INTERNATIONAL SOCIETY OF DRUG BULLETINS ISDB

Newsletter

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CONTENTS

WELCOME TO THE THIRD ISDB NEWSLETTER OF 2025

This third issue of 2025 includes updates on following ISDB members' published articles:

- An editorial from DTB BMJ (UK) on AI and DTB: the computer says no.
- An article from Cadime (Spain) on evidence for tirzepatide in the treatment of type 2 diabetes mellitus.
- News on various ISDB member publications/activities: menopausal hormone therapy, the rationale for stopping antidepressants and health literacy in a population of migrants and homeless people.

We are looking forward to meet many of you in Verona at the ISDB General Assembly meeting early October (see the program below). Around 30 participants registered. As you know, the General Assembly will elect a new Executive Committee. ISDB is a members-based organization. Its activities depend on the active participation of its members. We are actively looking for candidates for the new committee. We count on you!

Program of the General Assembly (GA), Verona (Italy)

Wednesday, 1st October 2025	
1 pm	Registration
1.30-3.30 pm	Inaugural session: Contextualisation of the ISDB principles in the current environment
3.30 - 4 pm	Coffee break
4-6 pm	Presentation and discussion of the ISDB strategic plan
Evening	Get-Together dinner
Thursday, 2nd October 2025	
9-10.30 am	Health Technology Assessment: a big reform in the European Union with the launch of joint clinical assessments - Challenges for evidence requirements and transparency
10.30-11.00 am	Coffee break
11.00-12.30 am	Training session on "emulated trials". Usefulness, pitfalls and dangers in the use of emulated trials
12.30-2.00 pm	Lunch
2.00 - 4.00 pm	Lessons from the unknown, the expected, the false, the hidden and, maybe, the worthwhile: The Covid-19 vaccines case
4.00-4.30 pm	Coffee break
4.30-6.00 pm	The framing of obesity as a disease and obesity drugs
Friday, 3rd October 2025	
9- 12.30	ISDB internal affairs: GA including the election of a new executive committee

News from ISDB Members

EDITORIAL

AI and DTB: the computer says no

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In an era increasingly defined by technological advancement, the use of artificial intelligence (AI) in clinical, academic and editorial spaces is becoming ubiquitous. Large language models (LLMs), including ChatGPT and its counterparts, now play roles in summarising research, generating plain-language summaries, assisting with data analysis and even proposing drafts for scientific manuscripts. Yet the idea of delegating the responsibility of authoring an editorial—particularly one published in a trusted source such as the *Drug and Therapeutics Bulletin* (*DTB*)—to AI raises a host of concerns, both practical and philosophical.

First and foremost, there is the issue of accountability. Editorials in journals like *DTB* are not just summaries of facts or neutral recitations of evidence. They represent informed judgement. They interpret nuance, challenge orthodoxy and, in many cases, express dissent. Authorship implies not only intellectual ownership but ethical responsibility for the arguments presented. AI, regardless of sophistication, cannot be held accountable for its claims. It cannot justify its reasoning beyond what its statistical models predict as likely continuations of text. This lack of accountability creates a vacuum where no one can be definitively responsible for potential errors, misinterpretations or biased reasoning.

Second, there is the question of bias and trust. While AI models are often seen as neutral or objective, they are only as unbiased as the data they are trained on—and that data includes centuries of human writing, replete with the prejudices, blind spots and cultural assumptions of their time. Moreover, commercial AI systems are black boxes: they provide outputs without transparency about sources, weighting or evidence grading. This runs counter to *DTB*'s commitment to evidence-based, critically appraised and independent analysis. An editorial in such a publication must be anchored in a clearly traceable and verifiable engagement with the literature, something current AI systems cannot robustly deliver without close human oversight.

Relatedly, AI-generated editorials risk homogenisation of thought. LLMs operate by predicting statistically probable continuations based on training data. The result is content that tends to reflect consensus or previously dominant narratives. While this can be useful for summaries, it is antithetical to the purpose of an editorial, which should, at its best, disrupt consensus when warranted, challenge lazy assumptions and provoke critical reflection. *DTB* has a long-standing tradition of scepticism, independence and critical appraisal—qualities that do not easily emerge from models trained to predict the next most likely word.

