Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i3.5030

THE ROLE OF PHARMACISTS IN MANAGING GESTATIONAL DIABETES MELLITUS: A DESCRIPTIVE REVIEW

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Abstract

Background: The management of diabetes poses challenges due to the array of available medications and the absence of comprehensive comparative trials. To address this, the Spanish Diabetes Society commissioned a Working Group to create a dynamic document tailored to national context.

Objective: The document emphasizes individualized treatment decisions by healthcare providers, considering patient characteristics and treatment safety. Regular updates ensure alignment with evolving evidence and expert insights.

Key Aspects:

1. Goals of Control: Initial treatment typically involves lifestyle modifications and metformin. For patients with HbA1c above 8.5%, insulin therapy may be initiated, possibly in combination with oral medications. Stepwise adjustments and close monitoring are essential to optimize patient outcomes and minimize complications.
2. Inertia Therapy: Monitoring metabolic control, tolerance to treatment, and associated complications are crucial after therapy initiation. Regular reassessment and adjustments are necessary to maintain optimal control.
3. Staggered Therapeutic Approaches: Medication choice is influenced by factors such as HbA1c levels, risk of hypoglycemia, and patient characteristics. Various alternatives to metformin, including sulfonylureas, DPP-4 inhibitors, glinides, thiazolidinediones, and basal insulin, are considered based on individual patient responses.

4. Combination Therapies: Combinations of medications, such as metformin with sulfonylureas, DPP-4 inhibitors, or GLP-1 receptor agonists, are explored for efficacy and safety. Insulin therapy is considered in cases of poor metabolic control or intolerance to oral medications.
5. Treatment Algorithms: Algorithms guide the sequential addition of medications based on patient response, aiming to achieve optimal metabolic control while minimizing adverse effects.

Conclusion: The comprehensive framework outlined in the document aims to guide clinicians in navigating the complexities of diabetes management. It emphasizes individualized treatment approaches tailored to patient needs and safety considerations, with regular updates to reflect evolving evidence and expert consensus.

INTRODUCTION

a few scientific organizations 1-6 agreed with suggestions for control goals, dosage staging for various medications, and tailoring both to the patient's characteristics. Given the challenge created by the lack of randomized clinical trials with sufficient power that directly compare the many advised therapy regimens, some concordances, and differences exist among them. Due to this, the Board of Directors of the Spanish Diabetes Society (SED) decided to ask our Working Group to create a document that would, as closely as possible, tailor the available data and various recommendations to the context of our nation. The doctor will always be in charge of determining the best course of treatment since they must tailor it to each patient's specific needs. The Working Group has considered the need for this document to be dynamic and updated regularly in accordance with new evidence and recommendations from the SED members.

GOALS OF CONTROL

As demonstrated by numerous studies with long-term follow-up, both in patients with type 1 diabetes (DCCT/EDIC)7 and type 2 diabetes (UKPDS), achieving adequate metabolic control can avoid or delay the onset of microvascular and macrovascular problems.8. However, tight glycemic control may increase mortality (ACCORD) in patients with well-developed diabetes, advanced sequelae, or significant concomitant pathologies in addition to preventing cardiovascular disease (ADVANCE9 y VADT10) (Yang, Min et al. 2023). This is why it is advised to attain very rigorous control in the early stages of treating diabetes (glycosylated hemoglobin [HbA1c] 6.5%), provided the patient is under the age of 70, has extensive micro or macrovascular problems at the time of diagnosis, or has any of the following conditions (Erukulapati, Ganguri et al. 2023) .

7.5%, or at its best, giving the treatment's safety, suitability for the patient's condition, and compatibility with related drugs a top priority. After around ten years of progression, most patients will need combined treatment, often with insulin, when monotherapy treatment is typically insufficient. Unless the traditional objective of 7% is feasible while prioritizing security, it may be wise to raise the control target to one HbA1c 7.5%. It is important to remember that hyperglycemia is another cardiovascular risk factor for diabetes patients, along with other risk factors, including dyslipidemia, hypertension, obesity, and smoking. These will significantly influence whether problems develop and if the patient survives (Fujihara and Sone 2023).

INERTIA THERAPY

Some factors need to be evaluated after the start of therapy or if therapeutic modifications have been made, including metabolic control, as determined by measuring HbA.1c and using capillary glycemia profiles (when indicated), tolerance to the improvements made, and the development of associated complications and pathologies. After the acute phase of treatment adjustment, all of this will be done every three months, at the very least, until the situation stabilizes. All patients will then be reassessed at least twice a year once the goals have been met. Suppose the changes made weren't beneficial regarding the control target after the first three months, and there weren't any coexisting diseases or drug use to support it. In that case, Maintaining good meta-control embolism, especially in patients with a short period of evolution, who may be asymptomatic despite not having achieved control

objectives. The main barriers to the intensification of treatment can occur when the therapeutic change requires additional diabetes education; for example, with the introduction of secretagogues or insulin, situations that we must anticipate to avoid unnecessary delays (Meneghini 2023).

