Original Article

Ocimum Sanctum Linn Extract As An Adjuvant Therapy For Effective Glycaemic Control In Type II Diabetes Mellitus

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Abstract

Ocimum sanctum Linn extract as an adjuvant therapy for effective glycaemic control in type II diabetes mellitus, a case control study was conducted at selected hospitals of Sangli, Miraj, Kupwad corporation area. The objectives of the study were to assess the blood glucose levels in diabetic patients before and after treatment with Ocimum sanctum Linn extract combined with oral hypoglycaemic agent and to compare these blood glucose levels in experimental and control groups. The hypothesis H0 was that there would be no significant difference between after the administration of Ocimum sanctum Linn leaves extract on blood sugar level of experimental and control group and H1 there is significant difference between pre-test and post-test blood sugar level of experimental and control group. The study used the quantitative research approach. The conceptual framework was used in this study was ERNESTINE WIEDENBACHS PRESCRIPTIVE THEORY. Total 60 samples were selected for the study by non-probability convenient sampling technique (30 for experimental 30 for control group). Experimental group had given Ocimum sanctum Linn extract with OHA for 20 days,whereas control group continued OHA treatment only. Demographic variables and blood glucose level data was collected. The data was analysed using the descriptive and inferential statistics such as mean, standard deviation, frequency and percentage were utilised as well as inferential analysis such as chi square test, paired t and unpaired t test. The study results suggested that the mean value of pre and post-test fasting blood glucose levels in the experimental group were 166.00 and 132.37 mg% respectively. The mean pre-test and post-test fasting blood glucose levels in control group were 169.63 and 163.50 mg% respectively. The mean value of pre and post-test post prandial blood glucose levels in the experimental group were 170.27 and 141.31 mg% respectively. The mean pre-test and post-test post prandial blood glucose levels in control group were 166.47 and 159.87 mg% respectively. The result of comparison of post prandial blood glucose levels in experimental and control groups had calculatedt value of 50.18 and pvalueo f 0.000 w h i c h suggests that there is a significant difference in the post prandialblood sugar levels of the experimental and the control groups. The study concluded that Ocimum sanctum Linn can be recommended for the treatment of moderate diabetes mellitus in combination with oral hypoglycaemic agents to get the synergistic effect of both the medicines for effective control of hyperglycemia.

Key words – Diabetes mellitus type II, Ocimum sanctum Linn, blood glucose level.

Introduction:

Rising burden of diabetes mellitus worldwide is painful misery, especially in developing countries like India. India is home to the world's second-largest adult diabetes population and every sixth person with diabetes in the world is an Indian[1]. According to recent ICMR guidelines, the past three decades witnessed a 150 per cent increase in the number of people with diabetes in the country[2]. Both urban and rural population have observed progressive decline of the age at which diabetes is diagnosed, causing profound economic burden on healthcare system of India. Multiple risk factors are now identified for the risk for diabetes like ethnicity, genetic and family history, age, obesity and physical inactivity, unhealthy diet, and behavioural habits. Proper control of blood sugar levels

can prevent and/or delay the onset of diabetes complications. Effective management of diabetes and its complications is still a tough challenge for India due to heavy barriers like poor multisectoral approach, erroneous surveillance data, lack of awareness regarding diabetes, its risk factors and complications, compromised access to health care settings and affordable medicines[3]. Many alternative therapies have been studied as possible ways to treat or prevent type 2 diabetes, but there's no definitive evidence to support it.

The theme of this study is to explore the effect of combining alternative medicine and allopathic medicine on blood sugar level management and creating diverse usefulness of alternative medicine among diabetes patients. The medicinal properties of Ocimum sanctum Linn on diabetes mellitus are well known worldwide. It has an antidiabetic, antimicrobial, hepatoprotective, autoinflammatory, Anticarcinogenic, radio protective, immunomodulatory, neuroprotective, cardioprotective, and mosquito repellent properties[4].The leaves of this plant are packed with antioxidants that produce eugenol, methyl eugenol and caryophyllene, collectively these compounds help the pancreatic cells to function properly and increase sensitivity to insulin[5]. This case-control study is planned to investigate the synergistic effect of Ocimum sanctum Linn extract and standard allopathic oral hypoglycaemic agents on control of type II diabetes mellitus.

Material and methods:

Study Population – Study was done in the community-based setting of Sangli, Miraj, Kupwad corporation area. Study population was the patients diagnosed with type II diabetes mellitus and are on regular treatment with oral hypoglycaemic agents. A convenient sampling technique was used and total 60 patients were selected for the study. Patients were randomized by simple randomization technique into case and control group by coin flip method. Inclusion criteria were – All patients diagnosed with type II diabetes mellitus with fasting blood glucose level above 130 mg% and currently under treatment with oral hypoglycaemic agent within age group of 30-60 years. Comorbid patients, those who were on insulin treatment and unable to read or write in English, Marathiwere excluded from the study.

Ethical Clearance- The study was performed under the supervision of the Physicians. All the Procedure was informed to the patient in his native language. After taking their consent the subjects were enrolled and interviewed at their convenient timing to fill questionnaire which is prepared for research.

