Role of naturopathy on physical and biochemical parameters in patients with *Type 2 diabetes* mellitus

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Study was aimed to evaluate the effect of four months of naturopathy on *diabetes, symptom score, physical parameters, biochemical parameters and oxidative stress* in patients suffering from Type 2 diabetes (T2D). Total of 121 diabetic patients were enrolled. Treatment group included 60 patients taking naturopathy including abdomen mudpack, spinal cord massage and cold hip bath (CHB). Parameters recorded were glycemic status (plasma fasting and PP) *oxidative stress (*Glutathione peroxidase and Total Antioxidant Capacity {TAC}) *and symptom score (u*rination, visual symptoms, fatigue, drowsiness, hunger, Thirst). With naturopathy a significant reduction in sugar levels in Fasting (p<0.001), PP (p<0.01), HbA1c (p<0.001) was observed. Improvement in physical *parameters and symptom score* in diabetic patients was also observed. Urination frequency, visual symptoms, fatigue, drowsiness, hunger and thirst severity were found to be more normal in intervention group as compared to control group. There was a simultaneous improvement in parameters *of oxidative stress.* TAC value showed significant increase in both paired and non paired groups (p<0.05). Glutathione peroxidase levels showed increase only in paired group (p<0.01). Results of our study suggest that naturopathy can be considered as effective treatment modality in overall well-being of patients with T2D.

Keywords: BP, CHB, FPG, HbA1c, PP, T2D, TAC **IPC Code:** Int. Cl.¹⁹: A61P 17/18, A61P 7/12

Type 2 diabetes is a progressive disorder characterized by increasing hyperglycemia. It affected 415 million people worldwide in 2015, with a predicted rise to nearly 642 million by 2040¹. Early initiation of combination therapy has been proposed as an approach to achieve glycemic goals and delay the deterioration with possible better preservation of β -cell function². Tight glycemic control has been shown to reduce the risk of complications but is not easily achieved and maintained³. The disease is characterized by ongoing deterioration of glycemic control and worsening pancreatic function with the need to gradually intensify therapy to maintain proper glycemic targets⁴. Alleviation of hyperglycemia, regardless of the means, is the most important contributor to β -cell preservation. Striving for normoglycemia early at disease onset, or at the prediabetic stage and maintaining normoglycemia safely

by combination of medicines as required may change the natural history of disease⁵.

Lack of physical labour, stress, faulty lifestyle and wrong dietary pattern are some of the factors that spike the levels of blood sugar. Regular physical activity prevents or delays diabetes and its complications⁶. Blood Sugar can be controlled, managed and prevented to a larger extent through alternative medicine. The goal of treatment in T2D is to achieve and maintain optimal Blood Glucose (BG), lipid, and blood pressure (BP) levels to prevent or delay chronic complications of diabetes⁷. Many people with T2D can achieve BG control by following a nutritious meal plan and exercise program, losing excess weight, implementing necessary self-care behaviours, and taking oral medications, although others may need supplemental insulin⁸. With Naturopathic treatment of diabetes and right kind of diet and exercise, cases of pre-diabetes, insulin-resistance and T2D can be reversed.

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Naturopathic protocols for diabetes are considered safe wherein patients can lose weight, gain significant energy and reduce their glucose levels, lipid values, and blood pressure. Non-pharmacological lifestyle interventions are recommended for management of metabolic syndrome⁹. Conventional treatment for diabetes including a variety of medications may have short or long-term side effects. For this reason one may choose to try natural treatment to possibly avoid use of conventional medications or decrease dosages of conventional medications required to manage pre-diabetes or diabetes symptoms.

In this study, it was hypothesized that Naturopathy treatment if given to T2D patient may help to improve glucose tolerance, improve *physical parameters*, *symptom score and* decrease *oxidative stress* which may help to prevent or manage complications.

