International Journal of Contemporary Research In Multidisciplinary

Research Article

Comparative Efficacy of Herbal Formulations Versus Standard Oral Hypoglycaemic Drugs in Type 2 Diabetes Mellitus: A Critical Narrative Review of the Clinical Evidence

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DOI: https://doi.org/10.5281/zenodo.21427816

Abstract

Background: Type 2 diabetes mellitus (T2DM) affects a large and growing share of the world's population, and a substantial minority of patients — the majority in some South Asian, Middle Eastern and African settings — use herbal preparations alongside or instead of prescribed oral hypoglycaemic agents (OHAs). Whether such preparations are pharmacologically comparable to standard drugs remains contested.

Objective: To critically compare the antihyperglycaemic efficacy and safety of herbal single-drug and polyherbal formulations against standard OHAs, using published randomised evidence and quantitative syntheses rather than new primary data.

Methods: This is a narrative, critically appraised review of meta-analyses, systematic reviews and representative randomised controlled trials (RCTs) identified from MEDLINE/PubMed-indexed sources. No original patient data were generated; all effect estimates reported here are attributed to their published sources. Glycated haemoglobin (HbA1c) and fasting plasma glucose (FPG) served as the anchoring outcomes, with a reduction of 0.5% in HbA1c taken as the conventional threshold of clinical significance.

Findings: In an overview of 25 meta-analyses covering 18 plant-based remedies, Aloe vera leaf gel (mean difference [MD] -0.99%, 95% CI -1.75 to -0.23), psyllium fibre (MD -0.97%, 95% CI -1.94 to -0.01) and fenugreek seed (MD -0.85%, 95% CI -1.49 to -0.22) produced the largest HbA1c reductions; Nigella sativa, Astragalus membranaceus and the Chinese formulae Jinqi Jiangtang and Gegen Qinlian each lowered HbA1c by at least 0.5%. By comparison, metformin monotherapy lowers HbA1c by approximately 1.12% (95% CI 0.92-1.32) versus placebo. Point estimates for the best-performing botanicals therefore approach, but do not clearly exceed, first-line pharmacotherapy — while carrying far wider confidence intervals, shorter follow-up, weaker methodological reporting and no outcome data on microvascular or macrovascular endpoints. Serious adverse events were not reported in these syntheses, but pharmacovigilance data document undeclared synthetic hypoglycaemic adulterants in illicit herbal antidiabetic products, with associated hypoglycaemia and lactic acidosis.

Conclusion: Several botanicals demonstrate statistically and clinically meaningful glucose-lowering effects and are plausible adjuncts to lifestyle measures and conventional therapy. The available evidence does not, however, support substitution of herbal formulations for standard OHAs. Adequately powered, blinded, standardised-extract RCTs of at least 12 weeks' duration with active comparators and hard endpoints are required before equivalence claims can be entertained.

Manuscript Information

- **ISSN No:** 2583-7397
- **Received:** 09-05-2026
- **Accepted:** 14-07-2026
- **Published:** 18-07-2026
- **IJCRM:**5(4); 2026: 279-286

- **Plagiarism Checked:** Yes
- **Peer Review Process:** Yes

How to Cite this Article

Singh Y, Rani K, Bhardwaj U, Chaudhary B. Comparative Efficacy of Herbal Formulations Versus Standard Oral Hypoglycaemic Drugs in Type 2 Diabetes Mellitus: A Critical Narrative Review of the Clinical Evidence. Int J Contemp Res Multidiscip. 2026;5(4):279-286.

Access this Article Online

www.multiarticlesjournal.com

KEYWORDS: type 2 diabetes mellitus; phytotherapy; polyherbal formulation; metformin; HbA1c; Ayurveda; evidence-based medicine; adulteration.

1. INTRODUCTION

Type 2 diabetes mellitus is among the most consequential chronic diseases of the present era. An estimated 9.3% of the world's adult population approximately 463 million people were living with diabetes in 2019, a figure projected to rise to 578 million by 2030 and 700 million by 2045, with over 90% of cases being T2DM and more than one million attributable deaths annually. The economic burden is correspondingly large, with the United States alone spending in the order of USD 294 billion per year on diabetes management in adults aged 20-79 years.

