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Original Article

Factors Associated with Glycemic Control among Type 2 Diabetes Patients on Ayurveda Therapy

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ABSTRACT

Introduction: Globally, one in 10 adults is living with diabetes and nearly 40% remain undiagnosed making it a silent killer. India's traditional medical system, Ayurveda, has been practiced for thousands of years. As the treatment of Ayurveda has a high acceptability in the Indian subcontinent, it is commonly used for the treatment of Type 2 Diabetes mellitus (T2DM). The present study is planned to identify and explore the variables related to glycemic control in T2DM patients receiving Ayurvedic treatment. **Materials and Methods:** A total of 100 subjects were studied in cross-section taking into consideration the inclusion and exclusion criteria and selected through convenience sampling. Study subjects included patients of T2DM on Ayurveda therapy irrespective of their duration of therapy and disease. Ethical permission was taken and data collected after due consent from the study subjects. **Results:** About 40% of the patients did have a family history of T2DM with a first-degree relative. The mean age of diagnosis was early with the history of two or more affected family members. A significant association was observed between gender and glycemic levels. Age and duration of illness also had a significant association with HbA_{1c} levels among the subjects. **Conclusion:** It can be concluded from the study that the key features associated with diabetic control among patients on Ayurveda therapy are mainly the family history, age at diagnosis and thereby the duration of illness, current age and gender of subjects.

Keywords: Age, Ayurveda, Family history, HbA_{1c}, RBS, Type 2 DM.

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INTRODUCTION

The prevalence of diabetes mellitus (will henceforth be referred to as Type 2 Diabetes mellitus i.e. T2DM), one of the most prevalent long-term illnesses, is growing. Globally, one in 10 adults is living with the disease and nearly 40% remain undiagnosed making it a silent killer. Approximately 90% of adults diagnosed with Diabetes Mellitus have the type 2 variant.[1] It is a complex metabolic disorder with major health and socioeconomic consequences. In T2DM, chronic hyperglycemia is related to macro- and micro-vascular complications and death.[1,2]

In the Indian subcontinent, the ancient medical system known as Ayurveda has been practiced for thousands of years.[3,4] In the public healthcare system of India under the National Health Mission, medical officers from Ayurveda discipline have been appointed as clinical care providers.[5,6] Also, Ayurvedic doctors practice at private medical facilities.[5,7]

In Ayurveda, T2DM is referred to as "Madhumeha", which splits to madhuas meaning sweetness and mehaas meaning excessive urination.[8,9] Ayurveda texts in Sanskrit clearly mention about the disease and its management. In India one of the diseases for which the Ayurvedic consultants are commonly consulted for is T2DM. As the treatment of Ayurveda has a high acceptability in the Indian subcontinent, it is commonly used for the treatment. It also matches with the traditional customs and traditions of the Indians. Many people with T2DM dislike using allopathic medications due to the associated adverse effects and cost.[10-12]

Systematic reviews of previous clinical trials indicate that a number of Ayurvedic medications have positive benefits on T2DM-related outcomes, such as improved blood glucose, with no significant safety concerns.[13,14] It was therefore decided to carry out the study to identify different variables associated with glycemic control among patients on Ayurveda therapy for T2DM.

MATERIALS AND METHODS

The study conducted was cross sectional in nature. It was conducted at Parul Ayurveda Hospital for a period of 6 months with sample size of 100 subjects based on convenience of the investigator. The selection of the study subjects was also based on

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convenient sampling. For data collection, a tool was developed after validation with subject experts and was aimed at knowing the basic profile of the patients and their glycemic control taking different indices into consideration. The data was collected by directly interviewing the subjects and from their routinely conducted laboratory investigations. The commencement of data collection was done after relevant permissions from institutions and ethics committee of the University. Appropriate written and oral consent was taken from study subjects before enrolling them in the study. The custody of the data was kept with the principal investigator. The sources used were Patients case notes, interviewing the patient and medications charts and prescriptions. Using study papers from scientific literature, a data collection form was created for the Ayurvedic medical system and it was authorised by the Doctoral Research Committee. The form contained information on the patients' demographics, random blood sugar, HbA_{1c} (glycosylated haemoglobin) and mean glucose levels, medications that the patients were prescribed and other pertinent characteristics.