To the same extent that it is critical to plan the necessary treatment modifications in the event of acute concurrent processes (febrile syndromes, vomiting, diarrhea, etc.) that may result in a certain degree of dehydration or difficulties with eating, it is equally critical to plan for these processes to occur. These procedures may render the patient's standard of care hazardous and necessitate quick revision (Adam, McIntyre et al. 2023).

STAGGERINGTHERAPEUTIC

Metformin, sulfonylureas, glinides, thiazolidinediones, disaccharidase inhibitors, dipeptidyl-peptidase 4 (DPP-4), and peptide receptor agonists are only a few of the medications currently available for the treatment of diabetes. One glucagon-like peptide [glucagon-like peptide-1 [GLP-1]] can be used alone or in combination with insulin. These medications should only be taken after carefully reading their associated data sheets; some associations have shown their safety, some associations are not advised, and long-term safety is unknown in other associations (ElSayed, Aleppo et al. 2023). The ability to lower HbA1c, the risk of inducing hypoglycemias and the level of prior control, the impact on body weight and dyslipidemia, the preferential effect on basal or prandial glycemia, the complications or associated pathologies that the patient presents, the risk of hypoglycemia, the patient's age, and the patient's overall health will all influence the treatment option (Hinnen, Kruger et al. 2023).

The initial course of medication will change based on how well the condition is under control. 2010; 2(4): 154-161 COMMUNITY PHARMACISTSRomero González and C. Fernández-Santos. Prescription drug recommendations for the management of hyperglycemia in type 2 diabetes. The presence of accompanying diseases and concurrent drug usage. The algorithm (Figure 1) shows that treatment typically begins with one medicine and progresses to two drugs in the second stage. Finally, if the level of patient control necessitates it, salinization or triple therapy may be required (Jacob, Leschke et al. 2023).

FIRST STEP

PATIENTS WITH HBA$_{1c}$ FROM 6.5 TO 8.5

Sometimes, the control target (HbA1c\<6.5%) can be achieved with lifestyle modifications[14]. However, this approach is not always practical since it depends on the characteristics of the patient and their degree of adherence to the recommendations. For this reason, the SED advises from the beginning to associate metformin concomitantly with most patients.[15,16]. In any case, delaying the introduction of metformin for more than three months is not advisable if the control objective is not achieved (Naseralallah and Aboujabal 2023). To improve tolerance to this drug, a progressive titration of the dose is recommended.[17]; for example, with half a tablet of 850-1,000 mg initially, increasing to half a tablet every 12 hours after 4-5 days if there is good tolerance, and so on until reaching a dose of 850-1,000 mg every 12 hours. If intolerance is observed, it should be reduced back to the previously tolerated dose, and the increase should be reattempted over a more extended time (Dao, Choi et al. 2023).

As alternatives to treatment with metformin, in case of contraindication or intolerance, the following are proposed:

• First alternative: sulfonylureas.

Potent secretagogues have a considerable risk of hypoglycemia with an HbA control1c goal of less than 6.5%, while this risk varies depending on the active component used18–20. Because of this, it is advised to consider a cautious dose titration and to utilize prolonged-release gliclazide or glimepiride instead of glibenclamide or chlorpropamide (TILINCA, SZEKELY et al.). According to

specific research, sulfonylureas cause secondary beta-cell degeneration before taking gli bowls or metformin21. Additionally, they are linked to weight gains of 1-3 kg22,23. Some recommendations advise against using them during this treatment phase (Malkani and Aroda 2023).

• Second alternative: DPP-4 inhibitor.

If metformin is not tolerated, they offer clear advantages in this treatment phase. In monotherapy, they pose a negligible risk of hypoglycemia and do not affect the patient's weight.24,25. The most significant barriers to its use now are its high cost and the absence of studies proving its long-term usefulness and safety. Only sitagliptin has received approval for this indication so far.26, even though permission for other active principles from the same family is still pending.27,28 (Erukulapati, Ganguri et al. 2023).

• Third alternative: glinides.

The reply nida29 is the option in this phase. Nateglinide should be taken with other medications because of its potency and pharmacodynamic properties30. Although it shares many of the same drawbacks as sulfonylureas in theory, some patients who have dietary and exercise abnormalities may respond better to it because of its unique properties and administration style (Yang, Min et al. 2023).