Against this background, pharmacotherapy with oral hypoglycaemic agents, led by metformin, remains the cornerstone of glycaemic management once lifestyle modification proves insufficient. Yet conventional therapy is imperfectly delivered and imperfectly tolerated. In a national cross-sectional survey in the United States, 45% of adults with T2DM had not achieved adequate glycaemic control, with poor medication adherence a major contributor. In a retrospective analysis of the United Kingdom Clinical Practice Research Datalink, fewer than half of patients prescribed metformin were adherent and approximately one-third discontinued within twelve months. Adverse effects are the commonest stated reason for non-adherence, and as many as 62% of patients taking metformin report diarrhoea.

This therapeutic gap is one reason plant-based treatment retains such reach. Diabetes has been treated by traditional systems of medicine in Egypt, China, India and Africa for millennia, and roughly 1,200 plant species are reported to be used worldwide for it. Contemporary use is not marginal: herbal medicines are used by around 68% of patients with diabetes in Saudi Arabia, 62% in Mexico, 62% in Ethiopia and 58% in Sudan, while in India approximately 67% report using Ayurveda or naturopathy. Critically, most do not disclose this to their treating physician — a failure that converts a pharmacological question into a patient-safety one.

The clinical question addressed here is therefore not whether herbs are used, but how their measured antihyperglycaemic efficacy compares with that of the drugs they are often taken alongside — or quietly substituted for. This review compares the two classes on their own published terms, and is deliberately sceptical in both directions: it neither dismisses botanicals for which replicated randomised evidence exists, nor accepts equivalence claims that rest on small, unblinded, poorly reported trials.

2. Scope, sources and methodological stance

This article is a narrative review with critical appraisal. It presents no original patient-level data, and every quantitative estimate cited below is attributed to a published systematic review, meta-analysis or randomised controlled trial. This declaration is not a formality: the literature on herbal antidiabetics is unusually prone to the recycling of unsourced effect sizes, and a comparative paper that manufactures its own numbers would reproduce precisely the defect it seeks to criticise.

Evidence was drawn preferentially from (i) quantitative syntheses of RCTs in adults with T2DM, (ii) Cochrane reviews where available, and (iii) individual RCTs employing an active OHA comparator. HbA1c was the anchoring outcome, with FPG and postprandial glucose as supporting measures; following established convention and the threshold adopted by the principal overview cited throughout, an HbA1c reduction of at least 0.5% was treated as clinically significant and an FPG reduction of at least 0.5 mmol/L as its analogue. Methodological quality is discussed rather than re-scored, since AMSTAR-2 and Cochrane risk-of-bias appraisal has already been applied to these datasets by their original authors, whose judgements are reported here.

3. The comparator: what standard oral hypoglycaemic drugs actually deliver

Any comparison is only as meaningful as its reference standard, and the efficacy of conventional OHAs is often overstated in rhetoric and understated in the herbal literature. Quantitatively, metformin monotherapy lowers HbA1c by approximately 1.12% (95% CI 0.92 to 1.32) relative to placebo, and by 0.95% (95% CI 0.77 to 1.13) when added to existing oral therapy. Its effect on fasting glycaemia is of the order of -2.0 mmol/L (95% CI -2.4 to -1.7). Newer agents are not uniformly stronger: sitagliptin as monotherapy lowers HbA1c by about 0.94% and FPG by roughly 1.2 mmol/L.

The sulfonylureas remain widely used, particularly in resource-constrained settings, and their comparative position is instructive. A meta-analysis of RCTs comparing glimepiride with metformin in monotherapy found metformin was not significantly superior for HbA1c, postprandial blood sugar, fasting insulin, blood pressure or HDL cholesterol; metformin was superior only for total cholesterol, LDL cholesterol and triglycerides. The adverse-event profiles diverged predictably, with glimepiride more likely to induce hypoglycaemia and metformin carrying higher risk of gastrointestinal upset.

Three points follow, and they frame the rest of this review. First, the realistic benchmark for any new antihyperglycaemic intervention is an HbA1c reduction approaching 1%, not a token statistical signal. Second, conventional agents are differentiated as much by safety and extraglycaemic effects as by potency — standard herbal formulations are rarely held to. Third, the standing of metformin rests not only on glycaemic data but on decades of outcome and safety data; no herbal formulation possesses an equivalent evidentiary base for microvascular or cardiovascular endpoints, and no degree of HbA1c equivalence substitutes for that.

