



Research Article

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A PILOT STUDY ON *QUASSIA AMARA* LINN.: A NEWLY EMERGING DRUG FOR TYPE 2 DIABETES

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ABSTRACT

Though the awareness about Health in community is raising, changes in dietary habits and lifestyle of people from all age groups has resulted emergence of various non communicable diseases. Among these non communicable diseases diabetes tops the list and has overtaken communicable diseases with respect to overall mortality, even in developing countries like India. *Quassia amara* Linn. an ethno medicinal plant finds no direct reference in Ayurvedic classics, Quassin constituent of *Quassia amra* in it is one of the bitterest substances found in nature. The bitters plants are generally showing anti-diabetic and tonic action. For this clinical study, 58 cases of recently diagnosed, mild to moderate cases of type 2 diabetes were administered capsules filled with heartwood powder of *Quassia amara* Linn., 3 capsules (500mg each) twice daily before food with lukewarm water along with controlled diet for 60 days. To assess the effect of trial drug fasting Blood sugar, post prandial blood sugar, lipid profile and BMI were done before and after the completion of 60 days of the treatment. It was observed that treatment with cap. *Quassia amara* provided statistically highly significant reduction of 19.33% in fasting blood sugar level and of 22.05% in Post Prandial Blood Sugar levels. Similarly, significant decrease of 9.95% in serum Cholesterol level and that of 13.63 % in S. Triglyceride level and 1.52% decrease in BMI was found. It showed the potential of *Quassia amara* Linn. heartwood powder as single herb therapy in patients of type 2 diabetes.

Keywords: *Quassia amara* Linn. Type 2 Diabetes, Anti diabetic effect

INTRODUCTION

High prevalence rates of diabetes are seen not only in affluent migrant Indians, but also in those living within the subcontinent. Indeed, the epidemic of diabetes is now spreading to the middle and lower income groups in India¹. The disease currently affects more than 62 million Indians, which is more than 7.1% of India's adult population². Globally, as of 2010, an estimated 285 million people had diabetes, with type 2 making up about 90% of the cases³. Fatty diets and decreased physical activity have accompanied the benefits of modernization. Exercise has been engineered out of our daily lives, both in the work place & leisure. These lifestyle changes and effects of pre-existing genes are cause of type 2 diabetes epidemic that the world is witnessing today.

The description of *Quassia amara* is available in 'The Wealth of India' (CSIR).⁴ It is available wildy in abundance and readily available source of medicine. *Quassia amara* Linn. being an ethnomedicinal plant assumes importance and no clinical data in patients of type 2 diabetes was available on this plant. Quassin constituent in it is one of the bitterest substances found in nature and it has been used in management of type 2 diabetes.

the anti diabetic activity studies were carried out in diabetic rats treated with oral doses of 100 and 200mg/kg of *Quassia amara* Linn. extract. Both doses of *Quassia amara* Linn. extract significantly reduced elevated fasting blood glucose levels in diabetic rats, significantly increased the glucose tolerance compared with the vehicle and effectively normalized dyslipidemia associated with streptozotocin-induced diabetes⁵. The anti-hyperglycemic effect of wood powder of *Quassia amara* Linn. was evaluated in normal and in alloxan diabetes-

induced rats and it showed anti-hyperglycemic effects, similar to metformin in the diabetic animals when compared to the control group⁶. A desirable anti-diabetic agent is that which would not lower the blood glucose level below the normal level in normoglycaemics and should have a good blood glucose lowering effect in hyperglycaemic subjects

Aims & objectives

To evaluate of anti-diabetic effect of heartwood '*Quassia amara* Linn.' in the patients of type 2 diabetes.

MATERIALS AND METHODS

For this clinical study, patients fulfilling the diagnostic criteria of the study were selected from O.P.D. and IPD of *Kayachikitsa* department, I.P.G.T & R.A, Gujarat Ayurved University, Jamnagar during the period of February 2014 to June 2015. Institutional ethics committee approval was taken prior to initiation of research vide letter No. PGT/7-A/Ethics/2013-14/2753 Dt.9-12-2013. Study was registered in CTRI with no. CTRI/2014/07/004775 dated 25/7/2014. The market sample of heartwood of herb *Quassia amara* Linn. was procured from Mumbai. The pharmacognostical authentication and pharmacognostical analysis of *Quassia amara* Linn. was done on the basis of morphological features, organoleptic characters and powder microscopy of the sample drug and was performed at pharmacognostical and pharmaceutical laboratory of IPGT and RA, GAU, Jamnagar.

Criteria for Diagnosis⁷

Standard criteria of National Diabetes Data Group and the World Health Organization (W.H.O.) for Diabetes Mellitus were

adopted which was presence of symptoms of diabetes Mellitus like polyuria, polyphagia, polydipsia, etc., Random blood glucose concentration ≥ 11.1 mm d/L (200 mg/dL) or Fasting blood glucose ≥ 7.0 mm d/L (126mg/dL) or Two hours blood glucose ≥ 11.1 mm /dL (200 mg/dL) (Adopted by American Diabetic Association).