There is also a practical concern about hallucination, the term used to describe when AI models generate content that seems plausible but is factually incorrect. In medical writing, especially in commentaries on therapeutics, even a single unsupported claim can have serious implications. If AI writes an editorial advocating for a particular clinical approach based on hallucinated data or fabricated references, it undermines both patient safety and the integrity of the publication.

Finally, using AI in this way has broader implications for editorial identity and professional values. *DTB* is more than just a vessel for content; it is a curator of trusted perspectives. Editorials are not just informational—they are cultural artefacts that reflect the values, tone and voice of the institution. Outsourcing that voice to a machine—even a sophisticated one—risks diluting the editorial identity of the publication.

AI has a role in assisting editorial workflows, supporting research and facilitating drafting. But authorship—particularly of editorials—must remain a human responsibility. Editorials should reflect the lived experiences, critical faculties and professional integrity of expert clinicians. To ask AI to write an editorial for *DTB* is, ironically, to miss the very point of what an editorial is for.

This editorial, then, is a paradox: a warning, delivered by the very tool it cautions against. But it underscores the point. AI can assist, perhaps even augment, editorial processes. But to write with conviction, to challenge authority and to speak for a community of practitioners—these remain fundamentally human tasks. *DTB* must continue to champion independent, critical and human-led analysis if it is to maintain its role as a trusted voice in therapeutics. Let us not outsource our judgement to the algorithm.

Editor's note BMJ Journals' policy on the use of AI is available on the website: https://authors.bmj.com/policies/ai-use/

Competing interests None declared. Refer to the online supplementary files to view the ICMJE form(s).

Provenance and peer review Commissioned; externally peer reviewed.

Author note This editorial was written by ChatGPT in response to the following instruction: please write a one-page editorial for the Drug and Therapeutics Bulletin (DTB) that discusses the problems associated with using AI to write an editorial for DTB.

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Evidence for tirzepatide in the treatment of type 2 diabetes mellitus

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Abstract

Tirzepatide (TZP) is a dual agonist of the glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) receptors, administered weekly by subcutaneous injection. In Spain, TZP has been authorised (but not funded) for the treatment of type 2 diabetes mellitus (T2DM) in adults who are not adequately controlled with diet and exercise, as monotherapy when metformin is not appropriate due to intolerance or contraindication, or in combination with other antidiabetic agents. The recommended maintenance doses are 5 mg, 10 mg and 15 mg. The aim of this paper is to summarise the available evidence in terms of efficacy and safety from phase 3 trials.

Efficacy was evaluated in five phase 3 clinical trials (SURPASS 1-5), where tirzepatide (5, 10 and 15 mg) was shown to significantly reduce HbA1c and body weight. When compared with other arGLP-1s, in SURPASS 2, TZP was superior to subcutaneous semaglutide 1 mg, although the 5 mg dose did not reach clinical relevance. In monotherapy, it has been tested against dulaglutide (0.75 mg), showing TZP superiority in terms of significant reductions in HbA1c and weight. It should be noted that no comparisons have been made with higher therapeutic doses of semaglutide or dulaglutide, which may have shown more effective results on glycaemic control compared to TZP.

In terms of its safety profile, tirzepatide is comparable to other arGLP-1s, with gastrointestinal adverse effects being the most common. No cardiovascular benefit has been demonstrated, and data in patients with a body mass index (BMI) <23 kg/m², those over 85 years of age, or those with renal or hepatic impairment are limited. In view of the available data, TZP, compared to other arGLP-1s, does not represent a therapeutic advance in the treatment of type 2 diabetes mellitus (T2DM).

Keywords: Diabetes Mellitus, Type 2; Safety; Tirzepatide

Introduction

The treatment of type 2 diabetes mellitus (T2DM) begins with lifestyle changes. If these measures do not achieve adequate glycemic control, metformin monotherapy is the first pharmacological option, provided there are no contraindications (severe renal impairment (glomerular filtration rate (GFR) < 30 ml/min), hepatic impairment, acute alcohol intoxication, alcoholism, among others) or intolerance (1-3).

