



Effect of Poly-Herbal Formulation In Management Of Type-Ii Diabetes Mellitus

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Abstract

Introduction: Diabetes mellitus is a global problem and no single stream is able to address it. Presently Diabetes mellitus is correlated with *Madhumeha* which prevents the body from proper utilization of the energy from the diet. As it is a metabolic disorder it needs some external assistance of hypoglycemic and digestive drugs. Ayurveda has a great treasure of herbal drugs which are hypoglycemic and digestive in nature. In this perspective a Polyherbal formulation can be given as an adjuvant treatment along with standard medical management and its effect can be verified.

Aim & Objective: Study the effect of poly-herbal formulation in management of Type-II Diabetes Mellitus.

Methodology: Pre-diagnosed 30 cases of Type-II Diabetes Mellitus were randomly included in the study. Patients receiving hypoglycemic drug combinations of Glimperide, Metformin and Voglibose as per need and chronicity of cases were added a polyherbal formulation (Powders of *Triphala*, *Haridra*, *Daruharidra*, *Gudamar*, *Guduchi*, *Paneerphool*, *Jambuseed*, *Methiseed*, *Neembark*, *Musta*, *Vidangaseed* and *Punarnava*) as an adjuvant treatment in decoction form, 40 ml in BD dose before

meal for a period of 1 month and effect of treatment was recorded.

Results: The treatment effect was assessed by Sigmastat software 3.0 version using paired student's 't' test. The mean fasting blood glucose before treatment was 135.733 with ± 4.601 SD and after treatment was 115.267 with ± 5.93 SD. Mean Postprandial blood glucose before treatment was 179.467 with ± 6.559 SD and after treatment was 157.933 with ± 5.546 SD. 't' value in case of FBS is $t = 30.909$ ($P = <0.001$) and in case of PPBS is $t = 32.184$ ($P = <0.001$) which is significant in both cases.

Conclusion: The Polyherbal formulation including *Triphala*, *Haridra*, *Daruharidra*, *Gudamar*, *Guduchi*, *Paneerphool*, *Jambuseed*, *Methiseed*, *Neembark*, *Musta*, *Vidangaseed* and *Punarnava* had shown hypoglycaemic effect in cases of Type II DM and can be given as an adjuvant treatment along with medical hypoglycaemic agents.

Keywords: Diabetes Mellitus, Herbal, *Madhumeha*, *Prameha*

Introduction: Lifestyle disorders are more common now days, among them hypertension and diabetes are most common. Diabetes mellitus is a global problem and no single stream is able to address it. Presently Diabetes

mellitus is correlated with *Madhumeha* which prevents the body from proper utilization of the energy from the diet. [1] Most of the Indian population is suffering from Diabetes mellitus and despite of modern treatment modalities, number of patients is increasing day by day. The number of diabetics is projected to rise from 15 million in 1995 to 57 million by the year 2025 making it the country with the highest number of diabetics in the world. [2] There are hundreds of factors associated with Diabetes mellitus; insulin and blood sugar are few of them. Although, insulin and oral hypoglycaemic agents are the mainstay of treatment of diabetes, they have prominent side effects and fail to alter the course of diabetic complications. The high cost of some agents and potential for adverse effects have led several investigators to focus their attention on the traditional medicines. According to ethno-botanical information, about 800 plants may possess anti-diabetic potential. [3] As it is a metabolic disorder it needs some external assistance of hypoglycemic and digestive drugs. Ayurveda has a great treasure of herbal drugs which are hypoglycemic and digestive in nature. In this perspective a Polyherbal formulation can be given as an adjuvant treatment along with standard medical management and its effect can be verified.

Aim: Study the effect of poly-herbal formulation in management of Type-II Diabetes Mellitus.

Objective: To Study the adjuvant effect of Ayurvedic drugs along with modern medicine drugs.

Materials & Methods: Study Design - Experimental (Clinical Trial)

Pre-diagnosed 30 cases of Type-II Diabetes Mellitus were randomly included in the study.

Inclusion: Mild to Moderate DM cases with PPBS \leq 250 mg/dl, Age group between 35-70 Yrs of either sex. Patients receiving hypoglycemic drug combinations as per

need and chronicity of cases of following Categories were included.

