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"PRAMEHAGHNA DRAVYA AND GLYCAEMIC CONTROL: AN OVERVIEW OF SYSTEMATIC REVIEWS AND CLINICAL EVIDENCE FOR SINGLE DRUGS USED IN MADHUMEHA"

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ABSTRACT
Prameha and its subtype Madhumeha are described in classical Ayurvedic texts with a long list of drugs considered to pacify them (pramehaghna dravya). Several of these are now used by people with type 2 diabetes, often alongside conventional treatment. This overview summarises the evidence from systematic reviews and selected clinical trials for seven commonly used single drugs: Methika (*Trigonella foenum-graecum*), Twak (*Cinnamomum* spp.), Haridra (*Curcuma longa*), Karavellaka (*Momordica charantia*), Amalaki (*Phyllanthus emblica*), Meshashringi (*Gymnema sylvestre*) and Vijayasara (*Pterocarpus marsupium*). Fenugreek seed reduced fasting glucose by 0.96 mmol/L, two-hour glucose by 2.19 mmol/L and HbA1c by 0.85% in a meta-analysis of ten trials, with larger effects at doses of 5 g/day or more, but trial quality was poor. Cinnamon lowered fasting glucose by about 25 mg/dL without a significant change in HbA1c, with high heterogeneity. Curcumin produced moderate standardised reductions in HbA1c and insulin resistance in seven mainly Iranian trials. For bitter melon, a meta-analysis of nine placebo-controlled trials found no consistent effect, and positive results depended on analytic choices. Evidence for Amalaki comes mostly from combination products, and that for Meshashringi and Vijayasara from early or uncontrolled studies. Across drugs, trials were short and small, and few used classical preparations or doses. The current evidence supports a modest adjunctive role for some pramehaghna dravya, not their use as a substitute for proven treatment. We propose design standards for future trials.

KEYWORDS: Prameha, Madhumeha, type 2 diabetes, fenugreek, cinnamon, curcumin, bitter melon, Dravyaguna, overview of reviews

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INTRODUCTION

Prameha is a group of disorders described in the Brihattrayi, characterised by excessive and turbid urination, among which Madhumeha, with sweet urine, corresponds most closely to diabetes mellitus.[1] The classical texts attribute it to excess kapha, meda and kleda arising from overeating, sedentary habits and heavy, sweet and unctuous foods, and they distinguish an obese, strong patient (sthula pramehi) from a lean, weak one (krisha pramehi), who require different treatment.[1] Treatment combines diet, exercise, purification and drugs. Many single drugs and groups of drugs are named as pacifying prameha,[1,2] and several are now familiar as kitchen spices or dietary supplements.

People with type 2 diabetes in India and elsewhere frequently use these drugs, often without telling their physician and often alongside metformin, sulphonylureas or insulin. Professional guidelines in conventional medicine state that there is no clear evidence that herbal or spice supplements improve outcomes in diabetes.[3] A large number of individual trials and several meta-analyses have nevertheless been published. This overview brings together the evidence from systematic reviews and key clinical trials for seven pramehaghna dravya in common use, appraises its quality, and considers what it means for Ayurvedic practice and research.

METHODS

This is an overview of systematic reviews supplemented by key primary trials. We selected seven single drugs that are named in classical treatment of prameha or widely used in Ayurvedic practice for Madhumeha, and for each searched PubMed, publisher websites and open-access repositories for systematic reviews and meta-analyses of human trials reporting fasting glucose, postprandial glucose or glycated haemoglobin (HbA1c). Where no meta-analysis was found, we included the most informative clinical trials. We extracted the number of trials and participants, pooled effects, heterogeneity, and the authors' assessment of quality.

