REVIEW ARTICLE

How should clinicians and patients choose antihyperglycemic agents?

An evidence-based approach

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KEY WORDS

antihyperglycemic agents, clinical decision making, patient-centered care, type 2 diabetes

ABSTRACT

The choice of antihyperglycemic agents has become more complex as new drug classes have appeared and evidence about their efficacy and safety accumulates. Unfortunately, direct and fair comparisons are lacking and the clinician and patient are left to decide among agents with different safety and burden profiles. Furthermore, the relative efficacy of these agents beyond their ability to lower hemoglobin A_{1c} – that is, in their ability to reduce the risk of diabetes complications – remains uncertain. In this sea of uncertainty, interests other than those of the patient actively shape choices. It is our expectation that better evidence, better policy and better decisions will eventually become routine in the care of patients with diabetes.

Antihyperglycemic agents in an evidence desert

In 2011, there is an ever-increasing range of antihyperglycemic options for the treatment of patients with type 2 diabetes. Agents from more than 10 drug classes cover a broad range of mechanisms thought to affect glycemia, including insulin release, insulin action, glucagon secretion, gut motility, carbohydrate absorption, and urinary glucose handling. This physiologic range and the fact that most patients require more than one agent to achieve glycemic goals invites the use of combinations. The result of multitude of choices challenges clinicians and their patients to ask: how shall we choose?

The choice of which antidiabetic agent to use in a given patient is one that could be very easy to answer if we had high-quality evidence comparing their short- and long-term effect on outcomes that matter to patients including benefits, harms, and inconveniences.

Alternatively, one could consider only the ability of these agents to reduce glycemia. As such it should then be expected that the benefits of glycemic control would follow the use of an effective antihyperglycemic agent. There are two problems with this alternative. The first one refers to the range of effects of antihyperglycemic treatments. The second one is the state of knowledge about the benefits of pharmacologically induced normoglycemia.

Until recently, effective glucose reduction – with sulfonylureas and insulin – was associated with increased risk of hypoglycemia. In this narrow sense, antihyperglycemic agents have always required careful use. Also, knowledge of this effect led to selective use of available agents: clinicians generally avoid long-acting sulfonylureas in patients at high risk of hypoglycemia, such as the elderly. Unfortunately, and this is a key concept in modern diabetology, the effects of therapeutic agents on glycemia do not fully capture their impact on patients, i.e., these agents have nonglycemic actions that cause important adverse effects, including mortality. Also, there appears to be no net benefit of pharmacologically aided normo- or near-normoglycemia in patients with type 2 diabetes using contemporary therapies.[1]

This brings us back full circle: we need high-quality evidence comparing their short- and long-term effect on outcomes that matter

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TABLE Comparison of available antihyperglycemic agents[3]

Drug A	Drug B	Decrease in HbA_{1c}	Weight gain	Likelihood of hypoglycemia
Met	SU	A = B	A <B	A <B
Met	TZD	A = B	A <B	NA
Met	DPP-4	A >B	A <B	NA
Met	Meg	NA	NA	A<B
SU	Meg	A = B	A = B	A =B
SU	TZD	A = B	A <B	A >B
SU	GLP-1	NA	A >B	A >B

Abbreviations: DPP-4 – dipeptidyl peptidase 4 inhibitors (e.g., sitagliptin, saxagliptin), GLP-1 – glucagon-like peptide 1 analogues (e.g., exenatide, liraglutide), HbA_{1c} – hemoglobin A_{1c}, Meg – meglitinide (e.g., repaglinide, nateglinide), Met – metformin, NA – not available/applicable, SU – sulfonylureas (e.g., glipizide, glyburide, glimepiride), TZD – thiazolidinediones (e.g., pioglitazone, rosiglitazone)

to patients[2] including benefits, harms, and inconveniences.