4. Efficacy of single-herb interventions

The most rigorous available synthesis is an overview of meta-analyses that searched MEDLINE, EMBASE, CINAHL and the Cochrane Library and identified 25 meta-analyses reporting on 18 plant-based remedies in T2DM. Its findings deserve to be reported precisely, because they are frequently misquoted in both directions.

The largest effects on HbA1c were seen with Aloe vera leaf gel (MD -0.99%, 95% CI -1.75 to -0.23), psyllium fibre (MD -0.97%, 95% CI -1.94 to -0.01) and fenugreek seed (Trigonella foenum-graecum) (MD -0.85%, 95% CI -1.49 to -0.22). Four further remedies achieved reductions of at least 0.5%: Nigella

sativa seed, Astragalus membranaceus root, and the traditional Chinese formulae Jinqi Jiangtang and Gegen Qinlian. Several other preparations — Tianmai Xiaoke, ginger, sweet potato, olive oil, Momordica charantia and cinnamon — produced statistically significant but sub-threshold HbA1c reductions. Tea and tea extracts (Camellia sinensis) were unambiguously ineffective, with tight confidence intervals excluding benefit; ginseng likewise showed no clinically or statistically significant HbA1c effect in meta-analyses restricted to T2DM.

Two remedies illustrate the interpretive traps. Momordica charantia (karela) enjoys near-totemic status among South Asian patients, yet an early Cochrane review identified only a single small RCT (n=40) and found dried fruit powder ineffective, while a later review of six RCTs (243 participants) found a statistically significant but clinically modest HbA1c reduction of 0.26%. Cinnamon has been meta-analysed at least five times with divergent conclusions: only one review reporting HbA1c found a statistically significant reduction and none a clinically significant one, although the largest and most recent review restricted to T2DM did report a clinically meaningful FPG reduction of -1.07 mmol/L (95% CI -1.56 to -0.58). The divergence reflects heterogeneity in species (Cinnamomum cassia, C. verum, C. burmannii), preparation, dose (120 mg to 14.4 g daily across reviews) and population.

Gymnema sylvestre, perhaps the most heavily marketed Ayurvedic antidiabetic botanical, deserves particular mention for what is absent. A systematic review of Gymnema found no clinical trials meeting its inclusion criteria — an evidentiary vacuum that commercial claims have comfortably outrun. Similarly, Moringa oleifera has been evaluated only in pilot work.

The mechanistic diversity underlying these effects is genuine and pharmacologically coherent, which is why blanket dismissal is as unscientific as blanket endorsement. Gel-forming fibres delay gastric emptying and blunt intestinal glucose absorption (Aloe vera, fenugreek, psyllium); some plants inhibit alpha-amylase and alpha-glucosidase (nettle, Jinqi Jiangtang); others stimulate insulin release (fenugreek, Nigella sativa), inhibit gluconeogenesis (Nigella sativa), or enhance peripheral glucose uptake and insulin sensitivity. These are the mechanistic families exploited by acarbose, sulfonylureas and metformin respectively — a reminder that the herbal/conventional dichotomy is regulatory and cultural rather than pharmacological.

5. Polyherbal and proprietary formulations

Traditional practice rarely uses single herbs, and the polyherbal formulation is the unit of therapy in Ayurveda and Traditional Chinese Medicine alike. The largest synthesis in this space screened 32,519 records and included 219 articles representing 199 RCTs (21,191 participants) evaluating 98 Ayurvedic medicines. Statistically significant HbA1c reductions versus control were demonstrated for Aegle marmelos (MD -1.6%, 95% CI -3.0 to -0.3), Gynostemma pentaphyllum (-1.0%, -1.5 to -0.6), Plantago ovata (-0.9%, -1.4 to -0.3), Urtica dioica (-1.3%, -2.4 to -0.2), Trigonella foenum-graecum (-0.6%, -0.9 to -0.4), Boswellia serrata (-0.5%, -0.7 to -0.4), Tinospora cordifolia (-0.5%, -0.6 to -0.5), Nigella sativa (-0.4%, -0.6 to -0.1) and Momordica charantia (-0.3%, -0.4 to -0.1). Fasting blood glucose fell by 4-56 mg/dL across the range of medicines. The authors' own verdict is the essential caveat: methodology was not adequately reported in the studies reviewed, producing poor methodological quality scores; health-related quality of life was rarely assessed; and adverse events were frequently not reported at all.