Methodology

Trial design: The study was a randomized control trial carried out on T2D patients at Bapu Nature Cure Hospital and Yogashram (BNCH & Y). Ethical clearance for the study was given by Institutional Ethical committee of BNCH & Y. The subjects were randomly divided into two groups; control and intervention. Control group was given allopathic medicine and Intervention group was administered Naturopathy treatment in addition to allopathic medicines. Total duration of treatment was 4 months. In both the groups blood samples were taken at the start of treatment and after 4 months. Prior written consent was obtained from participating subjects.

Eligibility criteria: T2D Patients of either sex having age between 30-60 years, having disease for more than ten years and fulfilling diagnostic criteria as laid down by American Diabetes Association (ADA) for T2D patients (HbA1c \geq 6.5%, FPG \geq 126 mg/dL and Random **Plasma Glucose** \geq 200 mg/dL), were enrolled for the study.

Exclusion criteria: Poorly controlled T2D patients on Insulin therapy or patients having history of severe cardiac/hepatic/renal/pulmonary dysfunction/obesity grade III/Thyroid disorder/malignancy were excluded from study.

Stopping rules for discontinuing patients from study

To drop patient if s/he is unwilling to give written consent or having sugar value $\geq 300 \text{ mg/dL}$ on 2^{nd} month assessment or in case of life challenging illness or patient not co-operating or having irregular attendance. **Naturopathy treatments and its duration:** The total intervention period of study was 4 months. Naturopathy treatments included mud pack to abdomen, massage to spinal cord and abdomen and cold hip bath. During the first month patients were given treatment five times a week, second month thrice a week, third month twice a week and fourth month once a week.

Mud pack: Clay pack devoid of any contamination having thickness of about 1 inch was applied over the abdominal region on empty stomach for 20 min. The size of this pack varied from patient to patient as per their abdominal circumference.

Abdominal and spinal massage therapy: Massage using til oil was given to the patients for 10 min each on abdomen and spinal area.

Cold Hip bath (CHB): Cold hip bath (summer: 22°C, winter: 30°C) was given to the patients for 20 min. On the days when patients were not given therapies in the hospital, they were advised to practice the same at their homes.

Allopathic Medicines: Allopathic treatments were provided to both the groups. The prescribed medicines were Metformin, Glimeperide, Glibenclamide and Pioglitazone. The physician was consulted at the end of every month.

Parameters studied: Parameters investigated were glycemic status (blood glucose F, PP), *physical parameters (BP Systolic and Diastolic), biochemical parameters (Cholesterol, TG, HDL-C), oxidative stress (*Glutathione peroxidase and total antioxidant capacity (TAC) *and symptom score* (urination, visual symptoms, fatigue, drowsiness, hunger, thirst).

Glucose, *Cholesterol, TG, HDL-C* were estimated using standard Roche kit on C-501 fully Auto Analyser (Roche Make). *Oxidative stress* (Glutathione peroxidase and total antioxidant capacity (TAC) parameters were evaluated on AU 400 auto-analyzer.

Statistical methods: Data collected during the study period were analyzed using SPSS 20.0. The statistical significant was considered at p<0.05 levels for all the parameters and the values were expressed as mean \pm SD.

Results

The period of study was for 2 years i.e., 18-03-2015 to 17-02-2017. The study was conducted in the following three phases: -

PHASE-I: Pre-trial preparation March, 2015 to April 2015 (1st & 2nd month) during this period staff

was recruited and was imparted specialized training so as to meet the study requirements.

PHASE-II: Patient recruitment and Intervention therapy, May 2015 to August 2016 (3^{rd} -18th month). During this period of study, patients were recruited and were given intervention therapies as per study design. Patients were recruited in various batches. Each patient was given treatment for 4 months. A total of 140 diabetic patients were recruited. Out of which 19 patients opted out of the study. Remaining 121 patients were divided in 2 groups i.e., Group I consisting of 61 patients (male, n=34, female, n=27) received only Allopathic Medicine. Group II was intervention group. It consisted of 60 patients (male, n=30, female, n=30) and received naturopathy and allopathic medicines simultaneously.

PHASE-III: Analysis of data and preparation of report September, 2016 to February, 2017 (19rd to 24th month) - After completion of Phase II of study, data collected during the study was analysed.