When metformin is insufficient to achieve glycemic control, or in the presence of comorbidities, it is recommended to add a second drug, the choice of which will be based on the patient's characteristics and the predominant clinical condition. Thus, in patients with (3):

- Cardiovascular disease (CV), chronic kidney disease or obesity, an iSGLT-2 (selective inhibitors of the renal glucose transporter or gliflozins) or dual agonist of glucagon-like peptide-1 receptor (arGLP-1) is suggested;
- Heart failure: an iSGLT-2;
- Frailty: a dipeptidyl peptidase-4 inhibitor (iDPP-4);
- When there are no clinical conditions, a sulfonylurea (gliclazide or glimepiride), repaglinide or pioglitazone is recommended.

If glycaemic control is poor despite dual therapy, a third drug is recommended. Thus, in cases of hyperglycaemia symptoms, glycosylated haemoglobin (HbA1c) >9-10% or long-standing diabetes, insulin is the treatment of choice (3). (See algorithm in Spanish: https://www.cadime.es/images/documentos_archivos_web/ALGORITMOS/2024/CADIME_ALGORITMO_DM2_2024.pdf).

Tirzepatide (TZP) is a long-acting dual agonist that acts on glucagon-like peptide-1 (arGLP-1) receptors and glucose-dependent insulinotropic polypeptide (GIP) receptors. In Spain, it is authorized (without funding) for the treatment of adults with type 2 diabetes mellitus (DM2) who are unable to maintain adequate levels with diet and exercise, either as monotherapy, due to intolerance or contraindication to metformin (MET), or in combination therapy with other drugs.

Treatment is individualized and staggered. It is administered subcutaneously once a week (in the abdomen, thigh or upper arm), always on the same day, starting with 2.5 mg/week. After four weeks, the dose should be increased to 5 mg/week and can be increased every 4 weeks (by 2.5 mg/week) up to a maximum of 15 mg/week. The recommended maintenance doses are 5, 10 and 15 mg (1, 2). The aim of this paper is to summarise the available evidence in terms of efficacy and safety from phase 3 trials.

Efficacy

The efficacy of TZP has been evaluated in five phase 3 randomized clinical trials (RCTs) (**SURPASS 1-5**). The mean age of participants in the clinical trials ranged from 54.1 to 63.6 years, with women accounting for 45% of participants.

The objective of the SURPASS 1 and 5 trials (double-blind) was to establish the superiority of TZP over placebo, while the objective of the SURPASS 2, 3 and 4 trials (open-label) were to demonstrate non-inferiority and superiority over an active parenteral comparator. The primary endpoint was the change in glycosylated hemoglobin (HbA1c), and secondary endpoints included changes in body weight, lipid profile and quality of life, among others (1,4).

The studies showed a reduction in HbA1c values for all three doses of TZP, without a marked dose-dependent effect. Steady weight losses were observed from the start to the end of the study. All doses of TZP significantly reduced triglycerides and c-VLDL. However, reductions in total cholesterol and c-LDL were not statistically significant compared to semaglutide and insulin degludec (p>0.05). In addition, improvements in quality of life were reported, especially in aspects related to weight loss (1,4).

Subsequently, the **SURPASS-6** RCT (open-label design) evaluated the efficacy and safety of TZP (5, 10, or 15 mg) versus insulin lispro, both combined with insulin glargine, in 1,428 participants (baseline HbA1c: 8.8%) with poorly controlled DM2. At 52 weeks, the reduction in HbA1c with TZP was -2.1% compared to -1.1% with insulin lispro (difference: -0.98%; 95% CI: -1.17% to -0.79%), resulting in non-inferiority. Weight change was -9.0 kg with TZP and +3.2 kg with insulin lispro (difference: -12.2 kg; 95% CI: -13.4 to -10.9) (5).

Table 1. Characteristics of pivotal clinical trials of tirzepatide and efficacy results.