The latest evidence summary A recent systematic review of the available evidence comparing antihyperglycemic agents found that the available evidence was quite sparse, both for new and old agents, rarely assessed their impact on patient-important outcomes, and whatever evidence exists it is fraught with imprecision and inconsistency.[3] This is the best available evidence; an evidence-based approach must make use of this science, along with available mechanistic knowledge, to find a medicine that best fits the biology of the specific patient.

Interestingly, the recent systematic review focused on deriving head-to-head conclusions for both monotherapy and for second-line agents. Due to the inclusion criteria requiring that more than one agent be compared (i.e., no placebo-controlled trials), inferences for newer agents – all of which were compared against placebo – are limited. In addition, the authors suggest that the length of typical trials were brief and thus, long-term outcomes could not be assessed. Nonetheless, this review concludes that metformin is the best first-line agent and all two-drug combinations were similarly effective at reducing hemoglobin A_{1c} (HbA_{1c}) levels. Overall, monotherapy typically reduces HbA_{1c} by one percentage point, with greater reductions achieved proportional to the baseline HbA_{1c}, i.e., higher HbA_{1c} will be associated with larger HbA_{1c} reductions (TABLE).

The nature of choosing antihyperglycemic agents Unfortunately, glycemic control is not the only or most important goal for most patients with diabetes,[2] and the biology of the specific patient is not the only or most important context to consider in choosing a diabetes agent. We put forward that patients with diabetes value living their lives as healthy people, able to seek dreams, care for loved ones, and pursue challenges unhindered by symptoms or side effects, disease complications or treatment burdens. Thus, these goals – and their priority for each specific patient – must be considered in choosing a diabetes drug.

One important aspect of these medicines is their cost to the user. In the United States, the out-of-pocket costs for the patient for these medicines can range from 5 cents per day to 10 dollars per day, making cost an important determinant of which agent to use. Newer agents and those not yet available in generic form are most expensive. Most newer agents (glitazones, gliptines [dipeptidyl peptidase 4 inhibitors] and other incretins such as glucagon-like peptide 1 [GLP-1] analogues) lower glucose in a glucose-sensitive way, i.e., they are associated with a negligible risk of hypoglycemia (and thus require minimal glucose monitoring), something they share with biguanides (metformin) and α-glucosidase inhibitors, two older drug classes. Weight loss is most common with injectable GLP-1 analogues; gliptins and metformin are weight neutral; glitazones and sulfonylureas lead to weight gain. Additional considerations include the need to self-monitor glucose and how they are used (route and frequency of dosing). There appears to be small differences in the extent to which these agents lower HbA_{1c} (most powerful [HbA_{1c} reductions in the 1%–2% range] appear to be metformin, sulfonylureas, and glitazones; insulin is by far the most powerful glucose-lowering agent).

In addition to these considerations, clinicians need to keep up to date with revelations of long-term consequences of these agents.

1 Metformin has accumulated some evidence suggesting that it may have beneficial cardiovascular[4] and anticancer effects.[5] That this agent can cause lactic acidosis is poorly supported by indirect and weak evidence.[6] In patients with renal function impairment, caution often calls for restricting the use of metformin, but the threshold for discontinuation requires careful consideration of the remote yet potential risk of lactic acidosis against the disadvantages of the alternatives. Its main side effects appear to be gastrointestinal and, often, short-lived.

2 For some time, uncertainty existed about the cardiovascular effects of sulfonylureas. There

appears to be insufficient evidence to confirm the concern that emerged most clearly from the UKPDS trial (United Kingdom Prospective Diabetes Study), but that concern remains.[7]

3 In the last few years, the spotlight has been on glitazones. Both agents available in this drug class have been associated with an increased risk of heart failure.[8] Also, they reduce bone mineral density and in at-risk patients, e.g., postmenopausal women, can increase the risk of fragility fractures.[9] Rosiglitazone appears to increase the risk of myocardial infarction by about 40% (comparable but in opposite direction to the magnitude of risk reduction expected with high-dose statins).[10] Pioglitazone may also increase the risk of bladder cancer.[11]