Chinese patent formulae have generally been studied with tighter designs. In a double-blind, randomised, placebo-controlled, multicentre trial, 186 patients inadequately controlled on metformin received Jinlida 9 g three times daily or placebo for 12 weeks with unchanged metformin dosing; HbA1c fell by 0.92 +/- 1.09% in the Jinlida arm versus 0.53 +/- 0.94% with placebo. A meta-analysis of 26 RCTs (2,553 patients) of Gegen Qinlian decoction found that adding the decoction to metformin, versus metformin alone, reduced FPG (MD -1.79 mmol/L, 95% CI -2.31 to -1.27), 2-hour postprandial glucose (MD -1.72, -2.12 to -1.31) and HbA1c (MD -1.26%, -1.80 to -0.72), with no serious adverse effects identified. These are add-on designs, and they answer a different and arguably more clinically useful question than substitution trials do.

Proprietary formulations marketed as metformin alternatives require the most careful reading. GlycaCare-II, a standardised blend of Cinnamomum cassia, Momordica charantia, Pterocarpus marsupium, Gymnema sylvestre, Salacia reticulata and Eugenia jambolana with piperine as a bioavailability enhancer, was compared with metformin in a randomised, double-blind, two-arm study in prediabetic (n=29) and newly diagnosed diabetic (n=40) participants over 120 days, with significant improvements in HbA1c, fasting and postprandial blood sugar reported in both arms. The trial is well constructed for its size, but the arms are small, the population is early-stage disease with substantial room for regression to the mean, and the investigators were employees of the manufacturer — a conflict of interest that does not invalidate the result but firmly bounds its weight.

Similar constraints attach to the Indian literature. A prospective, randomised, parallel-group study allocated 93 newly diagnosed patients with T2DM to a standardised aqueous-extract polyherbal capsule containing Cyperus rotundus, Berberis aristata, Cedrus deodara, Emblica officinalis, Terminalia chebula and Terminalia bellirica (500 mg/day up-titrated to 3 g/day) or metformin (500 mg/day up-titrated to 2 g/day) for six months; both arms significantly reduced blood glucose and HbA1c relative to baseline, and the polyherbal arm additionally improved triglycerides and total cholesterol, with no adverse effects reported and no conflict of interest declared. A within-arm reduction from baseline, however, is not evidence of non-inferiority: an active-controlled trial that reports only pre-post change in each group, without a pre-specified non-inferiority margin and adequate power, cannot support the equivalence claim that such studies are routinely cited to support.

6. Direct comparison: how close is 'as effective as'?

Placing the two datasets side by side yields a defensible summary. The best-supported botanicals — Aloe vera, psyllium and fenugreek — have point estimates for HbA1c reduction of roughly 0.85% to 0.99%, against approximately 1.12% for

metformin monotherapy versus placebo. On point estimates alone, the conclusion that several medicinal plants appear to be as effective as conventional antidiabetic treatments for reducing HbA1c is defensible, and it is the conclusion the principal overview itself reaches.

That conclusion should nonetheless be read with its confidence intervals attached. Psyllium's interval extends to -0.01%, meaning the data are compatible with a negligible effect; Aloe vera's lower bound is -0.23%. Metformin's interval (0.92 to 1.32) is narrow by comparison because it rests on far more, and far larger, trials. Precision is not a technicality here — a therapy whose true effect might be near zero is not interchangeable with one whose true effect is confidently near 1%, even when their central estimates converge.

Three further asymmetries matter. Follow-up in the herbal trials was most commonly 4-12 weeks, and in some cases under 8 weeks, which is insufficient for HbA1c to express its full effect; only three of the 25 reviews included studies with follow-up of a year or more, so almost nothing is known about long-term adherence or durability. Comparator choice differs: 19 of the 25 reviews used placebo controls, so most of the herbal effect sizes quoted are versus placebo, not versus an active drug. And the outcome hierarchy differs absolutely: the herbal literature stops at surrogate glycaemic markers, whereas conventional agents are judged additionally on retinopathy, nephropathy, cardiovascular events and mortality.

7. Safety, adulteration and interactions

The safety story is genuinely favourable in the trial literature and genuinely alarming in the marketplace, and conflating the two is the commonest error in this field.

Within the 25 meta-analyses reviewed, no serious adverse events were reported, and in most cases, there was no significant difference in adverse-event incidence between treatment and control. Where side-effects occurred, they were predominantly mild gastrointestinal symptoms, notably with Momordica charantia and fenugreek. The large Ayurvedic synthesis reached the same conclusion with an important qualification: adverse events were simply not reported in many studies, and where reported were mostly absent to mild and gastrointestinal in nature. Absence of reported harm in trials that did not systematically ascertain harm is weak reassurance.

