Contents available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

International Diabetes Federation

Effect of the IADPSG screening strategy for gestational diabetes on perinatal outcomes in Switzerland

Evelyne M. Aubry [a,*], *Luigi Raio* [b], *Stephan Oelhafen* [a]

[a] *Department of Health Professions, Bern University of Applied Sciences, Murtenstrasse 10, 3008 Bern, Switzerland*
[b] *Department of Obstetrics and Gynecology. Inselspital, University of Bern, Bern, Switzerland*

ARTICLE INFO

Article history:
Received 19 February 2021
Received in revised form
8 April 2021
Accepted 19 April 2021
Available online 22 April 2021

Keywords:
Gestational diabetes mellitus
International Association of the Diabetes and Pregnancy Study Groups
Perinatal outcomes
Prevalence

ABSTRACT

Aims: To evaluate the impact adoption of the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria on prevalence of gestational diabetes mellitus (GDM) and risks of perinatal outcomes.

Methods: Retrospectively, 155,103 women screened with selective two step criteria in Switzerland in period 1 (2005–2010) were compared to 170,427 women screened with IADPSG criteria in period 2 (2012–2017). GDM prevalence over time was established and multivariable regression used to assess variation in risks for GDM related events and perinatal outcomes.

Results: GDM prevalence increased steadily over both study periods from 1.8% to 9.0%. A risk reduction of GDM-related events was shown only for women with one or two risk factors for GDM present (relative risk (95% confidence interval)): (0.93 (0.90,0.97), 0.90 (0.83,0.96)). The comparison of perinatal outcomes between the two study periods revealed a significant lower risk for newborns large for gestational age (LGA) (0.93 (0.91–0.95)), preterm delivery (0.94 (0.92–0.97)) and neonatal hypoglycemia (0.83 (0.77–0.90)) in period 2.

Conclusion: The introduction of the IADPSG criteria for the screening of GDM increased prevalence by threefold with no substantial improvements in GDM related events for women without risk factors but reduced the risks for LGA, neonatal hypoglycemia and preterm birth.

1. Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance resulting in hyperglycemia with onset or first recognition during pregnancy [1]. Its prevalence is rapidly increasing due to obesity epidemics, older age at pregnancy and more sedentary lifestyle. It ranges between 7 and 10% of all pregnancies worldwide according to different GDM diagnostic criteria [2–5]. In Switzerland estimates showed an average of 5.1% of total women diagnosed with GDM since 2005 [6].

Overt diabetes mellitus in pregnancy is highly associated with risks of adverse perinatal outcomes and health complications later in life [7]. It is therefore important to screen and identify women at risk for GDM and ensure effective and appropriate treatment. Although, detection of GDM in

* Corresponding author.
E-mail address: evelyne.aubry@bfh.ch (E.M. Aubry).
https://doi.org/10.1016/j.diabres.2021.108830

pregnancy is essential for the wellbeing of mother and baby, screening strategies, methods and even diagnostic optimum of glycemic thresholds for GDM remain subject of controversial debate [8].

While GDM was initially defined based on the maternal risk for developing postpartum diabetes, it was subsequently adapted by taking in consideration the adverse maternal and neonatal outcomes [5]. The study of the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) showed a continuous and linear association between increasing level of maternal blood glucose on a 75 g oral glucose tolerance test (OGTT) and adverse pregnancy outcomes. GDM diagnostic criteria were therefore set on the odds ratio (OR) of 1.75 for specific outcomes, relative to their mean [7]. Based on this findings, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) issued recommendations of a GDM screening strategy using a universal one-step 75 g OGTT between 24 and 28 weeks of gestation [9].

The new IADPSG screening strategy has been topic of extensive debate, as a rise in incidence of GDM and an increased burden on a number of health care systems were shown [10–12]. Even though, by adopting the IADPSG screening criteria, cost savings and improved pregnancy outcomes have been found in some studies [13,14], others did not find similar benefits [15,16]. This former switch from a risk-based to a universal GDM screening recommended by the IADPSG has been also criticized for contributing to a medicalization of previously healthy pregnancies, with potential implications on women's quality of life [10]. Consequently, European countries such as France, Italy and Ireland adopted the IADPSG criteria only in women with GDM risk factors [17,18]. Such a selective screening leads to a concentration of diagnostic efforts being made on women in risk of acquiring GDM but has been shown to miss up to 40% of cases [12,19].

