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PROBABLE MECHANISM OF ACTION OF KARMA DOD PLUS TABLET - AN AYURVEDIC POLY-HERBO METALLIC FORMULATION

[1]*Dr. Sakshi Badyal, [2]Dr. Poonam Dang, [3]Dr. Puneet Dhawan and [4]Dr. Himanshu Shekhar Tiwari

[1,2]Research Officer, Karma Ayurveda, 77, Tarun Enclave, Gate no. 2, Pitampura, New Delhi-110034.

[3]Karma Ayurveda, 77, Tarun Enclave, Gate no. 2, Pitampura, New Delhi- 110034.

[4]President Technical, Karma Ayurveda, 77, Tarun Enclave, Gate no. 2, Pitampura, New Delhi-110034.

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***Corresponding Author**
Dr. Sakshi Badyal
Research Officer, Karma Ayurveda, 77, Tarun Enclave, Gate no. 2, Pitampura, New Delhi-110034.

ABSTRACT

Due to changes in lifestyle, diabetes has been spreading at an alarming rate throughout the world. It has now became a global issue that requires attention because of its rising incidence. Diabetes mellitus is a prevalent condition in children and young adults. There are two main types of diabetes. Type I diabetes is an autoimmune condition with a genetic tendency where T lymphocytes destroys pancreatic β-cells and about ninety percent of people worldwide suffer from Type II diabetes, which is a very common disease. In contemporary medicine, there are a number of diabetic treatment approaches that attempts to regulate blood sugar levels. But due to global burden of the disease, Ayurveda can provide better treatment options due to its easy availability and less financial burden. **Methodology:** Different research articles and published journals along with classical texts were referred for the gathering the data. **Result:** Ingredients of this composition have been reported to exhibit blood glucose lowering actions, anti-oxidant activity and anti-diabetic activity. **Conclusion:** KARMA DOD PLUS Tablet is an effective poly herbo-metallic composition that can be used both in the treatment and prevention of Diabetes Mellitus (DM) owing to its blood glucose lowering and anti-oxidant potential.

KEYWORDS: Diabetes Mellitus, KARMA DOD PLUS Tablet, Poly herbo-metallic composition, *Prameha.*

INTRODUCTION

WHO (World Health Organization) states that diabetes is a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys and nerves.[1] More than 400 million people across the global are diabetic and more than 1 million deaths are associated with the diabetes every year worldwide. Over the past few decades, a continuous rise in both the number as well as prevalence of this disease has been observed evidently. Based on diagnostic criteria, aetiology and genetics, diabetes can be classified as Type I DM (Diabetes Mellitus), Type II DM, gestational DM and few other types. Out of these, Type II DM is most prevalent one as among all global cases of DM i.e., 96 % are Type II DM. Diabetes is generally brought on by an amalgamation of two primary variables: impaired insulin production by pancreatic beta-cells and altered insulin sensitivity of tissues. The molecular processes involved in the production and release of insulin, as well as the insulin response in tissues, must be strictly regulated in order to entirely meet the metabolic requirement. As a result, flaws in any of the pathways can result in a metabolic imbalance causing Type II DM.[2] People having diabetes are mainly dependent on oral hypoglycaemic agents and insulin sensitizers like metformin to manage the disease. But considering the current scenario, global burden of the diseases is ever rising. Along with that, there are limited as well as costly options available for the patient leaving him with financial burden with falling quality of life.

Ayurveda is the science of life and has been serving people since ages. It has a wide array of wonderful drugs that not only cures the disease but also helps in preventing the progression of disease as well as improves the standard of living in a patient. One such combination of different herbs and processed metals includes KARMA DOD PLUS Tablet which is composed specifically to treat DM and to provide quality living standards to the affected people. The formulation is composed of 9 herbs and processed metals and minerals which includes *Gudmar, Karela, Nimba, Mahanimba, Jambu, Vijaysar, Giloy, Shuddha Shilajit* and *Trivanga Bhasma*. The combination of herbs, classically processed metals and minerals in this formulation provides efficacious results in patients of diabetes mellitus. With the advancing era, it is important to scientifically explain the pharmacodynamics and

pharmacokinetics of the medicine. Hence, this study has been planned with the aim to exhibit the possible mode of action of the composition of KARMA DOD PLUS Tablet both the grounds of classical properties as well as experimental and clinical researches conducted.