The marketplace tells a different story. A case series from Hong Kong identified 27 cases involving 29 adulterated herbal antidiabetic products; 17 patients (63%) had clinical toxicities attributable to the products, with hypoglycaemia the commonest adverse effect followed by lactic acidosis. Analysis revealed eight undeclared registered or banned oral antidiabetic agents: glibenclamide (in 22 of 29 products), phenformin (18), metformin (6), rosiglitazone (6), gliclazide (2), glimepiride (2), nateglinide (1) and repaglinide (1). Non-antidiabetic drugs including hydrochlorothiazide, cimetidine, prednisolone and tadalafil were also detected, and up to four adulterants were found within a single product. Analytical surveillance studies from India, China and elsewhere have repeatedly detected the same class of synthetic adulterants in supposedly 'all-natural' antidiabetic products, sometimes at concentrations exceeding usual prescription doses.

The clinical implications are direct. An apparently dramatic hypoglycaemic response to an unregulated herbal product should raise suspicion of adulteration rather than of pharmacognostic potency — phenformin in particular was withdrawn from most markets because of fatal lactic acidosis. Unrecognised additive pharmacology is also a real hazard, since additive hypoglycaemia is mechanistically predictable for insulin secretagogue-like botanicals taken alongside a sulfonylurea. Physicians must therefore ask about herbal use explicitly, because patients overwhelmingly do not volunteer it.

8. Why the comparison remains unsettled: methodological appraisal

The limitation is not that herbal medicines have been found wanting; it is that they have largely been tested in ways that cannot settle the question.

Quality appraisal using AMSTAR-2 in the overview of 25 meta-analyses found only three reviews scoring 'yes' on all criteria — all three Cochrane reviews. Most lacked a pre-registered protocol, most lacked a comprehensive search including grey literature, most did not list excluded studies or report funding sources of included trials, seven did not adequately investigate publication bias, and six did not report conflicts of interest. One review — the psyllium meta-analysis, which supplied one of the largest effect estimates in the field — was led by a company marketing a psyllium product and was judged at high risk of bias. One further meta-analysis of fenugreek was excluded outright for having incorrectly reported the underlying data of its included studies.

Standardisation is the second structural problem. Botanical drugs are chemically variable by nature: species substitution, plant part, harvest conditions, extraction solvent and dose all move the pharmacology. Doses across reviewed trials spanned orders of magnitude — cinnamon from 120 mg to 14.4 g daily, fenugreek from 1 g to 100 g. A meta-analysis pooling such preparations under a common name may be answering no coherent pharmacological question at all. The most effective fenugreek preparation appeared to be a standardised total-saponin extract, not the ground seed used in most trials, and the most effective Aloe vera preparation was freshly extracted juice — distinctions invisible in a pooled estimate.

Third, publication and language bias plausibly inflate the traditional-medicine literature, particularly for Chinese formulae; the principal overview explicitly notes its inability to search Chinese-language databases and grey literature. Fourth, blinding a bitter decoction or aromatic powder is genuinely difficult — though HbA1c, laboratory-measured and integrating 8-12 weeks of glycaemia, is comparatively robust to unblinding, which is one reason it should be the mandatory primary endpoint in this field.

9. Guideline and regulatory position

Major clinical guidelines have not been persuaded. The American Diabetes Association's Standards of Care in Diabetes-2026 states that there is insufficient evidence to support routine use of herbal supplements and micronutrients such as cinnamon, curcumin, aloe vera or chromium to improve glycaemia in people with type 1 or type 2 diabetes, and

recommends (grade C) that supplement intake be assessed while such products are not recommended for glycaemic benefit. This position has been consistent across successive iterations of the Standards.

The tension between this and the meta-analytic signal described above is resolved not by declaring one side wrong but by recognising that guidelines weight certainty, reproducibility, standardisation and outcome data rather than point estimates. A pooled estimate drawn from heterogeneous, short, small, incompletely reported trials of non-standardised preparations does not meet the threshold for a population-level recommendation, however encouraging it is as a research signal. Regulatory frameworks differ accordingly: in India, AYUSH-licensed formulations are approved largely on classical textual authority and safety rather than the comparative efficacy dossier demanded of a new chemical entity — which explains how products may be lawfully marketed for diabetes while remaining, in the evidence-based sense, unproven.