• Fourth alternative: thiazolidinediones or glitazones.

They take between 10 and 12 weeks to reach their peak effectiveness and efficacy in reducing HbA.1c, comparable to sulfonylureas and metformin (Williams, Uddin Ansari et al. 2023). Whether or whether there are differences between rosiglitazone and pioglitazone, as has been shown in certain observational studies, potential adverse effects include weight gain, edema, anaemia, fractures, and heart disease failure.36, thus, the matter is still up for debate until the results of investigations directly compare the two molecules. Patients with severe metabolic syndrome37 and non-alcoholic fatty liver disease38 may benefit from them more (Fujihara and Sone 2023).

• Fifth alternative: disaccharidase inhibitors.

Own less potent than those mentioned so far and, in monotherapy, are not associated with hypoglycemia. Its most significant limitation is intestinal intolerance, which makes it necessary to suspend treatment in many patients.[39]. Their most considerable benefit is that they seem to improve cardiovascular risk (STOP-NIDDM)40 significantly. Two preparations have been marketed: acar bosa and miglitol (Meneghini 2023).

• Sixth alternative: basal insulin.

They are reserved in this step for patients who present contraindications for the use of oral drugs.

INITIAL TREATMENT FOR PATIENTS WITH HBA_{1C} >8,5%

Treatment with insulin must typically begin in patients with many hyperglycemia symptoms (cardinal symptoms and weight loss at the time of debut)41–43. Insulin may be used alone or in combination with metformin. Probably, insulin requirements will gradually decline after early control and improvement in glucose and lipotoxicity. In some situations, power can be maintained with oral medications, either in monotherapy or combination. In asymptomatic individuals, it is advised to begin with metformin and titrate more quickly. Depending on the response, a second medicine may then be added, managing the short-term evolution to modify the long-term course of treatment (Adam, McIntyre et al. 2023).

SECOND STEP

In patients whose control objectives have not been achieved or who, after a period of reasonable control, present deterioration due to the evolution of their diabetes (without any other pathology or drug that increases blood glucose being associated), it is necessary to combine a second drug. Most drug associations suffer from a lack of long-term comparative studies, which makes decision-making difficult. In principle, it is recommended that the associated drugs have a different and complementary

mechanism of action. Depending on the response, the dose should be increased to the maximum practical amount, slightly less than the maximum allowed dose (ElSayed, Aleppo et al. 2023). It should also be borne in mind that the contraindications and limitations.

TABLE 1 MAIN CHARACTERISTICS OF ORAL ANTIDIABETICS

No
• No weight gain
• Improves lipid profile and other cardiovascular risk markers • Decreases mortality and complications
macrovascular disorders in obese patients (UKPDS)
• Decrease in
microvascular complications (UKPDS/ADVANCE)
• Not contraindicated in mild-moderate renal failure • Reduces postprandial blood glucose
• Not contraindicated in moderate renal failure • Pioglitazone improves the lipid profile and other markers of cardiovascular risk
• Glycemic control more
long-lasting (versus metformin or sulfonylureas)
• No weight gain
• Reduce blood glucose
he ate
• Decreased mortality and complications
cardiovascular
• No weight gain
• They reduce above all the
postprandial blood glucose
• Weight loss
• BP decrease
• Enhancement of lipids
• Above all, they reduce postprandial blood glucose
• Adverse effects
digestive (registered dose)
• Lactic acidosis
(very rare)
• interferes with the
vitamin B12 absorption
• Weight gain
• Duration of effectiveness
hypoglycemic lower than metformin and glitazones
• Weight gain
• Do not associate repaglinide with gemfibrozil
• Weight gain
• Edema
• Increased incidence of heart failure
• Increase in limb fractures in women
• 6-12 weeks are needed to assess the maximum effect
• Adverse GI effects
• Low efficacy if a diet low in GH
• Hypoglycemia should
treated with pure glucose
• Cases of acute pancreatitis have been reported
• Long-term safety and benefits unknown
• Vildagliptin: not indicated with insulin, monotherapy, or triple therapy
• Subcutaneous administration • Adverse effects
digestive (nausea,
vomiting, diarrhea)