CLASSICAL BASIS

Classical treatment of prameha is individualised. The obese patient is treated with reducing measures, including purification and drugs with bitter, astringent and pungent tastes that dry kapha and meda, whereas the lean patient is nourished.[1] Drugs named in prameha therefore tend to share bitter (tikta) and astringent (kashaya) tastes and a drying (ruksha) quality, and they are often given as decoctions, powders or with honey or Amalaki juice. The combination of Haridra with Amalaki (Nisha-Amalaki) is among the best known classical preparations for prameha. These features matter when interpreting modern trials, which mostly test a single drug as a capsule or extract in patients selected only by a biochemical definition of diabetes.

Methika

Fenugreek has the most consistent evidence among the drugs reviewed. A meta-analysis of ten trials found reductions in fasting glucose of 0.96 mmol/L, in two-hour glucose of 2.19 mmol/L and, in three trials, in HbA1c of 0.85%.[4] Effects were seen in people with diabetes but not in those without, and were clearer at doses of 5 g/day or more. Debittered seed powder showed the largest effects, but those trials also used the highest doses, so dose and preparation could not be separated. The authors judged trial quality to be generally poor and noted heterogeneity and possible publication bias.[4] The dose dependence is consistent with the fibre-rich seed acting partly in the gut, and the doses that worked are of the order used as a food rather than as a small-dose powder.

Twak

A meta-analysis of ten randomised trials with 543 patients found that cinnamon lowered fasting plasma glucose by about 25 mg/dL and improved lipids, but did not significantly change HbA1c.[5] Heterogeneity was high, doses ranged from 120 mg to 6 g daily for 4 to 18 weeks, and many trials did not specify the species. Because HbA1c is the outcome that best reflects long-term control, the absence of an effect on it is the more important finding.

Haridra

A meta-analysis of seven randomised trials, mostly from Iran, reported moderate standardised reductions in HbA1c and insulin resistance with curcumin supplementation in uncomplicated type 2 diabetes, but noted small samples and publication bias.[6] These trials used isolated curcumin or curcuminoids, often in enhanced-absorption formulations, not turmeric rhizome as used in Ayurveda. Curcumin is chemically unstable, poorly bioavailable and prone to interfering with laboratory assays,[11] so mechanistic claims should be treated with caution even where clinical effects are observed. Classical pairs Haridra with

Amalaki, and a recent trial found that Nisha-Amalaki churna alone did not significantly reduce fasting or postprandial glucose over 90 days, whereas groups receiving it with Naga bhasma did.[12]

Table 1. Summary of clinical evidence for selected pramehaghna dravya in hyperglycaemia and type 2 diabetes.

Drug	Best available evidence	Main findings	Quality and limitations
Methika (fenugreek seed)	Meta-analysis of 10 trials[4]	FBG −0.96 mmol/L; 2-h glucose −2.19 mmol/L; HbA1c −0.85% (3 trials); effects in diabetes only and at ≥5 g/day	Poor trial quality; I^2 80% for FBG; possible publication bias
Twak (cinnamon)	Meta-analysis of 10 RCTs, 543 patients[5]	FPG −24.6 mg/dL; HbA1c −0.16%, not significant; lipids improved	High heterogeneity; doses 120 mg to 6 g/day; species often not stated
Haridra (curcumin)	Meta-analysis of 7 RCTs[6]	Standardised reductions in HbA1c (d −0.42) and HOMA-IR (d −0.41)	Mostly from one country; small samples; publication bias; isolated curcumin, not turmeric
Karavellaka (bitter melon)	Meta-analysis of 9 placebo-controlled RCTs, 414 participants[7]	No consistent effect on FPG or HbA1c; nominal benefit only in post-intervention analysis	Short (4–16 weeks), underpowered trials
Amalaki	Systematic review of 18 studies, 951 participants[8]	Most studies reported lower FBG; 15 of 18 used combination products	No meta-analysis; heterogeneous products and designs

Karavellaka

Bitter melon is among the most popular dietary remedies for diabetes, and a meta-analysis of 66 animal studies reported large reductions in fasting glucose with fruit and seed extracts.[13] The human evidence does not match this. A meta-analysis of nine placebo-controlled trials with 414 participants found no consistent effect on fasting glucose or HbA1c; nominal benefits appeared only when post-intervention values rather than changes from baseline were analysed, and the authors concluded that the metabolic effect cannot be determined from the available clinical evidence.[7] The contrast between animal and human data illustrates how preclinical results can overstate clinical benefit.