Inclusion Criteria

- Age between 40 years to 70 years.
- Known patient of Type 2 diabetes and also the patients preliminarily diagnosed Type 2 diabetes on the basis of signs and symptoms of the disease were confirmed by FBS and PPBS.

Exclusion Criteria

- Age below 40 years & above 70 years.
- Patients of Type I diabetes.
- Patients suffering from: Malignant and accelerated hypertension, CVS disorder (CAD), Pregnant woman and planning to be pregnant within six months, Lactating mother, Secondary diabetes mellitus, diabetic ketosis, CNS disorder e.g. encephalopathy
- Patient undergoing regular treatment for any other severe illness and also patients suffering from tuberculosis, carcinoma endocrine disorders like, Thyrotoxicosis, Cushing Syndrome etc. and HIV positive patients.

Investigations

For the purpose of assessing the general condition of the patient and to exclude other pathologies investigations like complete haemogram, Blood urea, serum creatinine, SGPT, SGOT and ESR were carried out before intervention of treatment. To assess the effect of trial drug fasting blood sugar, post prandial blood sugar, lipid profile, Urine examination for routine and microscopic aspects were carried out before and after the completion of 60 days of the treatment.

Posology

The 58 patients were recently diagnosed patients, mild to moderate cases of type 2 diabetes were administered *Quassia amara* capsules (capsules filled with heartwood powder of *Quassia amara* Linn.) in the dose of 3 capsules (500mg each) (3 gm/day) along with Luke warm water orally twice a day before meals for the duration of 6 days along with controlled diet. For the present study, total 58 patients of type 2 diabetes were registered, out of which 55 patients completed full course of treatment. The data of 55 patients who completed the management course was analysed by statistical methods. Paired t -test was performed by using SigmaStat⁸ 3.1 software. The obtained results were interpreted as > 0.05 was considered as insignificant, ≤ 0.05 as significant and ≤ 0.01 as highly significant.

RESULTS AND DISCUSSION

Data on analysis revealed that trial drug provided highly significant reduction of 19.33% in fasting blood sugar level. On further analyzing the data it was found that fasting blood sugar level was significantly reduced by 20.02% in those patients, who were suffering from type 2 diabetes from 1-4 yrs. In patients of type 2 diabetes having chronicity of 5-10 years significant reduction ($p < 0.05$) of 18.25% in fasting blood sugar level was observed. The analysis of data depicts highly significant reduction of 22.05% in post prandial blood sugar levels in the patients. Further details of the data revealed that in patients of type 2 diabetes who were having chronicity of 1-4 years, highly significant reduction of 24.46 % in post prandial Blood Sugar levels was observed. Similarly, highly significant reduction of 18.05% in post prandial blood sugar level was observed in the patients. The data related to Serum Cholesterol on statistical analysis depicts highly significant decrease of 9.95% and that of 13.63% in Serum Triglyceride. (Table 1)

The test drug provided highly significant decrease of 20.64% in the patients who were having Kapha-Pitta Prakriti. Similarly, highly significant decrease of 26.68% was observed in patients of the diabetes who were having Pitta-Kapha Prakriti, However the parameters in the patients having Pitta-Vata Prakriti was insignificant. Significant decrease of 21.63% and 28.49% was provided by test drug in Post Prandial Blood Sugar level of patients of who having Kapha-Pitta Prakriti and Pitta-Kapha Prakriti, However, The test drug provided insignificant decrease of 14.92% in patients who having Pitta-Vata Prakriti. (Table 2)

Analysis of overall effect of the *Quassia amara* Linn. showed that treatment with this drug provided excellent response in 12.72% of the patients, marked response in 45.45 % of the patients, moderate response in 27.27% and mild response in 14.54% of the patients.

In recent years, ethno-medicinal research works are being widely carried out in order to document indigenous knowledge on the use of plants and for providing an inventory of useful plants from local flora. *Quassia amara* Linn. being an ethnomedicinal plant assumes importance as there is no planned study available on this plant. The plant finds no direct reference in Ayurvedic classics, although it is stated in Aadarsha Nighantu that Indian quassia (*Picrasma quassioides*) is having equal medicinal properties as that of *Quassia amara* Linn. Modern botanical texts, various floras, material medicas and glossaries explain the plant with its taxonomical description.

