrate a significant difference in our subgroup analyses. Lastly, a small number of studies reported data on delivery management and timing and on the adequacy of glycaemic control achieved during pregnancy, and, as a result, these prespecified stratified analyses could not be performed. The degree to which these factors contribute to or prevent stillbirth could therefore not be assessed.

Given the substantial heterogeneity in existing studies, there is inadequate data to clearly identify whether gestational diabetes is associated with an increased risk of stillbirth and findings should be interpreted cautiously. However, our review overall suggests that gestational diabetes does not confer an increased risk of stillbirth. Restricting analyses to

studies adjusted for confounders showed a decreased risk of stillbirth with gestational diabetes. The absolute risk of stillbirth with gestational diabetes was increased when including only late stillbirths (after 28 weeks), studies published prior to 2013 and studies of low quality. Although stillbirth is rare, each case is truly devastating for families. Additional high-quality research, particularly examining late stillbirth and adjusting for potential confounders is urgently needed to inform clinical decision making and guide management of women with gestational diabetes to improve perinatal outcomes.

Supplementary Information The online version contains peer-reviewed but unedited supplementary material available at https://doi.org/10.1007/s00125-021-05579-0.

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Data availability Individual participant data are not available as we used study-level data for our meta-analyses. Extracted data are available, on request, from the corresponding author.

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Contribution statement PL, JLB, LED and JMY conceived the idea for this systematic review and meta-analysis. PL and JLB conducted the literature search along with the initial title/abstract review, the full-text review and study selection. JMY contributed her expertise in systematic review methodology to the design and conduct of this systematic review. PL and NM conducted the data extraction and JMY did the statistical analysis. CP contributed to the interpretation of data and analyses. PL wrote the first draft of the manuscript with input from JMY. All authors contributed to critical review and approval of the final manuscript. JMY is the guarantor of this work.

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