	Surpass-1 (n=478)	Surpass-2 (n=1,878)	Surpass-3 (n=1,437)	Surpass-4 (n=1,995)	Surpass-5 (n=475)
Characteristics					
Baseline medication	Life style	MET	MET± iSGLT-2	1-3 OAD	IGLAR ± MET
Follow-up time	40 weeks	40 weeks	52 weeks	52-104 weeks	40 weeks
Average duration of DM2	4.7 years	8.6 years	8.4 years	11.8 years	13.3 years
Comparator	**Placebo**	**SE_{sc}**	**IDEG**	**IGLAR**	**Placebo**
Baseline HbA1c (%)	7.94 ± 0.87	8.28 ± 1.03	8.17 ± 0.91	8.52 ± 0.88	8.31 ± 0.85
BMI (kg/m^2)	31.9 ± 6.59	34.2 ± 6.93	33.5 ± 6.06	32.6 ± 5.54	33.4 ± 6.06
GFR (mL/min/1,73m^2)	94.1 ± 19.7	96.0 ± 17.1	94.1 ± 17.0	81.3 ± 21.1	85.5 ± 17. 8
Difference between baseline and final HbA1c%§					
TZP 5 mg	-1.75 #	-2.01 #	-1.85 #	-2.11 #	-2.11 #
TZP 10 mg	-1.71 #	-2.24 #	-2.01 #	-2.30 #	-2.40 #
TZP 15 mg	-1.69 #	-2.30 #	-2.14 #	-2.41 #	-2.34 #
Comparator	-0.09	-1.86 #	-1.25 #	-1.39 #	-0.86 #
Difference in weight (kg) at baseline and end of study§					
TZP 5 mg	-6.3 #	-7.6 #	-7.0 #	-6.4 #	-5.4 #
TZP 10 mg	-7.0 #	-9.3 #	-9.6 #	-8.9 #	-7.5 #
TZP 15 mg	-7.8 #	-11.2 #	-11.3 #	-10.6 #	-8.8 #
Comparator	-1.0	-5.7 #	1.9 #	1.7 #	1.6 ‡

BMI: body mass index; **OAD**: oral antidiabetic drug; **IDEG**: insulin degludec; **HbA1c**: glycosylated haemoglobin; **IGLAR**: insulin glargine; **MET**: metformin; **SEsc**: subcutaneous semaglutide 1 mg; **GFR**: glomerular filtration rate (mL/min/1.73 m^2); **TZP**: tirzepatide; (§) Efficacy evaluated as a treatment regimen regardless of adherence to the drug or rescue antihyperglycaemic therapy; (**#**) p<0,001; (**‡**) p<0,01

Regarding the comparison of TZP with other arGLP-1, in SURPASS-2, which is an open-label study comparing subcutaneous semaglutide 1 mg (SEsc) with TZP 5 mg, TZP was statistically superior in reducing HbA1c, but the difference (-0.15%) did not reach clinical relevance, defined as a reduction in HbA1c >0.3%. The 10 mg and 15 mg doses showed greater reductions (-0.39% and -0.45%, respectively). The comparison of TZP versus 2 mg doses of SEsc could have shown a better effect on glycaemic control (1.4), which could represent a bias in favour of TZP (6).

TZP (5, 10, or 15 mg) was also compared with dulaglutide (0.75 mg) in a phase 3 double-blind RCT (SURPASS J-mono) in 636 Japanese patients (baseline HbA1c: 8.2%; and body mass index (BMI): 28 kg/m2), 60% of whom had never received antidiabetic treatment. After 52 weeks, HbA1c decreased by approximately 1% more in the TZP groups than in the dulaglutide group, and the mean change in weight was -5.8 to -10.7 kg in the TZP group versus -0.5 kg in the dulaglutide group. All differences were statistically significant. Dulaglutide can be used at doses up to 4.5 mg, so the dose tested in this RCT may also explain the good results obtained with TZP (6,7).

Safety

The adverse effects of TZP are dose-dependent and very similar to those of arGLP-1, and may lead to treatment discontinuation at a higher rate than SEsc and DU. The most common adverse effects are gastrointestinal (nausea, vomiting, diarrhea, dyspepsia, constipation, and loss of appetite). By delaying gastric emptying, it can alter the oral absorption of medications. Pancreatitis, mild cholelithiasis, and more renal effects have also been reported with TZP than with placebo. The risk of hypoglycemia was low, but increased in patients treated with MET, and more severe cases were observed with TZP than with SEsc. Like other arGLP-1s, it is not recommended during pregnancy (1,2,4,6). People using tirzepatide and oral contraceptives should switch to a non-oral contraceptive method or add a barrier contraceptive method for four weeks after initiation and for four weeks after each dose increase (8).

Unlike SEsc and DU, TZP increased serum calcitonin levels, which precludes ruling out the potential long-term risk of thyroid cancer observed with other arGLP-1s. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) issued a report concluding that the available evidence did not support a possible causal relationship between arGLP-1 treatment and thyroid cancer (9).