Preparation of Ocimum sanctum Linn extract- good quality of Ocimum sanctum Linn leaves were harvested from local Ayurvedic rasshala. These leaves were cleaned and washed thoroughly with distilled water. Then leaves were wiped with tissue paper and dried at a room temperature for 3-5 days. The dry leaves ground coarsely with mortar and pestle to form an extract. Total 15 gm Ocimum sanctum Linn extract was mixed with 50ml of hot water at the time of administration.

Data collection method-

Initial Assessment: After written consent, the patients enrolled for the study underwent physical examination by the registered physician. The physical examination consisted of assessment of the parameters like height, weight, body mass index, blood pressure. Information related to pharmacological treatment (0ral hypoglycaemic agents), pre-existing comorbidities or diabetic complications, smoking status as well as demographic characteristics were obtained from the participants. These included age, gender, occupation, income, dietary and exercise pattern.

Administration of Ocimum sanctum Linn extract: The patients in the ‘case’ group were administered 15gm of Ocimum sanctum Linn extract mixed with 50ml of hot water after breakfast. The control group were only administered 50ml of plain hot water after breakfast. The extract was administered for total 19 days in this manner to patients in the ‘case’ group. Both patients in case and control group continued oral hypoglycaemic agent as before. All the participants continued the same dietary and exercise pattern as before during study period.

Laboratory investigations: All Laboratory investigations were conducted at central research laboratory using the set protocol and procedures established by the hospital. The biochemical profile was obtained in the form of fasting and post prandial blood glucose levels on first day for both case and control group. Repeat assessment of biochemical profile in the form of fasting and post prandial blood glucose levels were obtained on 10th and 20th day of the study for both case and control group. The data was meticulously recorded and analysed.

Results:

Table 1 depicts demographic variables.

n=30+30

SN	Variable	Groups	Experimental		Control	
			Frequency	**Percentage**	**Frequency**	**Percentage**
1	**Age (Inyears)**	below40	10	33.33	10	33.33
		41-50	8	26.67	7	23.33
		51-60	12	40.00	13	43.33
		above60	0	0.00	0	0.00
2	**Gender**	Male	20	66.67	17	56.67
		Female	10	33.33	13	43.33
3	**Education**	Primary	1	3.33	3	10.00
		Secondary	8	26.67	7	23.33
		Graduate	20	66.67	19	63.33
		PostGraduate	1	3.33	1	3.33
4	**Income (in Rs.)**	Below10000	3	10.00	5	16.67
		10001-20000	16	53.33	10	33.33
		above20000	11	36.67	15	50.00
5	**Occupation**	Farming	3	10.00	5	16.67
		Homemakers	3	10.00	5	16.67
		Job	16	53.33	13	43.33
		Business	8	26.67	7	23.33
6	**DietaryPattern**	Veg	8	26.67	7	23.33
		Non-Veg	0	0.00	1	3.33
		Mixed	22	73.33	22	73.33
7	**Exercise**	Yes	11	36.67	13	43.33
		No	19	63.33	17	56.67

Most of the patients were graduate males in the age group 51-60 years with average income from job.

Comparison of blood glucose levels-

Table 2 denotes fasting blood glucose levels on 1st, 10th, and 20th day.

n=30+30

Group	ObservationDay	Mean	S.D.	TValue	PValue
Experimental	Day1	166.00	12.42	20.06	0.000
	Day 10	151.63	54.66		
	Day20	132.37	13.91		

Control	Day1	169.63	9.68	5.75	0.078
	Day 10	166.50	2.63		
	Day20	163.50	10.53		

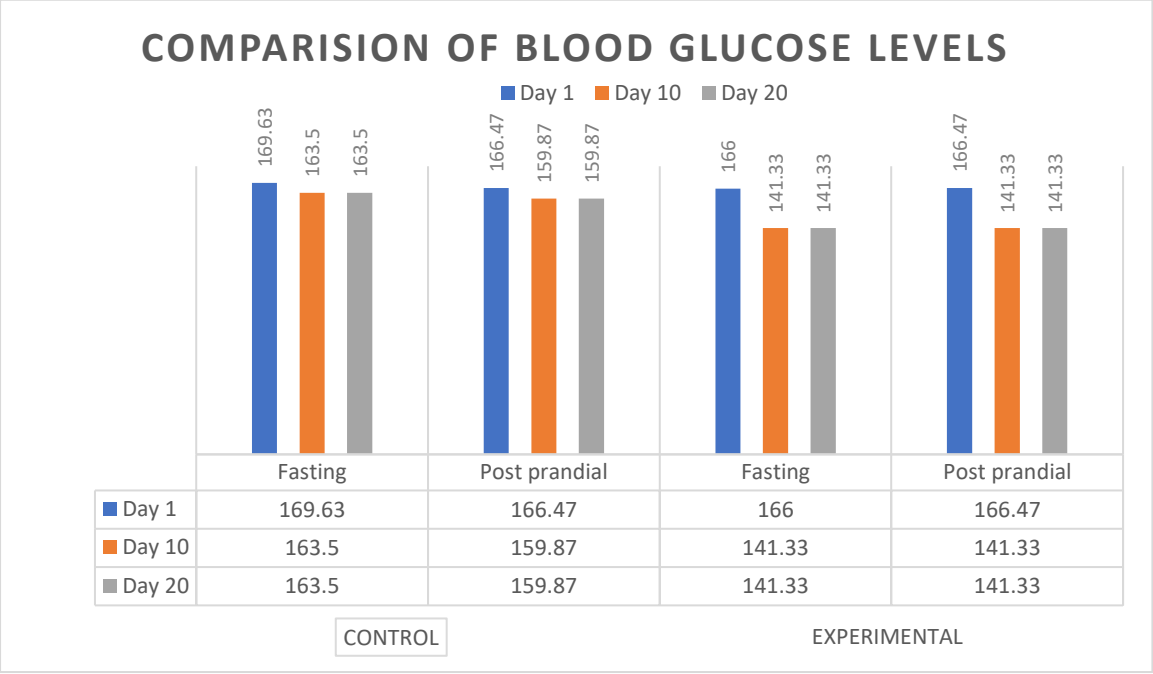
There is significant decrease in fasting blood glucose levels in experimental group as compared to control group. Progressive blood glucose level decline pattern is observed in experimental group over 20 days.

