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REVIEW

Pharmacological management of gestational diabetes

Abordaje farmacológico de la diabetes gestacional

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ABSTRACT

Recent studies indicate that metformin achieves glycemic control comparable to insulin and is associated with lower weight gain and a reduced risk of maternal hypoglycemia; however, it presents a greater need for insulin rescue. Nevertheless, metformin may be associated with higher therapeutic failure rates requiring rescue insulin. Glyburide presents the least favorable risk–benefit profile, potentially being associated with worse neonatal outcomes, such as hypoglycemia and macrosomia, compared with metformin or insulin. Objective: To synthesize current evidence on the comparative efficacy and safety of insulin, metformin, and glyburide in the management of Gestational Diabetes Mellitus (GDM). Methods: A systematic search was conducted in databases (PubMed/PMC, ScienceDirect, MDPI) to identify recent systematic reviews, meta-analyses, and randomized controlled trials (2018–2025). Study selection was guided by PICO criteria and followed PRISMA methodology. Maternal outcomes (glycemic control, weight gain, hypoglycemia) and neonatal outcomes (macrosomia, neonatal hypoglycemia, neonatal intensive care unit admission) were evaluated. Results: 11 studies that met the search criteria were included. According to the findings obtained, the systematic review provided a more detailed overview of the evidence. Recent data confirm the efficacy and safety of pharmacological treatment in gestational diabetes, highlighting primarily the use of metformin as a valid alternative to insulin due to its good adherence and lower cost. Insulin remains the reference treatment, especially in cases with poor glycemic control. In contrast, glyburide shows a higher maternal and neonatal risk. Long-term research is required to assess the metabolic effects on offspring exposed to metformin during pregnancy. Conclusion: Metformin emerges as an effective, short-term safe, and patient-preferred option, representing a first-line alternative to standard insulin therapy.

Keywords: Gestational Diabetes Mellitus, Metformin, Insulin, Glyburide

RESUMEN

Estudios recientes indican que la metformina alcanza un control glucémico equiparable al de la insulina y se asocia a menor ganancia de peso y menor riesgo de hipoglucemia materna; no obstante, presenta una mayor necesidad de rescate con insulina. Sin embargo, la metformina puede asociarse a una mayor tasa de fracaso terapéutico que requiere insulina de rescate. La gliburida presenta el perfil riesgo-beneficio menos favorable, asociándose potencialmente a peores resultados neonatales, como hipoglucemia y macrosomía, en comparación con metformina o insulina. Objetivo: Sintetizar la evidencia actual sobre la eficacia y seguridad comparada de la insulina, metformina y gliburida en el manejo de la Diabetes Mellitus Gestacional (DMG). Métodos: Se realizó una búsqueda sistemática en bases de datos (PubMed/PMC, ScienceDirect, MDPI) para identificar revisiones sistemáticas, metanálisis y ensayos clínicos aleatorizados recientes (2018-2025). La selección de estudios se guió por los criterios PICO y siguió la metodología PRISMA. Se evaluaron los resultados maternos (control glucémico, ganancia de peso, hipoglucemia) y neonatales (macrosomía, hipoglucemia neonatal, ingreso a UCI neonatal). Resultados: Se incluyeron 11 estudios que cumplieron los criterios de búsqueda. De acuerdo con los resultados alcanzados, la revisión sistemática permitió obtener una visión más detallada de los estudios. La evidencia reciente confirma la eficacia y seguridad del tratamiento farmacológico en la diabetes gestacional, destacando principalmente el uso de metformina como alternativa válida a la insulina por su buena adherencia y menor costo. La insulina continúa siendo el tratamiento de referencia, especialmente en casos con mal control glucémico. En contraste, la gliburida muestra mayor riesgo materno y neonatal. Se requiere investigación a largo plazo para evaluar los efectos metabólicos en la descendencia expuesta a metformina durante la gestación. Conclusión: La metformina emerge como una opción eficaz, segura a corto plazo y preferida por la paciente, siendo una alternativa de primera línea al tratamiento estándar con insulina.

Palabras clave: Diabetes Mellitus Gestacional, Metformina, Insulina, Gliburida

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is recognized as an impairment of glucose tolerance first diagnosed during pregnancy, in accordance with the guidelines of the WHO and the International Association of Diabetes and Pregnancy Study Groups (IADPSG). (1,2) This concept describes a transient but clinically relevant condition that requires timely diagnosis and adequate metabolic control.