4 Data is accumulating supporting the safety of incretins, while some concerns have recently emerged from data reported by clinicians to the Food and Drug Administration (FDA) about an increased risk of pancreatitis and pancreatic cancer with these agents.[12]

5 The use of insulin glargine, common in patients with type 2 diabetes, has been controversially associated with an increased risk of cancer.[13]

Pathophysiological explanations exist to support all these effects. When taken together, it is clear that: 1) patients are choosing between drugs with potentially important side effects of different impact; 2) to offset these adverse effects, important benefits must also result from their use, yet these benefits either do not exist or are yet to be demonstrated.

What should clinicians and patients do? It is difficult to argue for any other drug to be used as first line other than metformin. The main exception would be patients who are very hyperglycemic when first diagnosed. In these patients, insulin is most effective and fast in improving symptoms and achieving glycemic control. But not all patients will place a higher value on fast improvements while placing a relatively lower value on using injectable agents, self-monitoring, and experiencing hypoglycemia even for short periods; for these patients metformin alone or with sulfonylureas is usually sufficient (alongside lifestyle modifications). While there are contraindications to the use of metformin, most are only weakly supported by evidence of harm, and some have been superseded as weak evidence of benefit has emerged (e.g., patients with heart failure)[14].

We believe the patient should choose what agent to add to metformin after they begin experiencing hyperglycemia on metformin or with what to replace metformin if the patient cannot tolerate the drug. Here the distinct safety and burden profile of each of the available agents as we described above calls for patients and clinicians to consider these effects and choose which medicine best fits the patient's context. The careful prescriber should educate patients about the relatively high frequency with which new drugs are ultimately associated with previously unrecognized adverse consequences. Also, prescribers must be candid about their own preferences for these agents, as many may prefer to expose patients to new oral agents of relatively low potency rather than to embark with the patient on initiating insulin.

We have worked to develop interventions for use at the point-of-care that help clinicians and patients consider what is known about diabetes medicines and choose them based on the way they could affect issues patients consider important.[15] Given the paucity of evidence about long-term benefits and harms and short-term benefits (beyond reducing symptoms of hyperglycemia), we focus the conversation on choosing the medicines based on their nonglycemic effects and on the burden their use imposes on patients' daily routines. In a small randomized trial in primary care, we were able to show that these tools were very acceptable to clinicians and patients, patients were more knowledgeable at the time of making a choice, were more engaged in making a choice and doing so did not impact their HbA_{1c} or adherence to therapy.[16] Two larger trials evaluating these tools in primary care clinics are ongoing. These decision aids represent a patient-centered approach to the translation of the comparative effectiveness report.[17]

The alternatives to patient-centered approaches are formulary policies and clinical algorithms. Indeed, the American Diabetes Association and the European Association for the Study of Diabetes have proposed an algorithm that guides clinicians in choosing the ideal drug and drug sequence for most patients.[18] According to this algorithm, all patients without contraindications must start with metformin, with sulfonylureas and glitazones as second-line agents, and incretins as third-line agents. The guidelines recommend initiating insulin as second-line agent among individuals with a HbA_{1c} >8.5% or hyperglycemic symptoms. However, given the impact of initiating insulin on the patient's life, this decision needs to be thoughtfully and jointly considered by the patient and the clinician.

The reality and our hope An analysis of prescriptions written for diabetes drugs in the last few years in the United States shows that rather than a practice-inspired by algorithms or based on patient preferences, the practice appears to reflect the adoption of the latest drugs or drug combinations. This appears particularly problematic given our discussion above of the lack of evidence of safety or efficacy of many of these preparations.