Amalaki, Meshashringi and Vijayasara

A systematic review of 18 studies of Amalaki found that most reported lower fasting glucose, but 15 used combination products and no meta-analysis was possible.[8] For Meshashringi, an early systematic review summarised the available trials,[9] but few controlled trials have been published since. For Vijayasara, the main human evidence is a multicentre open trial coordinated by the Indian Council of Medical Research in newly diagnosed patients.[10] Without randomised, controlled data, the effects of these drugs cannot be separated from those of diet, regression to the mean and closer follow-up.

SAFETY AND INTERACTIONS

The drugs reviewed are generally well tolerated in trials, with gastrointestinal effects most commonly reported. The main clinical risk is additive glucose lowering when they are taken with sulphonylureas or insulin; an interaction between karela and chlorpropamide was reported as early as 1979.[14] Fenugreek has been associated with a raised INR in a patient taking warfarin.[15] Patients should be asked about these drugs, and glucose should be monitored when they are started or stopped alongside conventional treatment.

APPRAISAL AND DRAVYAGUNA PERSPECTIVE

Four general weaknesses run through the evidence. Trials were short, commonly 4 to 16 weeks, which is too brief to show a stable change in HbA1c. They were small and often of poor methodological quality.[4,7] They frequently did not characterise the material tested, so results cannot be linked to a defined preparation.[16] And few tested the drug as it is used in Ayurveda: a classical dosage form, at a classical dose, in a patient assessed by Ayurvedic criteria, and as part of a regimen that includes diet and

exercise.[1]

The classical distinction between the obese and the lean patient with prameha is particularly relevant. Drugs that are bitter, astringent and drying are intended for the obese, kapha-dominant patient and are expected to be unsuitable for the lean one.[1] A trial that enrols both and finds a small average effect may conceal a larger effect in one group. Stratifying by body habitus or by a validated Ayurvedic assessment is a testable way of bringing Dravyaguna logic into trial design.

Taken together, the evidence supports a modest adjunctive role for fenugreek seed and possibly for cinnamon and curcumin, does not support bitter melon as an effective glucose-lowering agent, and is insufficient for the other drugs. None of the drugs has evidence that would justify replacing conventional treatment of established diabetes, a position consistent with professional guidelines.[3]

RECOMMENDATIONS FOR FUTURE TRIALS

- Test the classical preparation (churna, kvatha or a defined classical yoga) at a classical dose, with chemical characterisation of the batch.[16,17]
- Use HbA1c as the primary outcome over at least 12 and preferably 24 weeks.
- Design trials as add-on to standard treatment, with glucose-lowering medication held constant or adjusted by protocol.
- Stratify or pre-specify subgroups by body habitus or validated Ayurvedic assessment.
- Register protocols prospectively and report according to CONSORT, including its extension for herbal interventions.
- Report hypoglycaemia and interactions systematically.

LIMITATIONS

This overview relies on the reviews and trials we identified and did not formally assess the quality of each review. Some reviews overlap in the trials they include. For three drugs we could summarise only the existence of evidence rather than its full findings, which should be completed from the original papers before publication.

CONCLUSION

The evidence base for pramehaghna dravya in type 2 diabetes is uneven. Fenugreek seed shows the most consistent glucose-lowering effect, cinnamon and curcumin have modest effects of uncertain clinical importance, and bitter melon, despite its reputation and strong animal data, shows no robust benefit in humans. For several classically important drugs, controlled human evidence is lacking. Future trials that test classical preparations as add-on therapy over clinically meaningful periods, in patients selected with attention to classical categories, would provide the evidence that both Ayurvedic and conventional practitioners need.

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