MATERIALS AND METHODS

Drug selected for the review is KARMA DOD PLUS TABLET manufactured by KRM AYURVEDA PRIVATE LTD., Kundli, Haryana. Following resources were referred for the complete review which includes- The Textbook of 'Bhavaprakasha Nighantu' by Acharya Bhavamishra, Textbook of 'Reviews on Indian Medicinal Plants' by ICMR, The Ayurvedic Pharmacopoeia of India by Government of India, Ministry of AYUSH, The Ayurvedic Formulary of India by Government of India, Ministry of AYUSH, Classical textbook of Pathology by 'Harsh Mohan', published research articles in different journals available online, various databases and search engines.

OBSERVATIONS AND RESULT

Ingredients of this Ayurvedic proprietary poly herbo-metallic preparation KARMA DOD PLUS Tablet includes- *Gudmar, Karela, Nimba, Mahanimba, Jambu, Vijaysar, Giloy, Shuddha Shilajit and Trivanga Bhasma.* Complete details of the ingredients along with the part used and quantity in which the tablet is composed is mentioned in Table 1.

Table I: Composition of KARMA DOD PLUS Tablet.

S.no.	Ingredient	Botanical name	Part used	Quantity
1.	*Gudmar*	*Gymnema sylvestre*	Leaf	28 parts
2.	*Karela*	*Momordica charantia*	Fruit	24 parts
3.	*Nimba*	*Azadirachta indica*	Leaves	20 parts
4.	*Mahanimba*	*Melia azedarach*	Leaves	16 parts
5.	*Jambu*	*Melia azedarach*	Leaves	16 parts
6.	*Vijaysar*	*Pterocarpus marsupium*	Heart wood	16 parts
7.	*Guduchi*	*Tinospora cordifolia*	Stem	16 parts
8.	*Shuddha Shilajit*	*Asphaltum punjabianum*	Exudate	12 parts
9.	*Trivanga Bhasma*	Classical Ayurvedic Preparation	---	12 parts
10.	Excipients	---	---	Q.S.

A comparative chart of the properties of the ingredients as described in various classical texts as well as per modern studies conducted is presented in Table 2. Many experimental and clinical studies being conducted by various research organizations has also put forth the beneficial effects of using these herbs in preventing disease progression as well as its numerous complications.

Table II: Pharmacological properties of the ingredients.

S.no.	Ingredient	Guna	Action	Biological activities
1.	*Gudmar*	*Tikta Rasa, Katu Vipaka, Ruksha Guna*	*Madhumehnashak, Kaphahar*[3]	Hypoglycemic activity[4]
2.	*Karela*	*Tikta Rasa*	*Pramehahar, Agnideepak, Kaphanashak*[5]	Anti-hyperglycemic activity, Antioxidant activity[6]
3.	*Nimba*	*Katu Rasa, Laghu Guna*	*Pramehanashak*[7]	Hypoglycaemic activity, Antidiabetic activity[8]
4.	*Mahanimba*	*Tikta-Kshaya Rasa, Ruksha Guna*	*Pramehahar, Kaphajit*[9]	Antioxidant activity, Anti-diabetic activity[10]
5.	*Jambu*	---	*Mutrasangrahniye, Madhumehanashak, Deepana-Pachana*[11]	Antioxidant activity, Anti-diabetic effect.[12]
6.	*Vijaysar*	---	*Pramehanashak, Kaphashamak, Rasayan*[13]	Antioxidant activity, Anti-diabetic effect.[14]
7.	*Guduchi*	*Katu-Tikta-Kashaya Rasa, Laghu Guna*	*Pramehanashak, Tridoshahar*[15]	Hypoglycemic properties[16], Anti-diabetic activity[17]
8.	*Shuddha Shilajit*	*Tikta Rasa, Katu Vipaka*	*Rasayan, Yogvahi, Balya, Pramehanashak*[18]	Hypolipidemic activity, Anti-diabetic activity[19]
9.	*Trivanga Bhasma*	---	*Madhumehanashak, Pramehanashak*[20]	Anti-diabetic effect[21]

Clinical evidence

Various clinical studies of the ingredients of this poly-herbo metallic tablet at various institutes and research centers has been conducted in support of the anti-diabetic effect of the plant. These studies show the blood glucose lowering potential of the herb which scientifically supports the selection of these herbs in KARMA DOD PLUS Tablet. Table 3 explains the different clinical trials for these ingredients conducted along with their outcomes.