Much discussion comes from the literature. But this literature, we have uncovered, is in great part determined by the financial relationships the authors of published opinions have with for-profit interests. Wang et al.[19] reported a very strong relationship between financial relationships and the direction of opinions about the safety of rosiglitazone and recommendations for its

continued use. These opinions likely delayed the removal of rosiglitazone from the European market and successfully kept this agent available in Canada and the United States. Similar financial interests appear to affect other aspects of diabetes care, including definitional changes, target choices ("HbA_{1c} <7% by 2007"), and extant guidelines.[20]

Large geographic variations also suggest that pharmaceutical detailing, lobbying, and deal-making with formulary administrations and other mechanisms are influencing prescription. Note that after the European removal of rosiglitazone from the market and the FDA restrictions in its use, Americans were still being actively prescribed this drug. In 2010, there were more than 2.5 million prescriptions filled for rosiglitazone in the United States. Prior to that we had observed significant geographical variation in use of these agents.[21] This suggests the role of forces other than clinical needs of the patient.

Finally, experts often feel they have to use the latest agents to both accrue experience with these agents and to impress their patients into thinking they are keeping up-to-date. The only fair way we see to justify this practice is that these clinician preferences are explicitly shared with patients, that the experience is accrued as part of a formal protocol, and that these clinicians retain an instinctive skepticism about marketing claims that may be pushing them to adopt new agents faster than what their wisdom would recommend.

Thus, we have expectations for impartial regulatory agencies less interested in promoting innovation than in promoting safety; for formulary designers less interested in making deals than in ensuring that the pharmacopeia remains conservative; for clinicians who prescribe drugs conservatively and thoughtfully; and for informed and engaged patients who will actively partner in choosing the best antihyperglycemic drug for their specific context. To the extent that these actors work for patients' well being, we see our expectations eventually satisfied. To the extent that health care delivery is seen as a profitable industry, our only hope will be a patient revolution.

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ARTYKUŁ POGLĄDOWY

Jak lekarze i pacjenci powinni wybierać leki przeciwcukrzycowe?

Podejście oparte na danych naukowych

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SŁOWA KLUCZOWE

cukrzyca typu 2, leki hipoglikemizujące, podejmowanie decyzji klinicznych, *patient-centered care*

STRESZCZENIE

Wybór leków hipoglikemizujacych stał się obecnie bardziej złożony niż dotychczas, gdyż pojawiły się nowe klasy leków oraz mamy coraz więcej danych na temat ich skuteczności i bezpieczeństwa. Niestety brak jest bezpośrednich i bezstronnych porównań tych leków i lekarze oraz pacjenci stoją wobec wyboru spośród leków różniących się profilem bezpieczeństwa i obciążeń. Ponadto nadal brakuje pewnych danych odnośnie do ich względnej skuteczności, w tym zdolności do zmniejszania ryzyka rozwoju powikłań cukrzycy, a nie tylko zdolności do zmniejszania odsetka hemoglobiny A_{1c}. Ponadto istotny wpływ na wybór leków mają interesy podmiotów innych niż pacjenci. Mamy nadzieję i oczekujemy, że lepsze dane naukowe, lepsza polityka oraz lepsze decyzje będą podstawą codziennej opieki nad pacjentami z cukrzycą.

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Erratum

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"Conflict of interest: none declared" on page 164 should have read "Conflict of interest: P. Jankowski has received fees and honoraria or funding for lectures, expert panel participation, articles, consultations, conference attendance, and research grants from Astra-Zeneca, MSD, Pfizer, Sandoz, and Sanofi-Aventis. He has also been the organizer of scientific events sponsored, among others, by Abbott, Astra-Zeneca, MSD, Pfizer, and Sanofi-Aventis."

"Nie zgłoszono sprzeczności interesów" on page 171 should have read: "Zgłoszono sprzeczność interesów: P. Jankowski otrzymywał honoraria za wykłady, udział w panelach ekspertów, artykuły, konsultacje, udział w konferencjach, a także granty od firm Astra-Zeneca, MSD, Pfizer, Sandoz i Sanofi-Aventis. Organizował także spotkania naukowe sponsorowane m. in. przez firmę Abbott, Astra-Zeneca, MSD, Pfizer i Sanofi-Aventis."

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