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## • Review

# Clinical and experimental studies on polyherbal formulations for diabetes: current status and future prospective

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**ABSTRACT:** Diabetes is a leading cause of morbidity and mortality in the world. There is currently an active search for antidiabetic drugs with greater effectiveness with fewer and less adverse side effects. Although numerous individual herbs have been experimentally or clinically reported to possess antidiabetic effects, considerably less research has been conducted on polyherbal compounds. It is believed that herbal compounds containing multiple plant products have synergistic antidiabetic effects and could enhance the desired actions. Several polyherbal formulations have been studied as therapeutic agents in diabetes management. To describe the current state of research on polyherbal compounds in the treatment of diabetes, an extensive review of literature was undertaken on several major databases. This paper presents what is known about the efficacy of these polyherbal formulations and compare their antidiabetic effects with those of current oral hypoglycemic drugs as reference. The percent decrease in blood glucose, lipids and other biochemical parameters achieved by each product in diabetic animals and patients is reported. Also, the possible mechanisms responsible for hypoglycemic action of polyherbal formulations are discussed.

**KEYWORDS:** diabetes mellitus; hypoglycemic agents; plants, medicinal; review

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## 1 Introduction

Diabetes is currently one of the major causes of morbidity and mortality in the world. The number of diabetic patients is markedly increasing in both developed and developing countries. According to the World Health Organization reports (October, 2013), 347 million people have diabetes worldwide. It is estimated that 3.4 million patients died from consequences of hyperglycemia in the year 2004; without urgent action, diabetes will be the 7th cause of mortality in 2030. This disease occurs either when  $\beta$ -islet

cells do not produce enough insulin (type 1 diabetes mellitus, T1DM) or when the tissues become resistant to insulin (type 2 diabetes mellitus, T2DM)<sup>[1]</sup>.

Both types of diabetes can damage nerves and blood vessels in different tissues and lead to serious complications. Therefore, over time, macrovascular complications like cardiovascular diseases and microvascular complications, such as neuropathy, nephropathy and retinopathy, occur in poorly controlled patients<sup>[1]</sup>. Insulin and oral hypoglycemic drugs, including insulin sensitizers, insulin secretagogues,  $\alpha$ -glucosidase inhibitors, incretin agonists and dipeptidyl peptidase-4 inhibitors, are the most widely used drugs for

management of diabetes. However, their clinical uses are limited due to their unpleasant side effects, such as lactic acidosis, peripheral edema and abdominal discomfort<sup>[2]</sup>. Therefore, the search for antidiabetic agents with lesser side effects and greater effectiveness is still of great interest.

Numerous herbs have been reported to possess antidiabetic effects. Many of these herbs have been shown to have hypoglycemic effects in animal studies or clinical trials<sup>[3-6]</sup>. Also, a number of them, such as *Panax quinquefolius*, *Morus alba* and *Cinnamomum cassia*, provide diabetes treatment so effective that their formulations have been approved in different countries as antidiabetic agents<sup>[7]</sup>. It is believed that herbal formulations containing multiple plants can have greater effects than the same herbs taken separately. These synergistic effects enhance the desired action<sup>[8]</sup>. Based on this belief, several polyherbal formulations have been studied as therapeutic agents for the control of diabetes. The current review focuses on effects of these polyherbal formulations on blood glucose, lipids and other biochemical parameters. It also compares their antidiabetic effects, using oral hypoglycemic drugs as reference.

## 2 Literature search

A literature search was conducted through the Google Scholar, MEDLINE and Scopus databases, which cover the most important and influential peer-reviewed articles. The search included literature published as late as 31 January 2014, and used Medical Subject Heading terms “diabetes”, “formulation”, “glucose”, “herb” and “medicinal plant”. Only herbal products prepared from at least two herbs were incorporated in the review. In some animal studies, effects of polyherbal supplements have not been compared with a standard antidiabetic drug. Results of these works have not been included in this paper. Also excluded from this review were studies that did not define constituents of polyherbal products and studies that did not report data in such a way that percent of effectiveness of products could be calculated.

## 3 Current status of polyherbal formulations

At least 16 polyherbal products have been tested for their beneficial effects on biochemical parameters of diabetic rodents. These products are listed in Table 1<sup>[9-24]</sup>. All products except of Karnim Plus, 5EPHF, Diakyur, DRF/AY/5001 and HAL, produced greater reduction in fasting blood glucose (FBG) than the reference drug used in that study. These drugs included glibenclamide, acarbose, rosiglitazone, pioglitazone, metformin and tolbutamide. Also, with the exception of DRF, all polyherbal formulations showed better effect on glycosylated hemoglobin (HbA<sub>1c</sub>) level compared with reference drugs. Interestingly,

all herbal products tested were better at increasing serum insulin level than the reference drugs. Of the formulations tested, Glyoherb showed the greatest reduction in FBG (75% decrease) and Cogent db showed the greatest increase in insulin (104% increase).

The antihyperglycemic effect of herbs can be achieved by many mechanisms, such as inhibiting glucose absorption in the intestine, enhancing insulin secretion from the pancreas, increasing glucose uptake by tissues, decreasing glucose production in the liver, increasing pancreatic tissue regeneration<sup>[25-28]</sup>. Since polyherbal compounds contain so many ingredients from different herbs, it is difficult to identify the exact mechanism of their action on hypoglycemia. It is likely that the antihyperglycemic effect of a polyherbal compound is achieved through various mechanisms. For example, Diasulin contains both *Cassia auriculata* and *Gymnema sylvestre*, which decrease blood glucose by inhibiting glucose absorption from the intestine and enhancing insulin secretion from the pancreas, respectively<sup>[29,30]</sup>. In addition, the presence of *Trigonella foenum-graecum* in this compound may induce hypoglycemia by enhancing insulin secretion, increasing glucose uptake by tissues, decreasing glucose absorption from the intestine and inhibiting glucose production in hepatocytes<sup>[31-33]</sup>.

Diabetic dyslipidemia, which is often present in diabetic patients, is one of the main risk factors for cardiovascular diseases. It is characterized by an elevation in serum triglyceride and low-density lipoprotein (LDL) levels accompanied by a decrease in high-density lipoprotein (HDL) concentration<sup>[34-37]</sup>. According to current guidelines, decreasing serum LDL concentration is the primary goal for management of diabetic dyslipidemia. Yet, despite forceful drug therapy, most diabetic patients do not reach the advised LDL concentration (<100 mg/dL)<sup>[37,38]</sup>. Among all the products listed in Table 1, only Karnim Plus, HAL, MAC-ST/001 and Cogent db failed to show greater hypolipidemic effect than reference drugs. Therefore, the herbal products have beneficial effects on lipid profile of diabetic rodents and they have the potential to be used as alternative or complementary agents for treatment of diabetic dyslipidemia.

Table 2<sup>[39-43]</sup> shows four polyherbal formulations that demonstrated antidiabetic effects in clinical trials on diabetic patients. Three of four compounds induced considerable hypoglycemic effects. However, none of the trials used insulin or any oral hypoglycemic drugs as control and therefore it is not possible to compare hypoglycemic action of these polyherbal compounds with that of a reference drug. Only Viswanathan *et al*<sup>[42]</sup> compared beneficial effects of their formulation on diabetic foot ulcer with silver sulphadiazine cream.

Analysis of constituents of the polyherbal products listed in Table 1 and Table 2 shows that *Momordica charantia*,

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