• Cases of acute pancreatitis have been reported
• Long-term safety and benefits unknown
• Not indicated with insulin, neither in monotherapy nor in triple therapy
• FG <60 mL/min
• Severe heart failure • Hepatic failure
• Respiratory failure • Alcoholism
• Use of iodinated contrasts
• Severe renal failure (GFR <30 mL/min)
• Severe liver failure • Allergy to sulfonamides
• Severe liver failure
• Heart failure
• Liver failure
• Rosiglitazone:
- Ischemic heart disease
- Peripheral vascular disease - Combined with insulin
• Miglitol
- FG <60 mL/min
• Acarbosa
- FG <30 mL/min
• Severe liver failure • Chronic intestinal disease
• FG <50 mL/min
• Vildagliptina:
- Liver failure
o ALT o AST >3 x LSN
• FG <30 mL/min
• Severe gastrointestinal disease

GFR: glomerular filtration rate; GI: gastrointestinal; HC: carbohydrates.
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COMBINATIONS WITH METFORMIN •Sulfonylureas and glinides.
The most researched combination has shown both its efficacy and safety to be metformin and sulfonylurea.42–45. At the same time, there is still debate over the increase in mortality in some subgroups of patients who began treatment with sulfonylureas and in whom metformin was associated in a second step, as noted in the UKPDS46. This issue has been covered in some observational studies., 47–51, which had some differences in their findings; conversely, their results might not have been superimposable with those attained using the most recent preparations. The same guidelines are still advised because the hazards for the control objective (HbA1c 6.5%) are comparable to those seen with monotherapy. Due to their brief duration of effect, glides are a good sulfonylurea substitute in patients with more irregular intakes.
of repaglinide[54].

• **DPP-4 inhibitors.** Together with the GLP-1 receptor agonists, they form a novel group of secretory gogos that act on both secretory.

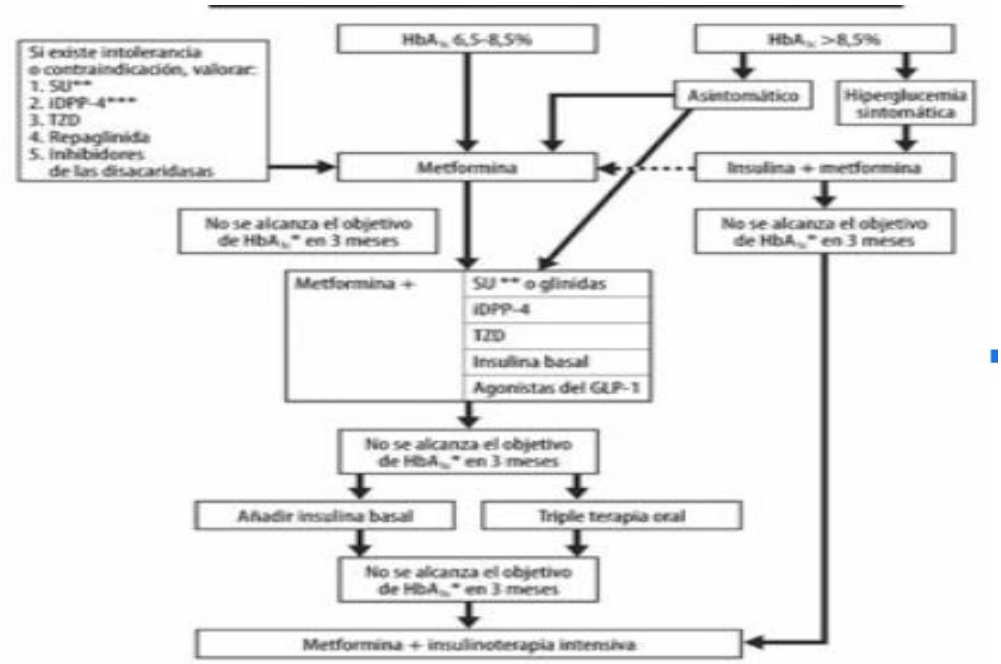

FIGURE 1 ALGORITHM OF THE SPANISH DIABETES SOCIETY ON THE PHARMACOLOGICAL TREATMENT OF HYPERGLYCEMIA IN TYPE 2 DIABETES

On that of glucagon as on that of insulin. They are superior to sulfonylureas and glinides due to their minimal risk of hypoglycemia and weight neutrality55,56. Its long-term safety and impact on the development of diabetes and its consequences are unknown, despite this. Regarding the decrease of HbA, its potency does not appear to be less than that of sulfonilureas.1c57,58. They might be the patients' first choice when hypoglycemia is not a viable alternative (Hinnen, Kruger et al. 2023).

• GLP-1 receptor agonists.