Although the possible risk of pancreatic cancer cannot be ruled out, a meta-analysis published in 2024, which included 90 RCTs with a mean follow-up of 3.1 years, found no significant association between arGLP-1 and the risk of pancreatic cancer (RR: 1.05; 95% CI 0.77-1.43) or any type of gastrointestinal cancer (RR: 0.99; 95% CI 0.86-1.13) in both patients with T2DM and obesity (10). Similarly, two population cohort studies found no statistically significant association between exposure to arGLP-1 and pancreatic cancer, both with a follow-up of 7 years (11).

Although patients at risk of diabetic retinopathy complications were excluded from the RCTs, a worsening of eye examinations was observed, and an RCT is currently underway to assess this risk. At the CV level, in SURPASS-4, TZP showed no increased risk, but an RCT is currently underway (SURPASS-CVOT) against DU to demonstrate CV benefits (1,2,4).

Conclusion

TZP is an antidiabetic drug with a dual mechanism of action (GLP-1 and GIP), although the effects linked to the activation of GIP receptors are not yet fully understood. It has been shown to be effective in glycaemic control and weight loss compared to placebo and in association with active comparators in five pivotal RCTs. Based on available data, TZP monotherapy should not be considered the treatment of choice, as there are alternatives with greater long-term experience (1,4,6).

Compared to other arGLP-1s (SEsc and dulaglutide), TZP reduced HbA1c, with statistically significant results in its favour, but not always clinically relevant. TZP has not been tested against arGLP-1 at higher doses: SEsc (2 mg) or dulaglutide (up to 4.5 mg), which could show similar efficacy to TZP. Weight loss was consistent, with a marked dose-response relationship. Its safety profile is comparable to other arGLP-1s. CV benefits continue to be studied, and data on its efficacy and safety in patients with BMI<23 kg/m², age ≥85 years, or renal or hepatic impairment are insufficient (1,4,6).

The American Diabetes Association (ADA) positions TZP as a highly effective drug when the primary goal is glycaemic control (at the same level as high-dose dulaglutide and semaglutide, among others); and highly effective for weight control in patients with DM2 (at the same level as semaglutide), noting that CV and renal effects are still under investigation (12). NICE recommends: a) TZP in triple therapy when MET and two other oral antidiabetic drugs are ineffective or contraindicated and in patients with a BMI ≥ 35 kg/m² and obesity-related comorbidities; or b) with a BMI <35 kg/m², if weight loss improves related complications or insulin has significant repercussions (13).

According to the available information, TZP does not represent a therapeutic advance as it is considered an alternative to other arGLP-1s, depending on the need for HbA1c reduction, weight loss goals or safety profile, as there are drugs with greater experience of use and better-known long-term safety, and proven CV benefits.

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Other publications on various topics: Menopausal Hormone Therapy, the rationale for stopping antidepressants and health literacy in a population of migrants and homeless people

Dr. Fugh-Berman (PharmedOut, USA) and Dr. Barbara Mintzes (Therapeutics Initiative, Canada) published "Menopausal Hormone Therapy: Limited Benefits, Significant Harms" in *American Family Physician*. In this editorial, they summarize the evidence on menopausal hormone therapy.

PharmedOut sent a letter signed by over 75 clinicians, researchers, and scientists demanding that no label changes be made to estrogen products unless the Food and Drug Administration (FDA) holds an advisory committee meeting with unconflicted experts and an opportunity for public comment. You can find the signed letter here. Among others, the letter is cosigned by several ISDB members including Adriane Fugh-Berman and Judy Butler (PharmedOut, USA), Nuria Homedes (Boletin Farmacos, USA), Barbara Mintzes and Thomas Perry (Therapeutics Initiative, Canada).

The 2025 July issue of the Therapeutics Letter (Therapeutics Initiative, Canada) discusses the rationale for stopping antidepressants, and provides guidance on safe and effective deprescribing. It recommends dose tapering tailored to a patient's individual risk, and adjusting an individualized care plan to the clinical response. Successful deprescribing also includes distinguishing withdrawal symptoms from possible relapse of a mental health condition. This Letter offers suggestions from physicians experienced in stopping antidepressants to manage challenging cases such as antidepressant withdrawal-induced akathisia or protracted withdrawal. The letter is available here.

In the 2024 May-June issue, Ricerca&Pratica (Italy) published an article on the level of health literacy in a population of migrants and homeless people. The article is available here.