10. Clinical implications

For the practising clinician, several conclusions can be drawn responsibly from the current evidence.

- Substitution cannot be endorsed. No herbal formulation has demonstrated non-inferiority to metformin in an adequately powered, blinded, non-inferiority-designed trial, and none has outcome data. Patients who stop OHAs in favour of herbal products should be understood to be accepting unquantified risk.
- Adjunctive use is defensible for selected preparations. Where a patient wishes to use a botanical, those with the most replicated evidence and the most benign profiles — fenugreek seed, psyllium husk, Nigella sativa seed powder, Aloe vera — are the rational choices, taken in addition to, not instead of, prescribed therapy, with glucose monitoring intensified after initiation.
- Dose and preparation must be specified. Advising 'cinnamon' or 'fenugreek' without specifying species, preparation and dose reproduces the incoherence of the literature. Effective doses in trials were often far higher than typical culinary or supplement exposure.
- Source matters more than species. Given documented adulteration with glibenclamide and phenformin, provenance and regulatory licensure should be verified before a product is endorsed, and unexplained hypoglycaemia in a herbal user should prompt consideration of an undeclared sulfonylurea.
- Ask, do not wait to be told. Non-disclosure is the norm, not the exception; a structured question about traditional and over-the-counter remedies belongs in every diabetes consultation.
- Do not dismiss the patient's framework. Herbal use frequently coexists with, and is partly driven by, intolerance or fear of conventional drugs. Engaging with it non-judgementally is more likely to preserve adherence to essential therapy than prohibition.

11. Limitations of this review

This is a narrative rather than systematic review; it was not registered, applied no reproducible search protocol, and involved no dual screening or quantitative pooling, so source selection — though weighted towards Cochrane reviews and large syntheses — remains susceptible to reviewer bias. Reliance on published meta-analyses inherits their limitations wholesale, including the exclusion of botanicals never subjected to quantitative synthesis. Most importantly, comparing herbal-versus-placebo effect sizes with metformin-versus-placebo effect sizes is an indirect comparison across trials differing in population, comparator and duration; it does not carry the evidentiary weight of a head-to-head trial, and no network meta-analysis was attempted here.

12. Research agenda

The path to resolution is not obscure. Priorities include chemically standardised extracts with declared marker compounds and stability data; RCTs of at least 12 weeks so that HbA1c can express its full effect, and ideally 24-52 weeks for durability; pre-registered protocols with pre-specified non-inferiority margins against an active comparator; adequate power, which almost no current trial possesses; systematic ascertainment of adverse events including hypoglycaemia; mandatory analytical screening of the investigational product for synthetic adulterants; declaration of manufacturer involvement; and the pragmatic add-on trial in patients inadequately controlled on metformin, the design that matches how these products are actually used and that the Jinlida and Gegen Qinlian literature has begun to model. Network meta-analysis of relative effects between botanicals, and updating of older syntheses — notably fenugreek, last synthesised in 2014 — would further strengthen the base.

13. CONCLUSION

The honest comparative verdict is neither the dismissal favoured by clinical orthodoxy nor the equivalence asserted by the supplement industry. Several botanicals — Aloe vera, psyllium fibre, fenugreek seed, Nigella sativa and certain standardised Chinese formulae — produce HbA1c reductions whose point estimates approach those of metformin monotherapy, are mechanistically coherent, and appear well tolerated in trial conditions. That is a substantial and underappreciated finding. But the estimates are imprecise, derived from short, small, methodologically weak, mostly placebo-controlled studies of poorly standardised preparations, unsupported by any outcome data, and shadowed by a real-world adulteration problem that has caused hypoglycaemia and lactic acidosis. Standard oral hypoglycaemic drugs remain the appropriate first-line therapy for T2DM. Herbal formulations, chosen carefully and sourced reliably, are reasonable adjuncts and a legitimate research frontier — not substitutes. Closing the gap between these two statements is an empirical task, and it is entirely achievable with trials the field already knows how to design.

Declarations

Funding: None. Conflicts of interest: None declared. Data availability: This review analyses previously published data; all sources are cited below. Author contributions: The author conceived, drafted and revised the manuscript. No original human-subject data were collected, and no ethical approval was therefore required.

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