With the ongoing debate about the implementation of the IADPSG strategy, there is a need for updates to gain a clear understanding about benefits and challenges of the adopting the new screening criteria. This study will take advantage of a large Swiss cohort to examine the influence of implementing the IADPSG screening strategy on prevalence of GDM and perinatal outcomes in women screened for GDM. Furthermore, the contribution by risk factors will be evaluated that might affect GDM-related events while comparing IADPSG to priori screening.

2. Research design and methods

2.1. Participants

The present study retrospectively analyzed anonymized data from 325,530 women in Switzerland who delivered singleton infants between 22 and 43 weeks of gestational from January 1, 2005 to December 31, 2017. Excluded were women with known type 1 or type 2 diabetes mellitus. Information on deliveries were retrieved from the Swiss obstetric study group database for obstetric and gynecological hospital admission as described in Aubry *et al.*, 2019 [6]. Briefly, the group systematically records details about delivery admission, birth and discharge of all women from more than 100 Swiss obstetrics hospitals of various sizes and structures [20]. Data were collected using a two-step control system. The quality and completeness were firstly verified by a senior physician at the time of discharge and secondly by an independent quality control group. In case of data discrepancy, the hospitals were asked to verify and correct data. Items in the database contain the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) codes. Data for this study were extracted by removing all information related to a patient's identification. Because data were anonymized and irreversibly de-identified, this study did not need approval from the Swiss ethics committee, according to the Swiss Federal Act on Research involving Human Being (810.30, Art. 2, 2) [21].

2.2. Screening methods and management of women with GDM

During period 1 (2005–2010), women were selectively screened based on risk factors for GDM and diagnosed with the two-step approach: usually, after 12 h of fasting, a 50 g oral glucose challenging test was performed. If glycemia after one hour was greater than 7.2 mmol/l, a 75 g or 100 g OGTT was carried out [22]. A GDM diagnosis was given with at least two values equal to or above the thresholds 5.3 mmol/l fasting, 10.0 mmol/l at 1 h, 8.6 mmol/l at 2 h or 7.8 mmol/l at 3 h. However, the use of alternative defined OGTT thresholds were at the discretion of caregivers [23].

During period 2 (2012–2017), women were screened by switching gradually to the IADPSG criteria: a 75 g OGTT was performed on all women after an overnight fast. A GDM diagnosis was confirmed if one value was equal to or above the following thresholds: 5.1 mmol/l fasting, 10.0 mmol/l at 1 h, 8.5 mmol/l at 2 h [24]. In both periods, women underwent screening between the 24 and 28 weeks gestational age or later if it was not possible before.

Follow up treatment protocols were similar between the two periods: Women diagnosed with GDM were referred to a multidisciplinary team including obstetricians, midwifes, diabetologists, dietitians, and nurse educators for glucose monitoring, treatment initiation, nutritional and lifestyle therapy. Regular check-ups to maintain optimal glycemic control were carried out by the primary gynecologist and if necessary, insulin treatment was introduced. In case of complications from GDM, women were referred to a secondary level care setting.

2.3. Risk factors, GDM-related events, and perinatal outcomes

Women were considered at risk for GDM if at least one of the following criteria was fulfilled: maternal age over 35, pregestational BMI over 30 kg/m^2, multiple gestations, conception by assisted reproductive technology, smoking during

pregnancy, chronic hypertension, priori macrosomia or non-Caucasian origin.

The following ICD-10 diagnoses were assigned to GDM-related events: pre-eclampsia (blood pressure ≥ 140/90 mmHg with proteinuria of at least 0.3 g/24 h) (O14, O14.1), large-for-gestational-age infant (birthweight > 90th percentile according to Nicolaides *et al.*, 2018 [25], obstructed labor due to shoulder dystocia (O66.0), transitory neonatal hypoglycemia (<2 mmol/L) (P70.4).