Data on clinical symptoms score of patients in both the groups are shown in Table 1. After 4 months of intervention urination frequency in control group reduced from 41% to 13% where as in intervention group it reduced from 36.7% to 3.3%. At the end of the study urination frequency was found to be normal in 47.5% of control group and 66.7% of intervention group

After 4 months visual symptoms in control group reduced from 26.2% to 14.8% whereas in intervention group it reduced from 15% to 5%. At the end of the study visual symptoms was found to be normal in 50.8% of control group and 70.0% of intervention group

After 4 months fatigue in control group reduced from 41% to 13% whereas in intervention group it reduced from 38.3% to 5.0%. At the end of the study fatigue was found to be normal in 36.1% of control group and 53.3% of intervention group

After 4 months drowsiness in control group reduced from 42.6% to 11.5% where as in intervention group it reduced from 31.7% to 5%. On completion of study drowsiness was found to be normal in 54.1% of control group and 73.3% of intervention group.

After 4 months hunger in control group reduced from 18% to 3.3% where as in intervention group it reduced from 10.0% to 1.7%. At the end hunger was found to be normal in 78.7% of control group and 85.0% of intervention group

After 4 months thirst in control group reduced from 44.3% to 4.9% whereas in intervention group it reduced from 45.0% to 3.3%. At the end of 4 months thirst was found to be normal in 44.3% of control group and 61.7% of intervention group

Systolic BP (Table 2), showed no significant effect after 4 months of intervention in control or intervention group. For diastolic BP, comparison of control and intervention groups after 4 months showed significant change (p<0.01)

In intervention group fasting plasma glucose was significantly reduced (p<0.01) after 4 months as compared to control group and as compared to the base line levels of intervention group (Paired group). Postprandial plasma glucose was also found to be statistically reduced after 4 months in intervention group as compared to control group (p<0.01) and also as compared to the base line levels of

Table 1 — Clinic	al symptoms	Score (%) in	diabetic pati	ents of control	and interventi	on group	
Test	Time	Intervention			Control		
	Time	Normal	Mild	Severe	Normal	Mild	Severe
Urination frequency (%)	Baseline	55.0	8.3	36.7	42.6	16.4	41.0
	4 th Month	66.7	30.0	3.3	47.5	39.3	13.1
Visual symptoms(%) (Blurred vision)	Baseline	60.0	25.0	15.0	42.6	31.1	26.2
	4 th Month	70.0	25.0	5.0	50.8	34.4	14.8
Fatigue (%)	Baseline	28.3	33.3	38.3	32.8	26.2	41.0
	4 th Month	53.3	41.7	5.0	36.1	50.8	13.1
Drowsiness (%)	Baseline	43.3	25.0	31.7	27.9	29.5	42.6
	4 th Month	73.3	21.7	5.0	54.1	34.4	11.5
Hunger (%)	Baseline	75.0	15.0	10.0	55.7	26.2	18.0
	4 th Month	85.0	13.3	1.7	78.7	18.0	3.3
Thirst (%)	Baseline	41.7	13.3	45.0	37.7	18.0	44.3
	4 th Month	61.7	35.0	3.3	50.8	44.3	4.9

intervention group (Paired group) (p<0.001) (Table 3, Fig. 1).

Effect of Naturopathy on biochemical parameters in T2D patients are shown in Table 4, Fig. 2. In cholesterol and TG level there was no significant effect. Paired t test comparison of HDL-c in control



Fig. 1 — Bar diagram for fasting and PP sugar of control and intervention group at baseline and after 4 months

and intervention group showed that there was significant increase in the levels after 4 months (p<0.01) in both the groups. TAC value showed significant increase in both paired and non paired groups (p<0.05). Glutathione peroxidase levels showed increase only in paired group (p<0.01).