Table 3 denotes post prandial blood glucose levels on 1st, 10th, and 20th day.

n=30+30

Group	ObservationDay	Mean	S.D.	TValue	PValue
Experimental	Day1	170.27	10.41	50.18	0.000
	Day 10	158.87	11.62		
	Day20	141.31	11.6		
Control	Day1	166.47	12.26	2.37	0.09
	Day 10	163.43	12.37		
	Day20	159.87	11,22		

There is significant decrease in post prandial blood glucose levels in experimental group as compared to control group. Progressive blood glucose level decline pattern is observed in experimental group over 20 days.



The data chart clearly indicates significant decline in both fasting and post prandial blood glucose levels in experimental group as compared to control group.

Table no.4

Comparisonofpostprandialblood g l u c o s e levelin experimental and control groups

n=30+30

Group	ObservationDay	Frequency	Mean	S.D.	TValue	PValue
Experimental	Day1	30	170.27	10.41	50.18	0.000
	Day20	30	141.31	11.6		
Control	Day1	30	166.47	12.26	2.37	0.09
	Day20	30	159.87	11,22		

Abovetable shows that the, in the experimental group on day 1 the mean post prandial blood glucose levelis 170.27 and SDis10.41 where as on 20th day mean post prandial blood glucose level is 141.33 and SD is 11.6. t valueis 50.18and p value is 0.000.

Incontrol group on day 1 mean post prandial blood glucose level is 166.47 and SDis12.26, whereas on 20th daymean post prandial blood glucose level is 159 .87 and SDis11. 22. Calculatedt value is 50.18 and pvalue i s 0.000 w h i c h suggests that there is a significant difference in the post prandialblood sugar levels of the experimental and the control groups.

Discussion:

Ocimum sanctum Linn have been traditionally recommended as an Indian herbal medicine for anti-diabetic, antihypertensive adaptogenic, antilipidemic, cardio protective properties. Many experimental studies have showed its antidiabetic effect but very few studies are performed to investigate the efficacy in actual diabetic patients. Agrawal et al reported reductions of 17.6% and 7.3% in the levels of fasting and postprandial blood glucose levels in arandomized placebo-controlled, single blind trial of holy basil leaves in patients with noninsulin-dependent diabetes mellitus[5].

Current study was planned to evaluate the synergistic effect of Ocimum sanctum with oral hypoglycaemic agents on blood glucose levels in the diagnosed patients of non-insulin dependent diabetes mellitus. Results were compared with control group.All the patients in control group continued their treatment of oral hypoglycaemic agent only. Ocimum sanctum was administered in an unprocessed and natural form in order to retain maximum pharmacological effect. The results of this study indicate that in the experimental group there was reduction of 24.67% and 25.14% in fasting and post prandial blood glucose levels respectively. While in the control group there was reduction of 6.13% and 6.6% in fasting and post prandial blood glucose levels. It is clearly evident that Ocimum sanctum acted as a mutual pharmacological agent with oral hypoglycaemic drug to reduce the blood glucose levels. These results are consistent with similar study conducted by G. Somasundaram et al[6]which suggested significant reduction in blood sugar levels in patients receiving Glibenclamide plus O. sanctum. Further this study suggested that very less subjects experienced hypoglycaemic episodes during treatment duration, highlighting the safety profile of this combination. In our study very minimal number of patients experienced hypoglycaemic episodes.

Results of this study indicate that OHA therapy alone may not be effective for sustained glycaemic control. Combining multiple oral hypoglycaemic agents my reduce safety profile of the regime as acute hypoglycaemic episodes are common. Considering the above factors, Ocimum sanctum Linn can be recommended for the treatment of moderate diabetes mellitus in combination with oral hypoglycaemic agents to get the synergistic effect of both the medicines. Our results also suggest that OHA combined with Ocimum sanctum has better safety profile, however further research is needed on larger population in this context.

Conflict of Interest

No conflict of interest involved.

Funding Source

The study was self-funded by researchers.

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