All other perinatal outcomes were defined as the following (ICD-10 codes in brackets): induction of labor (physical, systemic/vaginal prostaglandin use), cesarean delivery (primary, secondary and elective cesarean section) (O82), instrumental vaginal delivery methods (vacuum extraction and forceps) (O81), small-for-gestational-age infant (birthweight < 10th percentile according to Nicolaides *et al.*, 2018) [25], neonatal intensive care unit admission (NICU admission), respiratory distress of newborn (P22.9), stillbirth and infant death up to seven days post-partum (P95) were defined as early neonatal death [26], preterm delivery (<37 weeks of gestation).

2.4. *Statistical analysis*

To examine how the prevalence of GDM developed before and after the adoption of the IADPSG screening criteria, the annual frequency of GDM diagnoses was calculated and adjusted for maternal age, pre-pregnancy BMI ≥ 30 kg/m^2, parity, history of smoking during pregnancy, and Caucasian origin. GDM prevalence, GDM-related events and perinatal outcomes were analyzed by comparing data in period 1 (2005–2010) and period 2 (2012–2017), i.e. six years before and after the implementation of the IADPSG screening criteria in Switzerland. The year of the introduction of the new criteria (2011) was not included in the analysis. Estimates for relative risks (RR) and 95% confidence intervals (CI) associated with this implementation were derived from multivariable logistic regression for outcomes with a prevalence < 10% and multivariable poisson regression for outcomes with a prevalence ≥ 10% [27]. All analyses were performed using R version 3.4 [28].

3. Results

In this analysis a total of 325,530 pregnant women were included, with 155,103 in period 1 and 170,427 in period 2. Even though women in both periods were comparable, there were slightly fewer smokers in period 2 (5.8% vs. 6.2%; p < 0.001) and fewer women with pregestational BMI over 30 kg/m^2 (6.8% vs. 7.4%; p < 0.001). Women in period 2 were also slightly older. The prevalence of GDM in period 2 was three times higher (8.3% vs. 2.7%; p < 0.001) when compared to the first period (Table 1).

The prevalence of GDM over the whole study period is presented in Fig. 1. The prevalence of GDM increased steadily over both study periods from 1.8% to 9.0%, while showing the greatest increase between 2010 and 2012 from 3.3% to 5.9%. GDM prevalence during the study period showed similar trends when adjusted.

The presence of either one or multiple risk factors was associated with a higher rate of GDM and of GDM-related events in both periods (Fig. 2). Relative risks calculated for each level of risk factor revealed a stronger effect of period (1 vs. 2) on GDM prevalence in women without risk factors (1.4% vs. 5.3%; RR 3.75 (CI 3.54,3.99)) than in women with 3 or more risk factors present (12.5% vs. 28.4%; RR 2.28 (CI 1.84,2.84)) (Fig. 2 A). The opposite pattern could be observed for GDM-related events, where the new screening criteria had no effect in women without risk factors (9.8% vs. 9.6%; RR 0.98 (CI 0.95,1.01)) but a small effect in women with one or two risk factors present (RR 0.93 (CI 0.90,0.97), RR 0.90 (CI 0.83,0.96)) (Fig. 2B).

A comparison of perinatal outcomes between the two study periods is shown in Table 2. While relative risk of labor outcomes strongly related to GDM such as shoulder dystocia (RR 1.16 (1.06–1.26)) and cesarean section (RR 1.04 (1.02–1.05)) were increased from period 1 to period 2, no significant difference was found for preeclampsia (RR 0.99 (0.93–1.05)). Furthermore, for the neonatal outcomes: the number of newborns large for gestational age, pre-term delivery and neonatal hypoglycemia, all three outcomes associated with GDM, significantly decreased from study period 1 to period 2 (LGA: RR 0.93 (0.91–0.95), preterm birth: RR 0.94 (0.92–0.97), neonatal hypoglycemia: RR 0.83 (0.77–0.90)). However, no positive effect could be observed for other outcomes typically associated with GDM, for example respiratory distress or neonatal intensive care unit admission.