Discussion

Exercise (structured or planned activities) and physical activity (PA) (all types of activities) have been validated to prevent or delay diabetes development as part of a comprehensive approach to lifestyle change. It is now well established that participation in regular PA improves blood glucose control and can prevent or delay T2D, along with positively affecting lipids, blood pressure. cardiovascular events, mortality, and quality of life¹⁰. Studies suggest that while exercise treatment programs may or may not reduce body weight but programs of sufficient intensity have been shown to decrease diabetes risk¹¹. Therefore, health care providers should inform patients at-risk of these benefits, in order to motivate them to engage in regular moderate-intensity physical activity. Moderate exercise, such as brisk walking or other activities of equal intensity, has been also observed to improve insulin sensitivity and reduce abdominal fat content in children and young adults^{12,13}. Both resistance training and endurance exercise seem to have beneficial effects on waist circumference, insulin sensitivity, and thus diabetes risk^{14,15} Naturopathy has the ability to

Table 2 — Levels of Blood pressure (BP) in diabetic patients of control and intervention groups given naturopathy.

Table 2 Devels of Diode pressure (D1) in diabetic patients of control and met vention groups given naturopathy.						
Parameter	Group	Baseline levels	levels after 4 months	p value (paired data)		
BP Systolic(mm)	Control	125.64+15.9	125.54+13.56	0.956		
	Intervention	127.63+17.62	125.12+10.91	0.224		
p value (unpaired data)		0.515	0.850			
BP Diastolic(mm)	Control	77.90+9.41	76.79+7.25	0.274		
	Intervention	79.40+14.22	80.47+6.34	0.566		
p value (unpaired data)		0.495	0.004**			
*(p<0.05), ** (p<0.01) and	l *** (p<0.001)					

Parameter	Group	Baseline levels	Levels after 4 months	p value (paired data)
Plasma Glucose PGF (mg%)	Control	139.82+49.34	155.39+48.82	0.065
	Intervention	149.95+42.27	132.82+29.48	0.006**
p value (unpaired data)		0.228	0.003**	
Plasma Glucose PP (mg%)	Control	232.54+52.48	233.54+67.23	1.000
	Intervention	239.37+59.34	204.73+50.29	0.000***
p value (unpaired data)		0.504	0.009**	

Table 4 -	— Levels of biochem	nical Parameters in T2D pat	ients of control and interve	ention group
Parameter	Group	Baseline	4 th month	p value (paired data)
Cholesterol (mg/dL)	Control	181.56+42.78	183.92+47.31	0.703
	Intervention	185.78+40.83	181.43+39.66	0.335
value (unpaired data)		0.579	0.755	
TG (mg/dL)	Control	168.95+73.79	155.1+62.95	0.060
	Intervention	165.25+63.94	164.93+70.57	0.972
value (unpaired data)		0.769	0.420	
HDL-c (mg/dL)	Control	42.97+11.14	47.33+14.49	0.003**
	Intervention	45.10+11.99	49.62+15.07	0.010*
value (unpaired data)		0.313	0.396	
AC(U/L)	Control	1.52+0.31	1.46+0.21	0.149
	Intervention	1.46+0.33	1.60+0.42	0.012*
value (unpaired data)		0.300	0.028*	
Glutathione peroxidise (U/L)	Control	323.52+67.81	323.84+59.64	0.964
	Intervention	310.35+62.12	328.65+58.74	0.005**
value (unpaired data)		0.226	0.658	
(p<0.05), ** (p<0.01) and **	* (p<0.001)			



Fig. 2 - Bar diagram for Biochemical parameters of control and intervention group at baseline and after 4 months

control diabetes at the earliest. Mud therapy, massage therapy, cold hip bath helps to energize and revitalize the body and can be beneficial for hyperglycemic patients. Naturopathic treatment modalities are also found to be beneficial as a complementary therapy with oral hypoglycemic drugs¹⁶ In our study these naturopathy treatments were administered to diabetic patients for a period of four months.

Hydrotherapy helps improve metabolism and enhances the body's ability to use glucose. The mechanism of cold hip bath, used in our study, is that it excites contraction of the muscular structures of viscera and thus helps to stimulate the functions of abdominal and pelvic organs including pancreas, liver and bladder and it also decreases tissue blood flow by causing vasoconstriction, thus reduces tissue metabolism, inflammation and muscle spasm¹⁷.

