Ayurvedic interventions for diabetes mellitus: a systematic review

Hardy M, Couler I, Venturupalli S, Roth E A, Favreau J, Morton S C, Shekelle P

Authors' objectives
The overall objective of the project was to assess the use of Ayurvedic medicine for the treatment of health conditions and to select a condition for a comprehensive review. This abstract is based on the systematic review of the efficacy of Ayurvedic medicine or therapies for the treatment of diabetes.

Searching
MEDLINE (1966 to 1999), HealthSTAR (1975 to 1999), EMBASE (1974 to 1999), AMED (1984 to 1999), MANTIS (1880 to 1999), CAB Health (1983 to 1999), BIOSIS Previews (1993 to 1999) and CINAHL (1982 to 2000) were searched. An extensive search of the Indian literature was also conducted; this included contact with experts, searching of journals not indexed in Western databases, pertinent thesis work and seminar proceedings. Further details were given in the report. The reference lists of all relevant articles were also screened. Only publications in the English language were eligible.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) of any size, or controlled clinical trials (CCTs) with at least one arm of more than 10 patients and a comparison group that did not receive an herb, were eligible for inclusion. Cohort studies and case series were also eligible if more than 10 patients were included.

Specific interventions included in the review
Studies of Ayurvedic therapy or herbs given as a single agent, a formula acting as a single agent, or a limited combination of products (three or fewer) acting as a single agent, were eligible for inclusion. The agent also had to be administered more than once. Botanical therapy was the most commonly studied treatment.

Participants included in the review
Studies of patients with diabetes were eligible for inclusion. Most included studies were of patients with type 2 diabetes.

Outcomes assessed in the review
Studies reporting at least one of the following outcomes measured at least 30 days after study commencement were eligible for inclusion: glycosylated haemoglobin, fasting blood glucose or post-prandial blood glucose (at either 2 hours or 1 hour). The studies also had to report pre-and post-intervention means, along with the standard deviation or standard error, for each group.

How were decisions on the relevance of primary studies made?
Two reviewers independently determined the eligibility of included studies and any disagreements were resolved by consensus.

Assessment of study quality
RCTs and CCTs were assigned a quality score (1 being the lowest and 5 the highest) using the Jadad instrument to assess reporting of randomisation, blinding and withdrawals. The authors did not state how many reviewers performed the quality assessment.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.
Pre- and post-treatment means of clinically relevant outcomes were extracted and used to calculate the change for each treatment arm. The difference between treatments in this change was used as an estimate of the common effect size and presented with its 95% confidence interval (CI) for each study.

**Methods of synthesis**

**How were the studies combined?**
The results of the studies were tabulated and combined in a narrative, grouped by study design. Estimates of common effect sizes with 95% CIs were presented graphically for each relevant clinical outcome.

**How were differences between studies investigated?**
Differences between the results of studies included in the further analysis were apparent through visual inspection of the graphs. Clinical heterogeneity of the interventions and patient populations was also assessed.

**Results of the review**

Twenty-two studies were included in the evidence synthesis section of the review: 2 RCTs (n=100), 5 CCTs (n=266) and 15 pre-test post-test studies (n=1,262)). A further 40 studies were included in the appendices as they did not satisfy the inclusion criteria reported above, but their results have still been presented by the review authors.

There were several methodological limitations in the design of the studies (lack of randomisation, blinding and comparison groups) and small sample sizes. The studies were also heterogeneous in the herbs and formulas evaluated and in their method of preparation.

Two RCTs evaluated Coccinia indica and holy basil, respectively, and showed a favourable benefit in levels of fasting and post-prandial blood glucose compared with control.

The results of the CCTs showed a favourable effect on reducing fasting blood sugar (2 studies of gymnema and one of C. tamala), while 2 studies showed no statistically significant benefit (one of Coccinia indica and one of Eugenia jambolana). Four studies measured post-prandial blood sugar, of which two showed a favourable effect. Two studies of gymnema measured haemoglobin and both showed a favourable effect.

The majority of pre-test post-test comparison studies showed a benefit associated with treatment.

No serious adverse events were reported, although they were not always evaluated in the included studies and may, therefore, have been under-reported.

**Authors’ conclusions**

There is significant heterogeneity in the literature on the use of Ayurvedic therapy for diabetes, and most studies had methodological weaknesses. The majority of studies assessed patients with type 2 diabetes (non-insulin dependent), therefore no conclusion can be drawn on the effect of Ayurvedic therapy on patients with type 1 diabetes (insulin dependent). Several herbs and herbal formulas provided sufficient data to warrant further study.

**CRD commentary**

The review was based on a wider evidence report on Ayurvedic medicine, from which the condition of diabetes was selected for review and reported on in this abstract. The broad review question and inclusion criteria were clearly defined for studies eligible for the evidence synthesis part of the systematic review. An extensive literature search of the Western and India literature was undertaken. However, the inclusion of only English language publications was restrictive, especially as a reviewer who was fluent in both Hindi and English visited India to assess the literature there. Methods were used to minimise selection bias, although it was unclear whether methods to minimise reviewer error and bias were used in other phases of the review process.

The decision to combine the studies narratively was appropriate given the apparent differences across the included studies. The authors described each study and considered its methodological limitations, and they also presented the
treatment effects graphically. Only studies that satisfied certain criteria were eligible for the evidence synthesis. However, the authors' conclusions were also based on studies that they excluded from further analysis because of design limitations. It should therefore be noted that some of the conclusions about the benefits of certain herbs have been drawn from poor-quality evidence. The authors' overall conclusions reflect the heterogeneous nature and methodological problems of the included studies. The authors suggested that those treatments showing some beneficial effect undergo further research.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that several interesting areas of future research were identified. These included the need for rigorously conducted placebo-controlled clinical trials with adequate sample size and duration. The authors recommended the following herbs for further research: Coccinia indica, holy basil, fenugreek, Gymnema sylvestre, and herbal formulations D-400 and Ayush-82. Research is needed to compare single herbs and formula preparations, while field studies are needed to determine how Ayurvedic medicine can be used in clinical practice.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.