4. Discussion

The new IADPSG recommendation for screening of GDM was implemented in Switzerland in 2011 to standardize screening procedure for all pregnant women [24]. The new criteria allow a more strict and sensitive screening that include all pregnant women, regardless of their predisposition to GDM. However, the more stringent criteria have been reported to rise prevalence and potentially increase the cost of care [29,30]. In the current study, we observed that the prevalence of GDM increased by more than a factor of 4 from 2005 to 2017, and by 3 comparing the two study periods. This rise of prevalence is in line with previous studies after the new criteria were adopted [11,31,32]. In Spain, GDM prevalence increased 3.3 times (10.6–35.5%), in the USA 2.8 times (5.5–15.6%) and 4.5 times in Japan (2.9–13%) using the IADPSG criteria [13,33,34]. A large increase in GDM prevalence can also be attributed to other factors, however, we observed a similar pattern in our data when controlling for maternal age, pre-pregnancy obesity and other relevant population characteristics. Moreover, the largest increase occurred during the period of implementation of the new criteria. Therefore, it is reasonable to assume that the increase in GDM prevalence is at least partly due to the adoption of the new diagnostic criteria, potentially as the more sensitive and less selective testing includes more women with no risk factors and less severe forms of GDM [35].

Although, the HAPO study confirmed that GDM related complications correlate in a continuous fashion with levels of maternal hyperglycemia there is no conclusive evidence

Table 1 – Baseline characteristics. Data are mean ± SD or count (%). Period 1 (2005–2010) and period 2 (2012–2017).

Characteristics	period 1 N = 155103	period 2 N = 170427	*p*-value
Maternal age (years)	30.7 (5.18)	31.5 (4.94)	<0.001
Parity			<0.001
1	74162 (47.8%)	83,061 (48.7%)	
2	55,437 (35.7%)	61,489 (36.1%)	
3	19,185 (12.4%)	19,885 (11.7%)	
4+	6319 (4.1%)	5992 (3.5%)	
Birth weight in gram	3352 (516)	3350 (512)	0.316
Caucasian origin	143,446 (92.5%)	157,419 (92.4%)	0.210
Pre-pregnancy BMI $\geq$ 30 kg/m^2	11,531 (7.4%)	11,556 (6.8%)	<0.001
Smoking during pregnancy	9612 (6.2%)	9913 (5.8%)	<0.001
Gestational diabetes mellitus	4259 (2.7%)	14,147 (8.3%)	<0.001
Without risk factors for GDM	91,281 (58.8%)	97,113 (57.0%)	0.160

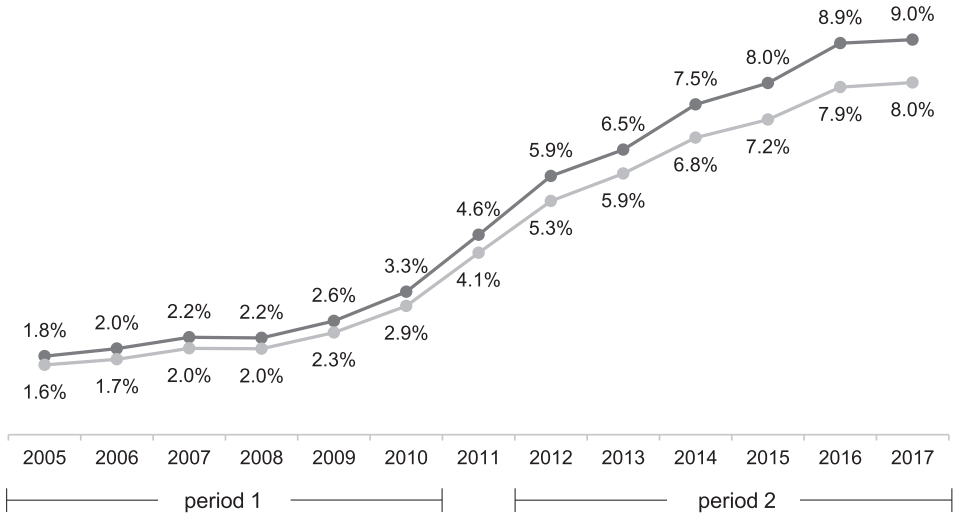

Fig. 1 – Prevalence of gestational diabetes in women with singleton deliveries in Switzerland from 2005 to 2010 (period 1). Unadjusted prevalence (black line) and prevalence adjusted for maternal age, pre-pregnancy BMI $\geq$ 30 kg/m2, smoking during pregnancy, and Caucasian origin (grey line).