The initial therapeutic approach is invariably nutritional therapy and increased physical activity. If these conservative measures fail to achieve optimal glycemic control within a reasonable timeframe, pharmacological intervention is required. (3)

Pharmacological options can be prioritized as follows:

Insulin: The traditional "gold standard." Its safety stems from its inability to cross the placental barrier in significant amounts. Disadvantages include the complexity of administration (injections), higher cost, and a potential association with greater maternal weight gain. (4,5)

Oral Agents: The use of oral antidiabetics, primarily metformin (Category B) and glyburide (Category C, sulfonylurea), has grown due to their convenience, cost, and patient acceptance. (6) Concerns center on their placental transfer and the unknown long-term impact. (2)

The need to clarify the optimal therapeutic approach in light of the proliferation of comparative studies justifies this review. The objective of this study is to synthesize the evidence on the comparative efficacy and safety of different pharmacological agents in the management of GDM. (7,8)

PATHOPHYSIOLOGY

During pregnancy, the progressive increase in placental lactogen, cortisol, progesterone, and estrogens induces physiological insulin resistance. This adaptation promotes glucose availability for the fetus; however, in women with metabolic susceptibility, the pancreatic beta-cell response is insufficient, leading to gestational hyperglycemia. The combination of reduced peripheral sensitivity and a relative defect in insulin secretion explains the rise in blood glucose levels in the second and third trimesters, with a direct impact on fetal growth and the risk of complications. (1,8)

This alteration is associated with additional mechanisms, including decreased incretin action (GLP-1 and GIP), the establishment of a chronic low-grade inflammatory state, increased oxidative stress, and mitochondrial dysfunction, which impair insulin signaling in skeletal muscle, the liver, and adipose tissue, genetic, and epigenetic factors may predispose to this response, while obesity and excess free fatty acids amplify peripheral insulin resistance. The result is maternal hyperglycemia, which causes fetal hyperglycemia and hyperinsulinemia, promoting macrosomia and increasing the risk of metabolic complications for both mother and child. (2,9)

RISK FACTORS AND COMPLICATIONS

Gestational Diabetes Mellitus is associated with multiple predisposing factors of maternal, metabolic, and environmental origin. Early detection during prenatal care enables targeted preventive interventions and reduces perinatal morbidity.

Some risk factors may be exogenous, maternal, pregnancy-related, familial, or spousal in origin, as shown in Table 1.

Once the disease is diagnosed or the presence of relevant risk factors for its onset is identified, it is necessary to act quickly to prevent or treat it appropriately, as it can lead to numerous complications for both the mother and the fetus. As described earlier, these complications can cause the pregnant woman to develop medium- to long-term metabolic and obstetric complications.

Some of the mentioned complications affect both the mother and the fetus, as described in Figure 1.

DIAGNOSIS

Gestational Diabetes Mellitus (GDM) is defined as an impaired glucose tolerance first diagnosed during pregnancy, in accordance with WHO and IADPSG guidelines. (1,2) This concept describes a transient but clinically relevant condition that requires timely diagnosis and adequate metabolic control.

Diagnosis is based primarily on the 75-g oral glucose tolerance test (OGTT), performed between 24 and 28 weeks of gestation, using the defined cut-off points for fasting blood glucose, at 1 and 2 hours, according to current international criteria.

However, the authors note considerable heterogeneity in the screening protocols and diagnostic criteria applied in the included primary trials, which hinders the comparability of results and limits the extrapolation of conclusions to broader populations. (7,8)

Some studies specify post-diagnostic treatment goals—for example, fasting blood glucose levels of ≤ 90–100 mg/dL and postprandial levels of ≤ 120–126 mg/dL—although these values refer to treatment management, not to the initial diagnosis.(1,2)

The reviewed studies agree that the timely detection of hyperglycemia during pregnancy is essential to prevent perinatal complications and optimize maternal-fetal outcomes.

PREVENTION

In the analyzed articles, primary prevention of GD (preventing its onset) is not the central focus of the reviewed evidence. Instead, most studies focus on preventing complications once the diagnosis has been established, which corresponds to a secondary prevention approach. (1,2)

Several systematic reviews maintain that maintaining strict glycemic control is the most effective intervention for reducing maternal-fetal complications, particularly macrosomia, neonatal hypoglycemia, the need for intensive care admission, and preeclampsia. (10)

In this context, pharmacological treatments other than insulin—particularly metformin—are associated with comparable or superior maternal-fetal outcomes and lower maternal weight gain, while maintaining safety and glycemic control efficacy. (2,10)

The network systematic review in BMC Endocrine Disorders (2021) ranks metformin as the option with the highest probability of therapeutic success and the lowest risk of neonatal complications, reinforcing its role in secondary prevention within the management of GDM.(7)

Table 1. Risk factors associated with gestational diabetes mellitus.