They are parenterally administered medications with a more substantial and longer-lasting effect on GLP-1 receptors than DPP-4 inhibitors. They have been demonstrated in published research to enhance short-term glycemic control, particularly postprandial blood glucose and, to a lesser extent, basal blood glucose.59. They achieve sustained weight loss in a sizable number of patients by slowing down stomach emptying, causing a sense of satiety.60,61. Additionally, they succeed in enhancing a few vascular risk factors62. Our nation has marketed Exenatide for parenteral administration twice daily (before the main meals, with at least a six-hour gap between the two), associated with metformin and sulfonylureas and metformin with glitazones[63], in patients with a body mass index greater than 30 kg/m^2 (ElSayed, Aleppo et al. 2023). At the time of writing this guide, the lira glutida is pending commercialization[64]Therefore, and we recommend studying its datasheet to assess its indications and limitations of use. They can be an instrumental group of drugs in patients in whom obesity is an actual problem, but their role compared to other medications or other treatment approaches, such as surgery, remains to be defined (Jacob, Leschke et al. 2023).

Thiazolidinedione.

They differ from metformin because they increase insulin sensitivity and are usually used in combination 65-68. In theory, the indication would concentrate on individuals with elevated baseline glycemia and good prandial glycemic control that metformin does not resolve. The limits are kept the same as in monotherapy because the side effects are similar to those of each medicine used alone (Dao, Choi et al. 2023).

Insulin basal.

Basal insulin and metformin represent promising therapeutic approaches with established efficacy and safety.69-71. It is best used on people with reasonable glucose control but an HbA1c over the

recommended level. Even though this regimen has more hypoglycemia, they are still far less frequent than those seen in patients receiving multiple insulin doses. It is a good alternative for individuals whose treatment options with glitazones are limited (Malkani and Aroda 2023).

• Disaccharidase inhibitors.
Its combination with metformin is risk-free because hypoglycemia won't happen, but its effectiveness is restricted because drops in HbA1c can't easily surpass 0.5%72. Digestion intolerance is its biggest drawback. It is not advised to be used in place of a second medicine in this healing phase due to all of these factors.

Third Step
In patients treated with two drugs with poor metabolic control, the following therapeutic step is salinization. Except for cases of insulin resistance, there are no "advantages" to delaying the introduction of insulin into the therapeutic regimen after the failure of dual combination therapy. The long-term benefit and safety of triple oral therapy versus insulin are uncertain since follow-up in the different clinical trials is not beyond 12 months.

Non-Insulin Combinations
The relationship between metformin, sulfonylurea, and glitazone is the most well-studied and often utilized among oral medications' various and legitimate associations. Therefore, it would be advised in most patients with type 2 diabetes whose condition was poorly controlled by dual therapy.73-77 (Doucet, Guérin et al. 2023). The combination of metformin, repaglinide, and glitazone may be safer for older patients78. The most logical substitutes for glitazone-limited people would be metformin plus sulfonylureas plus DPP-4.79 or metformin plus repa glinide plus DPP-480, albeit these options have the drawback of being less researched (ElSayed, Aleppo et al. 2023).

Combinations With Insulin
Most individuals have been treated with metformin and secretagogues in combination. Basal insulin will be connected in this instance. The control objective will be amended to less than 7.5% or the most significant achievable level that is patient-safe if the evolution time has exceeded ten years and problems or concurrent diseases have emerged. According to the 4T trial findings, this regimen can produce a period of reasonable control. Still, not one that lasts for too long. 81 Most patients will need an increased insulin regimen within three years. In this situation, it is advised to discontinue the remaining oral antidiabetic medications and continue metformin-insulin therapy (Doucet, Guérin et al. 2023).

Fourth Step
Regarding the possibility of quadruple therapy, whose approach (due to the different pathophysiological paths from the pharmacological point of view) is feasible, we consider that, at present, this possibility falls more into the field of research than in that of clinical practice (Mannucci, Gallo et al. 2023) .

CONCLUSIONS
Once lifestyle modifications have been made, the aim of drug therapy for type 2 diabetes will be to achieve optimal metabolic control while maintaining the highest level of safety. An HbA1c of 6.5% in the early stages of the disease and 7.5% in more advanced settings or with a risk of hypoglycemia should be considered the objective (Mannucci, Gallo et al. 2023). Metformin is the medication of choice when hyperglycemia (HbA1c: 6.5-8.5%) is not extreme. Other alternative medicines will only be utilized in cases of intolerance or contraindication. When hyperglycemia is severe (HbA1c > 8.5%), insulin infusions or a combination of various oral medications must be used as the first line of treatment (Williams, Uddin Ansari et al. 2023).

A second medicine with synergistic effects is added as the second phase. There are numerous solutions for this, which must be customized based on each patient's traits. The third and last phase entails the introduction of basal insulin as the preferred alternative to triple oral medication, which will only be used in cases of salinization resistance (Khadanga, Barrett et al. 2023).

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