yet if screening also women without risk factors and treating milder cases leads to better perinatal outcomes [7,36,37]. A recent Swiss study by Gariani *et al.*, 2019 observed significantly greater number of women who could achieve a good glycemic control without the need for insulin therapy with the use of the new criteria. However, there was no difference in the occurrence of most adverse perinatal outcomes associated with milder GDM cases [35]. Slightly more than half of the women in our population exhibited of no risk factor for GDM and were included in the screening by adopting the IADPSG criteria. Nevertheless, despite substantial increase in GDM testing in this population, and almost four times more women without risk factors diagnosed, treating those women did not translate in better pregnancy outcomes. Overall, the number of risk factors is clearly associated with GDM prevalence and the risk for GDM-related events. It was suggested that multiple risk factors would be very specific for GDM screening in selective approaches [38]. Interestingly, however, our study shows that in period 2 frequency and relative risks of GDM related events are slightly reduced with increased GDM risk factors pre-disposition. This may suggest that not identifying women with GDM because they were not eligible to screening might not be as detrimental as missing out cases of women with risk factors suffering from mild hypoglycemia. A study of Hung *et al.* showed that risk factors for GDM differ with the diagnostic criteria used [14]. They assumed that with lower thresholds for GDM diagnosis women with mild glucose intolerance triggered by other metabolic disorders and previously regarded as not having diabetes by the two-step were identified with the one-step method used by the IADPSG criteria [14]. Including and treating more mild cases of hypoglycemia in Switzerland with the new criteria slightly reduced GDM related events only in women with risk factors. Therefore, it could be argued that linearity of relationship between adverse outcomes and glycemia and thresholds set at OR1.75 by the HAPO study might differ with risk factor predisposition of the screened population [7].