Category 1 - Without any hypoglycemic medicine

Category 2 - Glimepiride + Metformin

Category 3 - Glimepiride + Metformin + Voglibose

Exclusion: Patient with other systemic Complications, Uncontrolled DM cases with PPBS \geq 250 which are on modern medicine hypoglycemic drugs and Patients with complications of diabetes.

Intervention: The following poly-herbal formulation was given as an adjuvant treatment in decoction form, 40 ml in BD dose before meal for a period of 1 month and effect of treatment was recorded.

Table: Poly-herbal Formulation contents & quantity

SN	Drug	Botanical Name	Quantity
1	<i>Triphala</i>	<i>Emblica officinalis</i> , <i>Terminalia Chebula</i> , <i>Terminalia bellerica Roxb.</i>	1½ Part
2	<i>Haridra</i>	<i>Curcuma Longa</i>	1 Part
3	<i>Daruharidra</i>	<i>Berberis Aristata</i>	1 Part
4	<i>Gudamar</i>	<i>Gymnema Sylvestre</i>	1 Part
5	<i>Guduchi</i>	<i>Tinospora Cordifolia</i>	1 Part
6	<i>Rishiyagandha</i>	<i>Withania Coagulans</i>	1 Part
7	<i>Jambuseed</i>	<i>Syzygium Cumini</i>	1 Part
8	<i>Methiseed</i>	<i>Trigonella Foenum</i> <i>Greacum</i>	1 Part
9	<i>Neembark</i>	<i>Azadirachta Indica</i>	1 Part
10	<i>Musta</i>	<i>Cyperus Rotundus</i>	1 Part
11	<i>Vidangaseed</i>	<i>Embelia Ribes</i>	½ Part
12	<i>Punarnava</i>	<i>Boerhavia Diffusa</i>	½ Part

The 2 gm of powder is added in 120 ml of water and it is reduced to around 40 ml for preparing this decoction. The decoction in BD dose i.e. before breakfast/meal in morning and before dinner in Night for 1 month period was given and effect of treatment was recorded. The patients were allowed to continue their modern medicine drugs as prescribed by physician.

Observations & Results

Prameha is categorized into two groups for treatment purpose according to Ayurveda i.e. i) *Sthula Pramehi-*

obese and strong & ii) *Krusha Pramehi*- lean and weak. Promotive or nourishment therapy is advocated to *Krusha* while *Apatarpan* or *Shodhana* (evacuation) in case of patients having abundance of *Dosha* and strength. However the *Santarpana* (saturation) is advised after *Shodhana* to *Shula Pramehi* also, if not then patient may be affected with *Gulma*, wasting, pain in penis and bladder and obstruction in urine. The digestive power should be taken into consideration during *Santarpana* of *Pramehi*. [4]

The dietary management is very crucial in diabetics Ayurved recommends light edibles in various forms such as *Mantha* (churned drink), extracts, linctus made of barley powder. *Pramehi* should drink meat-soup of wild birds particularly gallinaceous and peckers. Old *Sali* rice or wild rice with *Mudga* soup is good for vegetarian. The diet of diabetic patient should mainly consist of barley. *Danti*, *Ingudi*, linseed and mustard oils are better and can be taken along with bitter vegetables. Barley grain dipped in *Triphala* decoction for whole night make saturating food taken with honey. The meat of ass, horse, bull, swan and spotted deer can be added preparations of barley for non-vegetarians. The wheat and *Bambu* seeds can be used similar to barley. [5]

The powder of flowers of *Kampillaka*, *Saptacchada*, *Shala*, *Bibhitaka*, *Rohitaka*, *Kutaja* and *Kapittha* are advised to *Prameha* patients caused by *Kapha* and *Pitta*. It should be taken in dose of 10 gm along with *Amalaka* juice in time. After digestion of drug, food made up of old cereals along with delicious meat soup of wild animals should be taken. [6]

There are number of combinations given by Charak for treating the patients of *Prameha*. The *Doshas* has been given prime importance while making such combinations. Ten types of decoction are mentioned in each category of *Kaphaj* and *Pittaja Prameha*. For *Vata* and *Vata* associated conditions unction with oil or ghee blended