Inclusion criteria include T2DM Patients of either gender aged more than 30 years; newly diagnosed patients of T2DM or those already on medications and T2DM patients only on individual Ayurveda therapy. All the nursing mothers, patients with gestational diabetes and critical patients with unstable vitals or in coma stage are excluded.

A total of 100 patients were enrolled for the present study. For ethical concerns, the study protocol was submitted and approved by the Institutional Human Ethics Committee (Parul University) prior to the data collection with the approval number PUIECHR/PIMSR/00/081734/3205. The patients signed an informed consent form and the research was carried out.

The patients at the OPD and those who had been admitted were first checked for inclusion criteria and patients who met the study requirements were enrolled in the research after completing an informed consent form. The Patient Information Sheet was given to the patients. They also received an explanation of the anticipated results and advantages of the study. At the Ayurvedic study site, a group of patients were registered. The patient's blood sample was taken by the laboratory technician and sent to the lab for blood glucose testing (HbA_{1c} and RBS). The laboratory supervisor double-checked the produced reports before sending them to the patients. After collecting all the relevant patients' data, comparative results were analyzed.

RESULTS

A total of 100 patients on Ayurveda therapy for T2DM were studied. Gender wise, the study subjects were almost equally distributed with around 56% males. The majority of the study subjects were middle-aged (56%) followed next by the proportion of elderly (39%). All the patients had an old or a newly diagnosed T2DM. Most patients did have at least one member affected i.e. a family history of T2DM. However, there was a significant proportion of subjects having no such history. Among those with the family history, all patients were reported having first-degree relative with T2DM as shown in Table 1.

The mean age at detection was close to 50. This was not affected by the history of family member (whether one or more) having the disease. Those not having a family history also had their detection at a similar age as shown in Table 2.

A significant association was noted between Glycoslated Hb levels and gender. Males had higher proportion with Glycosylated Hb in the diabetes category. The association was sought using chi squared test (X^2=6.249, df=2, p<0.05) as shown in Table 3. The study participants' mean HbA_{1c} values were 8.4. The levels was lesser among the males (about 8.2) and higher in females (around 8.5). The mean random blood glucose also showed a similar picture. The level was quite similar on an average among all subjects and also among both genders. There was some reported difference between the categories in the mean glucose levels but the difference was minimal as shown in Table 4. There was a statistically significant association found between age and glycosylated Hb levels. As the age increased the levels were also seen to increase among study subjects (X^2=11.297, df=4, p<0.05) as shown in Table 5.There is no statistically significant association found between age and Random blood glucose levels (X^2=7.42, df=4, p=0.115). It was however seen that those aged more than 40

Table 1: Frequencies of self-reported individuals with T2DM with details of Family History of Diabetes (Parents and/or siblings only) (*n*=100).

Family history of Type 2 diabetes among study subjects	Frequency (Number)
No family history.	61
One affected family member.	25
Two or more affected family members.	14
Details with respect to degree of relation with diabetics in family	
First Degree Relative.	39
Second Degree Relative.	0

Table 2: Association between family history and mean age at diagnosis among study subjects (*n*=100).

Status of family history of T2DM	Mean age at diagnosis (yrs)
Without Family History (*N*=61).	48.95 (95% CI, 46.41-51.49)
With Family History (*N*=39).	52.3 (95% CI, 49.18-55.42)
Segregation with number of family members affected (*n*=39)	
One affected family member (*N*=25).	52.4 (95% CI, 48.50-56.30)
Two or more affected family members (N=14).	52.14 (95% CI, 46.96-57.32)

years had higher chances of blood sugar recorded more than 200 mg/dL i.e. in diabetic category as shown in Table 6.

Statistically, there was a significant association found between duration of diabetes and glycosylated Hb levels. Higher the duration of diabetes, higher were the levels of glycosylated Hb among subjects (X^2=15.439, df=6, p<0.05) as shown in Table 7.

Table 3: Association of Gender and Glycosylated Hemoglobin status among study subjects.

Gender vs. HbA_{1C}	Category of Glycosylated Hb			Total
Gender	<5.6	5.7-6.4	>6.5	
Female	1	11	32	44
Male	0	5	51	56
Total	1	16	83	100

Table 4: Gender wise distribution depicting laboratory based glycemic status of study subjects.