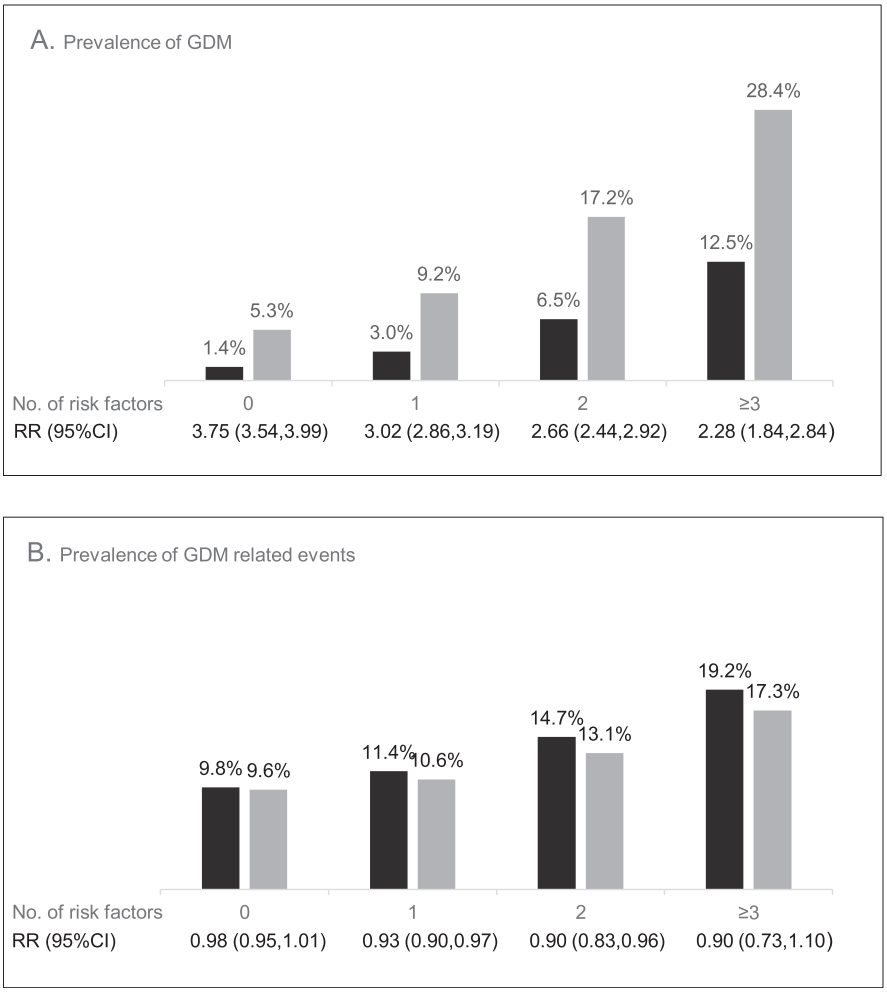

Fig. 2 – Prevalence of gestational diabetes in pregnancy (A) and GDM-related events (B) by the number of risk factors for GDM in period 1 (2005–2010, black) and period 2 (2012–2017, grey). For each level of risk factors present (0, 1, 2, ≥3), data are % or relative risks (RR) with 95% confidence intervals (CI) for changes in period 2 vs period 1. GDM-related events included at least one of the following diagnosis: preeclampsia, shoulder dystocia, neonatal hypoglycemia, large-for-gestational age infants.

Nevertheless, a recent *meta*-analysis of randomized controlled trials provided evidence that the one step approach significantly improves perinatal outcomes independently of risk factors [39]. Their main findings were a reduction of 54% in LGA, 51% in NICU admission, 48% in neonatal hypoglycemia. Consistently, we showed that women screened with the one step approach had a slightly decreased risk of neonatal outcomes linked to GDM, including LGA, neonatal hypoglycemia und preterm birth. However, no significant changes in the risk reduction of NICU admission were found. It is likely that including more mild cases in a GDM therapy not requiring insulin by adjusting maternal diet and physical activity, may results in fewer newborns having LGA or neonatal hypoglycemia but would be less effective on other labor outcomes [40].

Several other observational studies have explored the changes in perinatal outcomes associated with hyperglycemia during two successive periods of time [31,32,41–43]. But few studies exhibit of a large enough sample size to detect changes in adverse perinatal outcomes by comparing the total population. In Japan, despite a substantial rise in GDM diagnosis frequency from 2.9% to 13%, a significantly decreased odds were only observed for NICU admission and neonatal hypoglycemia [34]. With a similar change in GDM prevalence (2.6% vs. 9.7%), the introduction of the IADPSG criteria resulted in reduction in incidences of LGA, macrosomia and hypertensive disorders in Slovenian pregnant women [43].

Although some studies show slight improvements in selected perinatal outcomes it remains unclear whether these improvements can counterbalance the costs of treating more pregnant women with milder hyperglycemia. In this study, the prevalence of GDM almost quadrupled in the large group of women without risk factors, with no reduction in the number of GDM-related events. By contrast, Duran et al. concluded that the IADPSG criteria resulted in a significant decrease of multiple adverse perinatal outcomes [13]. In particular, reductions of frequency in NICU admission and cesarean deliveries accounted for cost effectiveness over increased GDM prevalence [13]. However, it should be noted that GDM prevalence (35.5%) and risk factors occurrence in this Spanish population were particularly high compared to those reported

Table 2 – Comparison of perinatal outcomes of period 1 (2005–2010)and period 2 (2012–2017). Data are n (%) or adjusted relative risks (RR) with 95% confidence intervals (CI) for changes after the implementation of the IADPSG criteria (period 1/period 2) and the association of perinatal outcomes to GDM during (period 1 and period 2 combined/ GDM). Poisson (prevalence ≥ 10%) or logistic (prevalence < 10%,) models adjusted for maternal age, pre-pregnancy BMI ≥ 30 kg/m^2, ethnicity, parity and smoking during pregnancy. ‡ additionally adjusted for cesarean section.