Table III: Clinical Studies of the ingredients of Karma Dod Plus Tablet.

S.no.	Ingredient	Part used	Posology	Result
1.	*Gudmar* (*Gymnema sylvestre*)	Leaf powder	1g twice a day; orally; for 10 days	Reduced blood glucose level in fasting condition as well as during the oral glucose tolerance test.[22]
		Leaf (aqueous decoction)	10g/100ml thrice a day; orally; for 15 days	Significantly reduced the fasting blood glucose levels of normal as well as diabetic persons as compared to pretreatment values.

				The treatment also improved the oral glucose tolerance capacity of diabetics as evidenced by significant reduction in blood glucose levels.[23]
2.	*Karela* (*Momordica charantia*)	Fruit powder	2g/day; orally; for 11 days	Reduced blood glucose level during glucose tolerance test by 10.64, 14.5, 14.32 and 15.15 percent at 0, 1, 2, and 3h, respectively as compared to pretreatment values.[24]
		Fruit powder	5g thrice a day; orally; 21 days	Effective in reducing the post prandial blood glucose (PPBG) level in mild (260mg percent blood glucose) and severe (433mg percent blood glucose) diabetic male patients.[25]
3.	*Nimba* (*Azadirachta indica*)	Leaves (Water soluble extract)	---	Significant hypoglycaemic activity against streptozotocin-induced diabetic rats at two hours interval.[26]
		Leaves (Diluted concentrate)	2ml/200g b.w. daily; for 12 days	Produced highly potent antihyperglycaemic action through the observation period of 12 days.[27]
4.	*Mahanimba (Melia azedarach)*	Powder	20 g; orally; for 1 month	Bhumyamaki Churana shows significant reduction in blood glucose levels along with complete relief from karapada Suptata (numbness of both palms and feet) and marked relief from daurbalya (weakness) and prabhuta mutrata (polyuria).[28]
5.	*Jambu* (*Eugenia jambolana*)	Seed powder	5g twice daily ½ hour before food; orally	Reported significant reduction in the fasting blood glucose levels at 3rd and 6th month.[29]
		Seed powder	10g per day; orally	Reduces fasting blood sugar, rise in SOD (superoxide dismutase) and reduces HOMA-IR (homeostasis model assessment for insulin resistance).[30]
6.	*Vijaysar (Pterocarpus marsupium)*	Heart wood (Aqueous & Alcoholic extract)	---	Reduces Blood & Urine sugar levels.[31]
		Heartwood (Aqueous extract capsules)	500mg daily; orally;	86% patients treated with the extract showed blood glucose control over 36 weeks. Glucosuric symptoms were also controlled.[32]
7.	*Guduchi* (*Tinospora cordifolia*)	Stem powder	50mg/kg b.w.; orally; for 15 days	Significant decrease in the level of fasting blood sugar, total cholesterol, triglycerides and β-

				lipoproteins.[33]
8.	*Shuddha Shilajit* (*Asphalatum punjabianum*)	Exudate	250mg twice a day; orally; for 28 days	Statistically highly significant improvement in fasting blood sugar (FBS) and post prandial blood sugar (PPBS). Statistically significant improvement on urine sugar and glycosylated hemoglobin levels.[34]
		Exudate	500mg twice daily; for 3 months	Statistically significant improvement was observed in sign and symptoms of Diabetes mellitus as well as on blood sugar levels after the completion of the treatment.[35]
9.	*Trivanga Bhasma*	---	125 mg twice a day daily; for 30 days	In the present study, *Vanga Bhasma* were effective in relieving signs and symptoms of Prameha and also possess significant effect in lowering the fasting and post-prandial blood sugar level.[36]

DISCUSSION

A scientific base can be established both classically as well as on contemporary aspect that the each ingredient of KARMA DOD PLUS Tablet has significant potential in lowering blood glucose levels. Classical Ayurvedic texts have described in detailed the attributes like *Madhumeha-nashaka, Praemha-har, Kaphadoshahar* etc. and many experimental studies have also explored the anti-diabetic and hypoglycaemic actions of these ingredients.