Exogenous	Sedentary lifestyle, smoking, use of hyperglycemic medications.
Maternal	Advanced maternal age, obesity, polycystic ovary syndrome, hypertension, excessive weight gain during pregnancy.
Pregnancy-related	Multiple pregnancy, polyhydramnios.
Family	Family history of diabetes mellitus.
Spouse	Partner with obesity or type 2 diabetes, shared unhealthy habits.

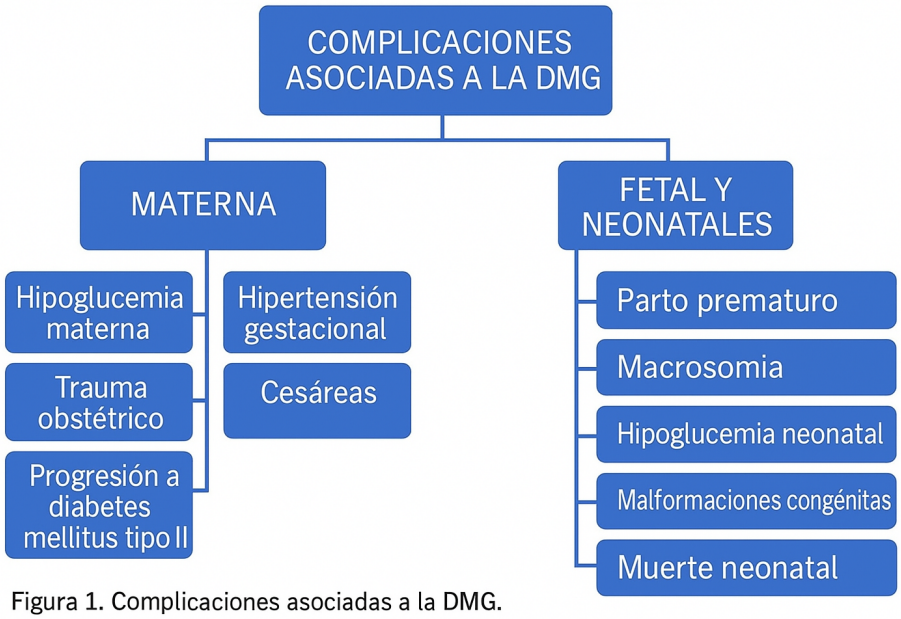

Figura 1. Complicaciones asociadas a la DMG.

Figure 1

Table 2. Secondary prevention methods (pharmacological segment and fetal complications)

Category	Main Strategies
Pharmacological	Metformin treatment as a safe alternative to insulin; reduces macrosomia, neonatal hypoglycemia, and preeclampsia, while maintaining efficacy in glycemic control.
Prevention of r fetal complications	Frequent obstetric and ultrasound monitoring, early therapeutic adjustment, and scheduled delivery based on metabolic control and fetal growth.

MATERIALS AND METHODS

The protocol for this review was developed in accordance with the PRISMA statement.

Eligibility Criteria (PICO):

Population (P): Pregnant women diagnosed with gestational diabetes mellitus.

Intervention/Comparison (I and C): Insulin vs. Metformin, Insulin vs. Gliburide, Metformin vs. Gliburide, or combination therapy.(3,7)

Outcomes (O): Maternal (glycemic control, glycated hemoglobin, weight gain, maternal hypoglycemia, risk of hypertensive disorders) and Neonatal (macrosomia, neonatal hypoglycemia, admission to the Neonatal Intensive Care Unit [NICU], preterm birth).(4)

Search Strategy: Searches were conducted in databases (PubMed/PMC, ScienceDirect, MDPI, etc.) using a predefined combination of keywords (e.g., metformin, insulin, glyburide, gestational diabetes, systematic review).

Selection and Data Extraction: The process of screening articles and extracting outcome data was performed in a standardized and independent manner by two reviewers (if applicable to your thesis), ensuring the integrity of the information.