Outcomes	period 1	period 2	period 1/period 2			period 1 and period 2 combined/ GDM		
	N = 155103	N = 170427	RR	(95% CI)	*p*	RR	(95% CI)	*p*
Comorbidities								
preeclampsia	1884 (1.21%)	2047 (1.20%)	0.99	(0.93–1.05)	0.6413	1.17	(1.04–1.31)	0.0108
Labor outcomes								
Instrumental vaginal delivery‡	18,125 (11.7%)	19,459 (11.4%)	0.95	(0.93–0.97)	<0.001	1.00	(0.96–1.06)	0.8437
Induction of labor	30,207 (19.5%)	32,352 (19.0%)	0.98	(0.97–1.00)	0.0470	1.69	(1.64–1.74)	<0.001
Cesarean section	43,159 (27.8%)	50,551 (29.7%)	1.04	(1.02–1.05)	<0.001	1.17	(1.14–1.20)	<0.001
Epidural anesthesia	41,620 (26.8%)	48,307 (28.3%)	1.05	(1.04–1.07)	<0.001	1.04	(1.01–1.08)	0.0042
Fetal heart rate abnormality	34,840 (22.5%)	42,169 (24.7%)	1.08	(1.07–1.10)	<0.001	1.02	(0.99–1.16)	0.1623
Prolonged labor	9890 (6.4%)	13,994 (8.2%)	1.28	(1.25–1.31)	<0.001	1.01	(0.96–1.07)	0.7179
Failure to progress in labor	10,059 (6.5%)	10,573 (6.2%)	0.92	(0.90–0.95)	<0.001	1.02	(0.96–1.08)	0.5420
Shoulder dystocia	1000 (0.6%)	1245 (0.7%)	1.16	(1.06–1.26)	<0.001	1.68	(1.44–1.94)	<0.001
Neonatal outcomes								
LGA	14,857 (9.6%)	14,930 (8.8%)	0.93	(0.91–0.95)	<0.001	1.43	(1.38–1.48)	<0.001
SGA	17,158 (11.1%)	19,007 (11.2%)	1.00	(0.98–1.02)	0.7628	0.87	(0.83–0.92)	<0.001
5′ Apgar score ≤ 7	7613 (4.9%)	10,187 (6.0%)	1.21	(1.17–1.24)	<0.001	1.10	(1.03–1.17)	0.0035
Neonatal hypoglycemia (<2 mmol/L)	1184 (0.8%)	1193 (0.6%)	0.83	(0.77–0.90)	<0.001	2.68	(2.37–3.02)	<0.001
Respiratory distress of newborn	6106 (4.0%)	7544 (4.4%)	1.11	(1.08–1.15)	<0.001	1.27	(1.18–1.35)	<0.001
Intensive care unit admission	6681 (4.3%)	7359 (4.3%)	0.99	(0.96–1.02)	0.6185	1.28	(1.20–1.37)	<0.001
Early neonatal death	702 (0.5%)	677 (0.4%)	0.87	(0.78–0.97)	0.0089	0.76	(0.57–0.97)	0.0379
Preterm delivery (<37 weeks of gestation)	8959 (5.8%)	9437 (5.5%)	0.94	(0.92–0.97)	<0.001	1.18	(1.12–1.26)	<0.001

in our and other studies study population [32,34,41,43]. Conclusively, countries with high GDM prevalence and risk factor burden might benefit most from adopting of the IADPSG screening criteria to substantially improve perinatal outcomes to an extent of being able to ignore the drawbacks of increased medical cost. Further investigations will be needed to examine this cost benefit standpoint.

The strength of this study is that we retrieved data from a large sample size involving no less than 30% of all women that have giving birth in Switzerland over 12 years. However, a limitation of this study is that although, we included known confounders in our statistical models, there is still the possibility that other factors may have influenced the outcome over time and the effects cannot be solely attributed to the introduction of the new IADPSG screening strategy. Moreover, our study is limited to the analysis of perinatal outcomes, improvements in long term health of both mother and child that would be a second aim of GDM treatment was not examined. Furthermore, uniformly defined and standardized GDM screening in Switzerland was missing before the introduction of the IADPSG recommendation in 2011. Therefore, in this study we cannot determine the impact of different glucose values thresholds with the new criteria. However, before 2011, all clinics in Switzerland had performed according to a risk-based two-step GDM diagnostic procedure with two values over the threshold needed for diagnosis.

We conclude that in our sample, implementing IADPSG criteria resulted in a significant reduction of risks for LGA, neonatal hypoglycemia and preterm birth. However, there was no substantial improvement in GDM-related events for women without risk factors with the adoption of the new criteria, but up to a threefold increase in GDM prevalence. Nevertheless, we showed that women with risk factors might slightly benefit from a more sensitive screening.

Further research will be required to determine the validity of the IADPSG diagnostic criteria in Switzerland from a cost benefit perspective.

Acknowledgements

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Authors Contributions

E.A. and S.O designed the study, analyzed and interpreted the data, and wrote the manuscript. L.R. contributed to the design of the study, to the acquisition of the data and interpretation of the data. All co-authors critically revised the manuscript.

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