with *Tikta Dravyas* is recommended. Apart from that decoction of *Triphala*, *Daruharidra*, *Vishala*, *Musta* with paste of *Haridra* along with honey is indicated in all aggravated *Pramehi*. [7] Compared to Charak, Sushruta additionally added the herbs like *Soma*, *Palash*, *Aargvadh*, *Hatha* (*Jalakumbhi*) etc. Also he has described specific combinations of decoctions as per the types of *Prameha*. [8] The drugs such as *Shirish*, *Phalini*, *Kamal*, *Kantankateri*, *Khadir*, *Dhanvantara Ghrita*, *Lodhrasava* etc. are further more compared to Charak and Sushruta. [9] Many herbal remedies and other dietary supplements are indicated by ancient sages according to *Doshik* predominance as well as built of *Pramehi*. Keeping in mind this approach, a novel combination of drugs was prepared which may be given as general treatment for *Pramehi*. The Polyherbal formulation as specified in materials and methods was intervened to Diabetes Mellitus patients. The treatment effect was assessed by Sigmastat software 3.0 version using student's paired 't' test.

Fasting blood glucose

Normality Test: Failed ($P < 0.050$)

Treatment Name	N	Missing	Mean	Std Dev	SEM	't' value	P value
Before T/t	30	0	135.733	4.601	0.84	30.909	P = <0.001
After T/t	30	0	115.267	5.93	1.083		
Difference	30	0	20.467	3.627	0.662		

t = 30.909 with 29 degrees of freedom. ($P = <0.001$)

95 percent confidence interval for difference of means: 19.112 to 21.821

The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change ($P = <0.001$). (Power of performed test with $\alpha = 0.050$: 1.000)

Postprandial blood glucose

Normality Test:Failed (P < 0.050)

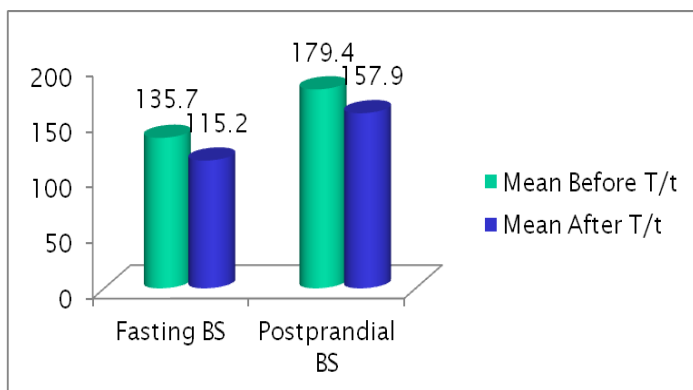
Treatment Name	N	Missing	Mean	Std Dev	SEM	't' value	P value
Before T/t	30	0	179.467	6.559	1.197	32.184	P = <0.001
After T/t	30	0	157.933	5.546	1.012		
Difference	30	0	21.533	3.665	0.669		

t = 32.184 with 29 degrees of freedom. (P = <0.001)

95 percent confidence interval for difference of means: 20.165 to 22.902

The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P = <0.001). (Power of performed test with alpha = 0.050: 1.000)

Graph: Difference of mean in Fasting and Postprandial blood glucose



't' value in case of FBS is t = 30.909 (P = <0.001) and in case of PPBS is t = 32.184 (P = <0.001) which is significant in both cases.

Discussion

The treatment approach to *Pramehi* according to Ayurved is individualized as it thinks of *Doshik* predominance and built of patient. It is clear that as per Ayurved view nourishment and saturation is instructed to both the *Pramehi*. Excluding *Asthi* and *Mamsa* all five *Dhatus* are included in *Dushya* of *Pramehi* which means these are also vitiated along with *Tridosha* in it. The tissue damage takes place fast in *Pramehi* so Ayurved compendia

suggest nourishment therapy in both the cases of *Prameha*.

However in *Brihatrayee* and other Ayurved compendia some common recipes for *Pramehi* are described. In case of food, barley is recommended in all form of diet. Wild rice or old *Sali* rice with *Mudga* soup is recommended for vegetarian while soups prepared from gallinaceous and peckers birds, animals like ass, horse, bull, swan and spotted deer is recommended for non-vegetarians.

In case of *Pramehi* having moderate built and aggravated *Dosha* the *Panchakarma* procedures are indicated. The milk, ghee and oil using for these patients should be blended with decoctions of drugs mentioned in anti-diabetic recipes as per the *Dosha* and *Prakruti* of individual. Exercise and other regimens are also explained by Ayurved for *Pramehi*.

In present study a Polyherbal formulation as specified in materials and methods was intervened to Diabetes Mellitus patients irrespective of their *Prakruti* and *Doshik* predominance of disease.