Risk of Bias Assessment: The methodological quality of the primary studies, primarily randomized controlled trials (RCTs), was assessed using the Cochrane Risk of Bias Tool (RoB 2.0) (or the instrument you use), ensuring the validity of the synthesized evidence.

This systematic review included articles that met the inclusion criteria and also the exclusion criteria, as shown in Table 3.

Table 3. Inclusion and exclusion criteria (systematic review – GDM)

INCLUSION CRITERIA	EXCLUSION CRITERIA
Articles published in peer-reviewed scientific journals between 2018 and 2025.	Studies or articles published outside the established period (2018–2025).
Open, full, and free access to the text of the selected articles.	Works that do not provide full access to the text, or that only present abstracts or partial excerpts.
Studies analyzing pharmacological treatments for Gestational Diabetes Mellitus (GDM), including comparisons between insulin, metformin, and glyburide, either as monotherapy or in combination.	Studies with insufficient methodology or without a direct comparison between pharmacological treatments.
Articles addressing the comprehensive management of GDM and reporting maternal and neonatal clinical outcomes, such as glycemic control, macrosomia, or neonatal hypoglycemia.	Duplicate publications, narrative reviews without systematic analysis.

RESULTS

Recent scientific evidence consistently supports the efficacy and safety of pharmacological treatment for gestational diabetes mellitus, highlighting the clinical and academic importance of the topic.

The literature review allowed for the collection of up-to-date and relevant information, with the aim of identifying the most effective and safe therapeutic strategies for glycemic control during pregnancy.

It provides a comprehensive overview of the different pharmacological alternatives available, as well as their maternal and neonatal implications.

In total, eleven scientific articles that met the pre-established selection criteria were included. The results were organized and classified by year, study title, and research objectives (see Table 4).

Table 4 – Studies included in the systematic review

No.	Title	Publication date	Authors	Objective
1	Metformin versus insulin in gestational diabetes: a systematic review.	September 9, 2024	Giovanna Noronha Berti, Igor Gutschov Oviedo Garcia, João Pedro Ruas Floriano de Toledo, Júlia Rodrigues Tatemoto, Lais Watanabe Marino, Mariana de Medeiros Legori, Sérgio Floriano de Toledo	To evaluate the use of metformin, alone or in combination with insulin, compared to insulin alone for the treatment of gestational diabetes, analyzing maternal and neonatal outcomes.
2	Efficacy and safety of pharmacological treatments for gestational diabetes: a systematic review comparing metformin with glibenclamide and insulin.	March 2025	Louise Bodier, Maela Le Lous, Hélène Isly, Christèle Derrien, Patricia Vaduva	To evaluate the efficacy and safety of pharmacological treatments used in gestational diabetes, comparing maternal and neonatal outcomes associated with metformin, glibenclamide, and insulin.
3	Cardiometabolic outcomes in children of women treated with metformin versus insulin for gestational diabetes: systematic review and meta-analysis.	September 2024	Dimple Rawat, Yashdeep Gupta, Arun Kumar Yadav, Manoj Kumar Tembhre, Priyanka Das, Saisree Bakkireddy, Neeta Singh, K. Aparna Sharma, Rinchen Zangmo, Avdhesh Chandra, Ashish Datt Upadhyay, Deepali Garg	To investigate the impact of two pharmacological interventions (metformin and insulin) on cardiometabolic outcomes in the children of women with gestational diabetes.