In diabetic state there is beta cell failure leading to reduced basal insulin secretion in fasting state, trial drug has shown fasting blood sugar lowering effect which is statistically significant. It shows possibility of beta cell protective or regenerative effect of *Quassia amara* Linn. The drug is fibrous and the possible mechanisms for metabolic improvements with dietary fibre include delay of glucose absorption, increase in hepatic extraction of insulin, increased insulin sensitivity at the cellular level, and binding of bile acids. Research studies reported that beta-sitosterol (constituent in *Quassia amara* Linn.) decreases the fasting hyperglycemia when was administered and increased the fasting plasma insulin levels.

Table 1: Effect of test drug *Quassia amara* on Fasting Blood Sugar level in the patients of Type 2 diabetes

Parameters	N	Mean Score		Mean diff	%	Paired 't' test				
		B.T.	A.T.			SD(±)	SE(±)	't'	P	Sig
		FBS	(n=55)			211.23	169.4	41.83	19.33↓	62.48
FBS level (chronicity 1-4 years)	(n=34)	209.23	167.38	41.85	20.02↓	62.20	10.66	3.92	<0.001	HS
FBS level (chronicity 5-10 years)	(n=20)	215	176	39.25	18.25↓	65.05	14.54	2.69	0.014	S
PPBS level (mg/dl)	A (n=55)	303.98	236.30	67.67	22.05↓	98.50	13.28	5.09	<0.001	HS
PPBS level (mg/dl) (chronicity 1-4years)	(n=34)	303.08	228.94	74.14	24.46↓	111.13	19.05	3.89	<0.001	HS
Serum Cholesterol	(n=55)	185.02	166.69	18.32	9.95↓	38.82	5.23	3.50	<0.001	HS
Serum Triglyceride	(n=55)	159.52	132.12	27.40	13.63↓	76.85	10.36	2.64	0.011	HS
Serum HDL	(n=54)	48.02	45.40	2.62	5.38↓	9.79	1.32	1.98	0.059	IS
SGPT	(n=55)	20.77	22.34	1.52	7.31↑	15.25	2.05	-0.74	0.461	IS
SGOT	(n=54)	28.79	31.21	2.83	9.82↑	10.5	1.41	-2.00	0.05	IS
S.Creatinine	(n=55)	20.77	22.34	1.52	7.31↑	15.25	2.05	-0.74	0.461	IS

BT: Before Treatment, AT: After Treatment,
 HS=Highly significant, S= Significant, ↓ = Decrease, Sig= significance,
 FBS: Fasting Blood Sugar, PPBS: Post Prandial Blood Sugar

Table 2: Classification according to *Dosha* wise

Parameters	N	Mean Score		Mean diff	%	Paired 't' test				
		B.T.	A.T.			SD(±)	SE(±)	't'	P	Sig
		FBS level of patients having <i>Kapha-Pitta Prakruti</i>	(n=19)			214.89	170.52	44.36	20.64↓	64.31
FBS level of patients having <i>Pitta-Kapha Prakruti</i>	(n=17)	234.29	171.76	62.52	26.68↓	70.92	17.20	3.63	0.002	HS
FBS level (mg/dl) (<i>Pitta-Vata Prakruti</i>)	(n=10)	180.70	164.90	15.80	8.74↓	42.32	13.38	1.18	0.26	IS
PPBS level (mg/dl) (<i>Kapha-Pitta Prakruti</i>)	(n=19)	310.68	243.47	67.21	21.63↓	114.3	26.22	3.56	0.020	S
PPBS level (mg/dl) (<i>Pitta-Kapha Prakruti</i>)	(n=17)	316.05	226.00	90.05	28.49↓	84.83	20.57	4.37	<0.001	HS
PPBS level (mg/dl) (<i>Pitta-Vata Prakruti</i>)	(n=10)	273.40	232.60	40.80	14.92↓	66.93	21.16	1.92	0.086	IS

BT: Before Treatment, AT: After Treatment,
 HS=Highly significant, S= Significant, ↓ = Decrease, Sig= significance,
 FBS: Fasting Blood Sugar, PPBS: Post Prandial Blood Sugar

In the present study, PPBS level was reduced significantly; this may be because of increased beta cell response to the oral glucose uptake, retarding the carbohydrate absorption from intestine and improvement in peripheral glucose uptake. Pancreatic α - amylase inhibitors offer an effective strategy to lower the levels of post prandial hyperglycemia via control of starch breakdown. Phytochemical analysis revealed the presence of tannins, cardiac glycosides, flavonoids and steroids as probable Pancreatic α - amylase inhibitory compounds of *Quassia amara* Linn^{9,10}

CONCLUSION

In the present scenario, *Ayurved* herbs have become more popular for the management of the chronic, progressive diseases like type 2 diabetes. From the findings of present clinical trial *Quassia* had proved to have anti-diabetic, anti- hyperlipidemic and anti hypertriglyceridemic effect in the cases of type 2 diabetes. Further large sample size study may help to establish *Quassia amara* Linn. as choice of drug for the treatment of type 2 diabetes.

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