Massage Therapy is considered a passive exercise and highly improves the activities of circulatory and nervous system. It relaxes the muscle and reduces stress. It is beneficial in increasing the circulatory activities of muscle, lymphatic and nervous system which helps in expelling the impurities through sweat or urine¹⁸. It reduces the tension in muscles and gives relaxation by reducing stress. The stress reducing effect of massage might be attributed to control of counter regulatory stress hormones permitting the body to use insulin more effectively¹⁹.

Mud Therapy synchronizes the balance of the digestive system with the endocrinal organs, which being underutilized in diabetic patients lead to toxins accumulation. Mud therapy has various therapeutic properties which are highly useful in the treatment of various diseases²⁰. Soil is found to retain moisture for a longer period, and when applied on the body it can cool down the system. It technically soaks up heat from the system and is found to be effective in eliminating excess heat from the body. It helps in the degeneration of morbid matter. Mud bath is one of the best methods to eliminate the toxins from the body. The intent of mud therapy was to improve blood circulation in the abdominal and pelvic regions to remove heat and congestion, absorb toxic substances, and tone up the tissues and organs which enhance the functional capacity of body^{21,22}. It increases the blood circulation, relieves inner congestion and eliminates morbid toxins from the body. Treatments like gastro-hepatic pack (GHP) and cold hip bath (CHB) was beneficial in T2D.¹⁶ GHP helps to reduce FBS by increasing peripheral

circulation and tissue oxygenation, and increasing metabolic rate.¹⁶ CHB also helps to increase the metabolic rate by thermogenic means²³. Application of a mud pack to the abdomen enhances peripheral circulation, increases metabolic rate, and hence helps reduce blood glucose levels.¹⁶

Diabetic patients were given above mentioned therapies of naturopathy because of their expected stress reducing outcome and consequential better glycemic control. The hypothesis of our study was to arrest diabetes and *improve symptom score, physical and biochemical parameters* by stimulation of abdominal organs by naturopathy.

Symptoms of diabetes are frequent urination, excessive thirst, extreme hunger, increased fatigue, high blood pressure, blurry vision, unusual weight loss, irritability and frequent infections. These patients may also experience nausea and decreased exercise tolerance²⁴. In our study, urination frequency, visual symptoms, fatigue, drowsiness, hunger and thirst severity was found to be normal in 47.5%, 50.8%, 36.1%, 54.1%, 78.7%, 44.3% respectively in control group. Whereas in intervention group these were found to be better and were normal in 66.7%. 70.0%, 53.3%, 73.3%, 85.0%, 61.7% respectively. Previous scientific literature shows that insulin therapy in elderly people with T2D can lead to an improvement of depressive symptoms and does not seem to affect negatively health-related quality of life (HRQOL) of the participants²⁵. So naturopathy seems to have added benefit in further improving these symptoms.

Systolic BP, showed no significant effect after 4 months of therapy of control or intervention group. For diastolic BP, intervention group showed significant increase (p < 0.01), levels of which were in normal range. In our study fasting blood glucose was significantly reduced (p<0.01) at 4th month in intervention group as compared to control group (unpaired) and as compared to the base line levels of its own intervention group (paired group). Similarly postprandial blood glucose was also found to be statistically reduced at 4th month in intervention group as compared to control group (unpaired) (p<0.01) and also as compared to the base line levels of its own intervention group (Paired group) (p<0.001). So in our study, FBG and PPBG decreased significantly in intervention group as compared to control group and as well to its own baseline levels. Naturopathy helped diabetic patients in better glycemic control as shown in

our study by improvement in symptom score by different types of naturopathy treatments. Insulin resistance together with β -cell dysfunction and apoptosis are the two fundamental mechanisms for the development of T2D²⁶. Weight reduction along with improvement in insulin sensitivity is often accompanied by favourable changes in components of metabolic syndrome and elevated levels of insulin have been reported to contribute to its pathogenesis of metabolic syndrome²⁷. By administering naturopathy treatments, body may be losing fat resulting in more number of receptors in muscle and adipose tissue due to reduction in weight. Previous literature report emphasizes the need for therapeutic strategies to achieve weight reduction in obese patients with T2D²⁸