In the early stage of type 2 DM, the predominant abnormality is reduced insulin sensitivity. At this stage, high blood sugar level can be reversed by a variety of measures and medications that improve insulin sensitivity or reduce the liver's glucose production.

Insulin level increases on high glucose level in body and decreases in low glucose. Insulin and pancreas are activated in raised glucose while Glucagon and liver get activates in lower glucose level. [10]

The probable mode of action of Ayurved Drugs in Diabetes can be explained as follows.

Triphala: Active ingredients are menthol and sorbitol which is believed to have hypoglycemic effect. [11]

Gudmar: Gurmarin is polypeptide found in it having hypoglycaemic effect. The antisweet effect of *Gudmar* is due to change in pH of tongue.

Neem: It has potent Antihyperglycemic activity in glucose uptake and glycogen deposition

Jambu: Increases serum insulin levels by stimulation of its secretion and inhibit insulinase activity from liver and kidney

Guduchi: Decreases glucose levels in blood and urine also reduces lipids in serum and tissues. It prevents a decrease in body weight by reducing blood glucose level and increasing glucose tolerance.

Punarnava: Increase in hexokinase activity, decrease in glucose-6-phosphatase and fructose bis-phosphatase activity, increase plasma insulin level, antioxidant. [12]

Action of other Ayurved Drugs for Diabetes: [13]

- Reduction in glycosylated haemoglobin A1c (HbA1c)
- Increase in HDL and reduction in LDL, cholesterol, triglycerides & total cholesterol
- Stimulate higher insulin levels and fasting C-peptide levels
- Secretagogue - Release of insulin from pancreatic beta cells
- Sulfur containing amino acid - S-methyl cysteine sulphoxide (SMCS) - decreases blood Glucose & Lipids thereby normalizes the activities of liver hexokinase, glucose 6-phosphatase and HMG Co A reductase.
- S-allyl cystein sulfoxide (SACS) - the precursor of allicin and garlic oil, is a sulfur containing amino acid which controls lipid peroxidation better than glibenclamide and insulin.
- Increase in hepatic metabolism results in insulin release from pancreatic β -cells and/or insulin sparing effect
- Effectively increases glucose tolerance
- Hypoglycemic activity by increasing glycogenesis thereby increase in liver glycogen

- Antihyperglycemic - by blocking of glucose absorption from GIT
- Decreases alloxan induced lipid peroxidation in erythrocytes, kidney and heart.
- Alteration in superoxide dismutase and catalase enzyme levels to reduce oxidative stress
- Restore the activities of enzyme lipoprotein lipase (LPL), glucose-6-phosphatase and lactate dehydrogenase
- Reduction of absorption of glucose from intestine
- Inhibition of glucose-6-phosphatase, 6-phosphatase in the liver and stimulation of hepatic glucose 6-phosphate dehydrogenase activities.

Apart from these herbal drug and other medicines some lifestyle modification like *Yogasana* and *Pranayama* should be advised to Diabetic as these are having effect on autonomous nervous system of body which helps to normalise disturbed body physiology and relieves the stress. [14]

The control over elevated glucose levels in blood and urine is not a single solution for Diabetes mellitus. There are number of things involved in it like disturbance of digestion and metabolism, tissue damage, glucose intolerance, obesity, dyslipidemia, oxidative stress, weight loss, neuropathy etc. Ayurved herbs acts by many pharmacological actions sometimes by active ingredients, alkaloids, Phenols, Saponine, SMCS, SACS and have Secretagogue activity, reduction in lipid peroxidation and diminution of absorption of glucose from intestine. So the polyherbal combination prepared from potent Ayurved herbs can definitely help to work on many disturbed mechanism of diabetic. The various actions of Ayurvedic drugs are summarized above and these herb acts synergistically. It can be concluded that the said polyherbal combination has good hypoglycaemic activity and can be given along with other hypoglycaemic agents.

Conclusion

Diabetes Mellitus is an emerging global problem to whom any single medical discipline can't treat completely and there is need of integration in treatments. The Polyherbal formulation including *Triphala*, *Haridra*, *Daruharidra*, *Gudamar*, *Guduchi*, *Paneerphool*, *Jambuseed*, *Methiseed*, *Neembark*, *Musta*, *Vidangaseed* and *Punarnava* had shown hypoglycaemic effect in cases of Type II DM and can be given as an adjuvant treatment along with medical hypoglycaemic agents.

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