Gender wise distribution	Laboratory values
Glycosylated Hb	
Male	8.321±2.02
Female	8.583±2.11
All	8.4±2.09
Random blood glucose	
Male	211.05±110.14
Female	203.7±110.4
All	207.82±109.89
Mean blood glucose	
Male	209.52±66.68
Female	225.36±68.17
All	216.49±67.86

The values are mean±SD.

DISCUSSION

The ancient medical practice of Ayurveda is becoming more popular in different countries as a complementary and alternative therapy for long-term illnesses. Type 2 diabetes is a chronic condition with significant long-term effects on both the people who have it and the healthcare system as a whole. Ayurveda is an age-old Indian medical system that incorporates lifestyle, exercise and food modifications. These modifications are crucial to the successful treatment of type 2 diabetes. Ayurvedic treatments for type 2 diabetes include exercise, weight management and a variety of additional procedures, but their main focus is on the use of herbal supplements. Similar to Western medicine, the aim of Ayurvedic treatment for type 2 diabetes is to lower the HbA_{1c} result into a range that is under control. Ayurveda varies in that it considers an individual's functionality within the framework of achieving equilibrium among their doshas, or life energies.[15] Finally, this research includes different parameters and their associations which is done in a teaching Ayurvedic hospital, Gujarat, India. Type 2 diabetic patients might ask about the complementary and alternative therapies that are currently being used to treat their condition. For patient counselling and care to be effective, awareness of these modalities is required. Offering a broad range of treatment alternatives has advantages, such as the potential to lower co-morbidities and HbA_{1c} with adjunct supplementation and mind-body techniques.

In the present study, 61% of patients had no family history which is similar to a study done by Iwata *et al.* where the FHD-had 49.4%.[16]

The patients who had family history with one affected family member had the mean age at diagnosis of 52.4 (95% CI, 48.50-56.30) where as with two affected family members had the mean age of diagnosis as 52.14 (95% CI, 46.96-57.32). These results are strongly supported by a similar study by Iwata *et al.*[16]

Table 5: Association between age group of the subjects and their HbA_{1c} levels.

Age Category		HbA_{1c} (%)			Total
		<5.6	5.7-6.4	>6.5	
Age	30-39 Years	0	4	3	7
	40-59 Years	0	8	48	56
	60-80 Years	1	4	32	37
Total		1	16	83	100

Table 6: Association between age group of the subjects and their Random blood glucose levels.

Age Category		Random Blood Sugar (RBS-mg/dL)			Total
		<140	141-199	>200	
Age	30 - 39 Years	4	0	3	7
	40 - 59 Years	10	16	30	56
	60 - 80 Years	8	13	16	37
Total		22	29	49	100

Table 7: Association between duration of T2DM and glycosylated Hb of the study subjects

Duration of diabetes mellitus in years		HbA_{1c} (%)			Total
		< 5.6	5.7-6.4	> 6.5	
	<2 yrs	0	6	20	26
	3-5 yrs	0	6	33	39
	6-10 yrs	0	4	24	28
	>10 yrs	1	0	6	7
Total		1	16	83	100

where at the time of diabetes diagnosis, patients in the FHD++ and FHD+++ groups were substantially younger than those in the FHD- and FHD+ groups (p<0.001).

CONCLUSION

Based on the study carried out in Parul Ayurved Hospital in T2DM patients, 39% of the patients reported to have first degree family history of Diabetes Mellitus. The mean age of diagnosis was early with the history of two or more affected family members than one affected family member. A significant association was observed between gender and glycemic levels. Age and duration of illness also had a significant association with HbA_{1c} levels among the subjects. It can therefore be concluded from the study that the key features associated with diabetic control among patients on Ayurveda therapy are mainly the family history, age at diagnosis and thereby the duration of illness, current age and gender of subjects. More research of this kind is required to gain a deeper comprehension of the effects and contributing aspects of Ayurvedic treatment for Type 2 diabetes.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

FHD -: Family history of diabetes; **FHD - :** Patients without FHD; **FHD+ :** Those with at least one sibling; **FHD++ :** Those with one parent; **FHD+++ :** Those with both parents; **HbA_{1c}:** Glycated or glycosylated haemoglobin; **T2DM:** Type 2 Diabetes mellitus; **CI:** Confidence Interval; **RBS:** Random Blood Sugar.

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