Besides measuring glycemic status and symptom score biochemical parameters were also measured. In cholesterol and TG level, naturopathy of 4 months had no significant effect. In HDL-C, paired t-test comparison of control and intervention group as compared to their base line levels showed that there was significant increase in the levels after 4 months (p<0.01) in both the groups (paired groups). HDL-C stimulates pancreatic *β*-cell insulin secretion and modulates glucose uptake in skeletal muscle in different experimental and human settings²⁹. Increased plasma HDL-C has been suggested as a novel therapeutic option to reduce risk of Type 2 diabetes³⁰. On the other hand low levels of HDL-C have been consistently associated with increased risk of T2D in epidemiological studies³¹. In our study in both control and intervention group, decreased levels of HDL-C were observed and these may be having a role in better glycemic control in both the groups.

Total antioxidant capacity (TAC) values showed significant increase in both paired and non paired groups (p<0.05). Glutathione peroxidase levels showed increase only in Intervention group (p<0.01). A depletion of the total antioxidant capacity is associated with a higher incidence of diabetic complications. Our results shows increased TAC and glutathione peroxidase levels after intervention therapy as compared to its own baseline levels.

Hyperglycemia in diabetic patients results in increased intracellular glucose which triggers several pro-inflammatory reactions producing highly toxic oxygen-derived free radicals³². A role for antioxidants has been demonstrated in restoring endothelium-dependent vasodilation impaired by hyperglycemia in particular³³, and in protection against the toxic effects of reactive oxygen species in general³⁴. The beneficial

role for dietary antioxidants to treat diabetic neuropathy and cardiac autonomic neuropathy is also indicative of the role of heightened inflammatory/oxidative stress in this entity³⁵. A depletion of the total antioxidant capacity is associated with a higher incidence of diabetic complications³⁶. Hyperglycemia promotes autooxidation of glucose to form free radicals. The generation of free radicals beyond the scavenging abilities of endogenous antioxidant defences results in macro and microvascular dysfunction. Oxidative stress, defined as excess formation and/or insufficient removal of highly reactive molecules such as reactive oxygen species (ROS) and reactive nitrogen species (RNS), increases in diabetes when free radical production exceeds the body's ability to neutralize them^{37,38} Despite the agreement on the increase of free radicals in diabetic patients, the level of antioxidants in diabetic patients has been reported to decrease³⁹, increase⁴⁰ or stay the same⁴¹. The effect of diabetes on total antioxidant levels seems to be complicated by the effect of diabetes on individual antioxidant systems. In our study because of naturopathy, TAC and Glutathione peroxidase has been found to increase which seems to have an overall positive impact on the control of hyperglycemia and symptom score. As per our knowledge this is study of its own kind where effect of naturopathy on oxidative status has been carried out.

Our study showed that life style improvement result in better glycemic control. This study will be helpful in understanding that ultimately altered lifestyle due to modernization, westernization is becoming more responsible for the generation of diabetes as compared to genetic predisposition. Naturopathy regime as developed, if adopted by T2D patients, can result in better control of diabetes which is slowly becoming an epidemic.

Trial limitation- There is a need to conduct scientifically larger clinical trials for a longer duration to evaluate the effectiveness of naturopathic care in T2D patients.

Conclusion

It is concluded that naturopathy not only helped in control of diabetes by improving glycemic status and improving symptom score but also by improving total antioxidant capacity. This study helped us to develop a natural regime for the treatment and management of diabetes. So, naturopathy therapies may be helpful for controlling diabetic conditions and reversing to normal physical and mental health with the prevention of disability, morbidity and mortality due to T2D. Patients should be encouraged to get naturopathy treatment and they should welcome these changes into their lives. Change in lifestyle habits will help in control of blood sugar in a natural way and will provide health benefits for years to come.

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