No.	Title	Publication date	Authors	Objective
4	Metformin for the treatment of gestational diabetes: What have we learned over the past two decades? Systematic review.	January 20, 2025	Angeliki Gerede, Ekaterini Domali, Christos Chatzakis, Chrysoula Margioula-Siarkou, Stamatios Petousis, Sofoklis Stavros, Konstantinos Nikolettos, Evanthia Gouveri, Sotirios Sotiriou, Panagiotis Tsikouras, Konstantinos Dinas, Nikolaos Nikolettos, Nikolaos Papanas, Dimitrios G. Goulis, Alexandros Sotiriadis	To analyze the evidence published over the past 20 years regarding the efficacy and safety of metformin compared with insulin or other drugs for the treatment of gestational diabetes.
5	Meta-analysis of the use of metformin and insulin on maternal and neonatal outcomes in patients with gestational diabetes.	December 2024	Rui Wu, Qingqing Zhang, Zuojing Li	To compare the effect of treatment with metformin versus insulin on maternal and neonatal outcomes in patients with gestational diabetes.
6	Use of insulin during gestational and pre-existing diabetes in pregnancy: a systematic review of study designs.	March 18, 2024	Kristin Castorino, Beatrice Osumili, Theophilus Lakiang, Kushal Kumar Banerjee, Andrea Goldyn, Carolina Piras de Oliveira	To analyze the available evidence on the use of insulin in pregnancy (gestational and pre-existing diabetes), evaluating methodological designs and reported clinical outcomes.
7	Long-term impact on offspring (ages 5 to 11 years) of metformin use during pregnancy in mothers with diabetes: systematic review and meta-analysis.	June 12, 2024	Deep Dutta, Meha Sharma, Lakshmi Nagendra, Saptarshi Bhattacharya, Ritin Mohindra, Chittaranjan S. Yajnik	To assess the long-term impact (5–11 years) of metformin use during pregnancy in mothers with gestational or pre-existing diabetes, analyzing anthropometric and metabolic parameters.
8	Comparative efficacy and safety of glyburide, , metformin, and insulin in the treatment of gestational diabetes: protocol for a systematic review and meta-analysis.	March 18, 2022	Jing Lin, Rong-zu Tu, Xun-yu Hong	To establish a protocol for comparing the efficacy and safety of treatment with glyburide, metformin, and insulin in gestational diabetes through a systematic review and meta-analysis.
9	Metformin versus glyburide in the treatment and management of gestational diabetes: systematic review with meta-analysis.	February 16, 2022	Marina Martins de Oliveira, Kayan Felipe de Oliveira Andrade, Giovanni Henrique Silva Lima, Thiago Casali Rocha	To compare the clinical outcomes of metformin and glibenclamide use in gestational diabetes, evaluating efficacy, safety, and maternal and neonatal effects.

No.	Title	Publication date	Authors	Objective
10	Metformin is comparable to insulin as a pharmacological treatment for gestational diabetes: a network meta-analysis evaluating 6,046 women.	May 2021	Omran A.H. Musa, Asma Syed, Aisha M. Mohamed, Tawanda Chivese, Justin Clark, Luis Furuya-Kanamori, Chang Xu, Egon Toft, Mohammed Bashir, Abdul Badi Abou-Samra, Lukman Thalib, Suhail A. Doi	Comparing the efficacy of metformin and glyburide versus insulin in the treatment of gestational diabetes using a network meta-analysis.
11	Glycemic control and neonatal outcomes in women with gestational diabetes treated with glyburide, metformin, or insulin: a paired and network meta-analysis.	May 25, 2018	David C. D. Barrett, Yingtian Hu, Jiwon Park, Lena M. Olsrud, Chao Song, Linda S. A. Oude-Luttikhuis, Sivamurthy Padmanabhan	To compare the impact of glyburide, metformin, and insulin on maternal glycemic control and neonatal outcomes in gestational diabetes.

DISCUSSION

The findings of this review, based on the synthesis of multiple recent meta-analyses, reinforce the role of metformin as a safe and effective alternative to insulin for the pharmacological treatment of GDM. (7,11) The practical and logistical advantages of metformin are notable, including the convenience of oral administration, which improves patient adherence, and a considerable reduction in costs compared with insulin. (6)

Insulin remains the gold standard of care and is irreplaceable in patients with poor initial glycemic control or in whom metformin fails, as it is the only medication that ensures the fetus is not exposed to significant concentrations of an antidiabetic drug. (4,9)

Glibenclamide is consistently less favored in clinical guidelines due to its association with a higher risk profile for the mother (hypoglycemia) and the newborn (macrosomia). (1,6,7)

The primary concern and a crucial area for future research is the longitudinal follow-up of offspring exposed to metformin in utero. It is essential to evaluate its long-term impact on the risk of obesity and T2D in 5- to 10-year follow-up cohorts to make fully informed clinical decisions. (6,9)

CONCLUSION

This systematic review confirms the importance of pharmacological treatment in gestational diabetes mellitus (GDM) and updates our understanding of available therapeutic management.

Metformin stands out as a safe and effective option, with glycemic control similar to that of insulin and additional advantages, such as less weight gain, lower risk of hypoglycemia, and better adherence due to its oral administration and low cost.

Insulin remains the standard of care for cases of poor metabolic control or metformin treatment failure, while glyburide has a less favorable profile and is recommended with caution.

The need for new longitudinal studies evaluating the long-term effects of fetal exposure to metformin is emphasized to ensure the safety and optimize future therapeutic strategies.

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