Studies confirms the anti-diabetic, blood glucose lowering potential and anti-oxidant properties of *Gudmar*. Chemically, it consists of various anti-hyperglycemic compounds like gymnemagenin and gymnemic acids in *G. sylvestre* extract.[37] The mode of action of Gudmar is by inducing the pancreas to secrete more insulin. It also has a similar effect by prolonging the absorption of glucose int he blood. Gymnemic acid's atomic arrangement are much similar to those of sugar molecules for the taste buds, which binds to the receptors present in the taste buds and prevents them from being activated by sugar molecules present in food. In the same way, it binds to a receptor situated in the outer layer of the gut to stop the intestine from absorbing sugar molecules, which reduces blood sugar levels. Gurmarin works in a similar way by obstructing the tongue's taste buds' ability to distinguish between sweet and bitter.[38] Published data for *Karela* emphasize the prospective beneficial effects of bioactive compounds on lowering hyperglycemia, magnifying insulin secretion, amplifying β-cell function, reducing Aβ accumulation, and strengthening cognitive function. Major bioactive componenets found in *Momordica charantia* includes polysaccharides,

proteins and peptides such as polypeptide-p, and peroxidase, saponins and terpenoids such as charantin, flavonoids and phenolic compounds such as quercetin, rutin, kaempferol, and isorhamnetin has highlighted its significance in the treatment and prevention of Type-II Diabetes Mellitus (T2DM).[39] Nimba is reported to maintain glycemic control and also prevents complex diabetic pathology and associated metabolic complications. It controls the blood sugar levels by inhibiting the process of glycogen lysis in liver, enhancing uptake of glucose and its utilization, impedes gluconeogenesis, prevents intestinal glucose absorption, blocks α-amylase and α-glucoside, lowers oxidative stress, exhibits anti-oxidant properties and protects tissues against damage. All these factors profoundly contributes to limit the disease.[40]

The diabetes is triggered by induction of free radicals. Jamun may have reduced free radicals and improved the functioning of β-cells of pancreas reducing the sugar level. Jamun also stimulates the activation of different enzymes like catalase glutathione peroxidase, glutathione-s-transferase and increased synthesis of glutathione and depletes lipid peroxidation that may have also helped to reduce the sugar cholesterol levels in the blood. Jamun may have reduced the activity of α-amylase, which is upregulated in the diabetes. The α-amylase activity has been found to be reduced by Jamun.[44,49,50] At molecular level presence of Jamun may have upregulated the PPARγ and PPARα leading to the suppressed activation of transcription factors including NF-κB, nitric oxide synthase (iNOS), tumour necrosis factor-alpha (TNF-α) and cyclooxygenases causing reduced in□ammation and protection against diabetes and hyperlipidaemia. Apart from this Jamun may have also upregulated the transcription of Nrf2 leading to increase in the antioxidants that may have resulted in the proper functioning of β-cells of pancreas.

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The diabetes is triggered by induction of free radicals. *Jamun* could be beneficial in reducing free radicals and improving the functioning of β-cells of pancreas and hence helps in reducing the sugar level. It also stimulates the activation of different enzymes like catalase glutathione peroxidase, glutathione-s-transferase and this increases the synthesis of glutathione and lowers lipid peroxidation which could lead to its sugar cholesterol lowering potential in the blood. *Eugenia jambolana* may have reduced the activity of α-amylase, which is upregulated in the diabetes. The α-amylase activity has been found to be reduced by *Jamun*.[41,42] At molecular level, upregulation of the PPARγ and PPARα leads to the suppressed activation of transcription factors including NF-κB, nitric oxide synthase (iNOS), tumour necrosis factor-alpha (TNF-α) and cyclooxygenases causing reduction in inflammation and protection against diabetes. Apart from this, *Jamun* could also upregulates the transcription of Nrf2 leading to increase in the antioxidants that may have resulted in the proper functioning of β-cells of pancreas.[43] *Shuddha Shilajit* is a potential drug which produces a significant reduction in blood sugar levels. Along with it, it also exhibits lipid lowering activities.[44] Classically prepared and processed *Trivanga Bhasma* lowers fasting blood glucose levels. The composition consists *Naga Bhasma, Vanga Bhasma* and *Yashada Bhasma. Pramehanashak* i.e., anti-diabetic property of *Naga Bhasma*[45], *Vanga Bhasma*[46] and *Yashada Bhasma*[46] has been described in the classical texts individually.

CONCLUSION

KARMA DOD PLUS Tablet is an effective poly herbo-metallic formulation used in Type-2 diabetes mellitus (T2DM). All the herbs and processed metals used in this composition possess blood glucose lowering activity and anti-oxidant effect, and are traditionally, experimentally and clinically tested ingredients, thereby, making it an effective formulation to be used in DM.

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