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A study to evaluate the effect of *gymnema sylvestre* in mother tincture and 50 millisimal doses on diabetes mellitus - type-2

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Abstract
Background: Diabetes Mellitus is metabolic disorder characterized by hyperglycemia resulting from inadequate insulin secretion, insulin inaction or both and insulin resistance. People living with Type-2 DM are more vulnerable to various forms of both short-term and long-term complications, which often lead to their premature death. *Gymnema sylvestre,* in various homoeopathic preparations, have reported beneficial effect for treating in Type-2 diabetes mellitus.
Aim and Objective: To understand the efficacy of *Gymnema sylvestre* in 50milisimal potency and in mother tincture on diabetes mellitus Type-2 patients.
Method: This prospective, open label, randomized controlled trial was conducted at OPD and IPD of Government Homoeopathic Medical College and Hospital, Bhopal and camps organized by department. A total 60 nos. of patients were enrolled for this study considering all ethical criteria and inclusion and exclusion criteria's as per institutional guidelines with 30 cases allotted randomly to GSMT and LM group. Data were recorded on standard case proforma, and entered Microsoft® Excel worksheet 2019, and exported into SPSS v21.0 (IBM, USA) for statistical analysis. Each case was followed up for a period of six months and outcome were assessed on QOLID scale. Normality of data was determined using Shapiro-Wilk test. Normally distributed variables were compared between two groups using independent t-test. Comparison within a group at two time-intervals was made using paired t-test. P value <0.05 was considered statistically significant.
Results: A significant difference in HbA1c levels in GSMT group compared to LM group at 6-month (6.77±0.41 vs. 7.13±0.27; P=0.003) was observed in this study, also a significant improvement in QOLID levels in GSMT group compared to LM group at 6-month (127.90±7.15 vs 115.20±3.38; P=<0.0001) was observed.
Conclusion: Homoeopathic preparations of *Gymnema sylvestre* is proved to effective in management of diabetes mellitus though it was observed that *gymnema sylvestre* mother tincture has more effective.

Keywords: T2DM, GSMT, LM, RBS, Hba1c, QOLID

1. Introduction
Diabetes mellitus (DM) is one of the oldest human disorders known to civilization. Elevated blood glucose levels are a symptom of diabetes, a heterogeneous, complicated metabolic condition caused by either resistance to the action of insulin, inadequate insulin secretion, or both [1]. The most prevalent kind of DM, Type-2 (formerly known as non-insulin dependent DM), is characterized by hyperglycemia, insulin resistance, and relative insulin insufficiency. The interplay of behavioral, environmental, and genetic risk factors leads to Type-2 diabetes [2]. People living with Type-2 DM are more vulnerable to various forms of both short-term and long-term complications, which often lead to worsening of quality of life and their premature death.
This condition is commonly classified into T1DM and T2DM, Insulin resistance and a relative lack of insulin secretion are features of T2DM. Although the absolute plasma insulin concentration (both fasting and meal-stimulated) is often higher, the plasma insulin concentration is insufficient to sustain healthy glucose homeostasis "relative" to the severity of insulin resistance while in persons with T1DM there is an utter lack of beta-cell function. Beta-cell death by the immune system is a prevalent cause, yet cases are still considered to be idiopathic.
The signs and symptoms of diabetes are disregarded by many because of the chronic progression of the disease. People do not consider this as a serious problem because unlike many other diseases the consequences of hyperglycemia are not manifested immediately.

This is unfortunate because recognition of early symptoms can help to get the disease under control immediately and to prevent vascular complications. Considering the asymptomatic nature of Type-2 diabetes in the early stages, it is essential that the people are educated regarding its warning signs such as: Unexplained weight loss, irritability, dry mouth, reactive hypoglycemia, acanthosis nigricans, frequent infection, delayed would healing.

Worldwide prevalence of diabetes mellitus is increasing. Its prevalence in India is also increasing during last few years. In India, more than 62 million people were diagnosed with disease. The prevalence of DM type-2 is predicted in 2030 may afflict upto 79.4 million individuals in India.In India, the burden of diabetes has been increasing steadily since 1990 and leaps and at a faster pace from the year 2000. In India, the incidence of diabetes increased from 7.1% in 2009 to 8.9% in 2019. IGT is thought to affect 25.2 million persons currently, and 35.7 million adults are thought to have it by 2045 [3].

Homoeopathy uses a holistic approach to treat a variety of illnesses and is practiced all over the world as an alternative medicine [4]. Homeopathy is a type of alternative medicine that makes use of ultra-dilution, or extremely high dilutions (like LM Potency) and mother tincture generated from organic compounds derived from plants, minerals, or animals to treat various diseases [5, 6]. according to homoeopathic philosophy, a persistent miasmatic states or condition is considered to be in background for development/manifestation of diabetes mellitus, in the same line the patient with diabetes mellitus is typically evaluated by patient's etio-pathology, family history, age of onset of disease, physical (renal function etc.) and mental health, miasmatic state and the severity of their complaints.

Majority of homoeopathic medicines are prepared for plants and vegetables, Gymnema Sylvester being one of them, also known as Gurmar and madhunashini is believed to might neutralize the excess of sugar present in the body in Diabetes mellitus patients [7]. It is a woody climber found in india, commom in deccan peninsula and in northern and western part of India. The taxonomy of the plant is described as Familly Aslepiadaceae, Genus gymnema, species sylvestre [8, 9].

Mechanism of action of *G. Sylvester* (Gymnemic Acid): Leaves of *gymnema sylvestre* have been demonstrated to cause hypoglycemia, and ayurveda and homoeopathic medicine have both used leaves to treat individuals with diabetes mellitus. World Health organization has recommended that effective work of *Gymnema sylvestre* on diabetes mellitus without side effects [10]. Several reviews showed that medical plants had anti diabetic activities [11, 12]. When a plant's leaf extract is given to a diabetic patient, the pancreas is stimulated, which results in an increase in insulin secretion. Additionally, it has been observed that these substances boost cholesterol excretion in the feces.[13] Some potential ways through which *Gymnema Sylvester's* leaf extract (also known as gymnemic acid) exerts its hypoglycemic effects includes:

1. It promotes regeneration of islet cells,
2. It increases secretion of insulin,
3. It causes inhibition of glucose absorption from intestine,
4. As a result of increased phosphorylase activity, decreased gluconeogenic enzymes, and increased sorbitol dehydrogenase activity, it promotes the consumption of glucose by insulin- dependent pathways.[14]

Aim and Objective: To understand the efficacy of *gymnema sylvestre* in 50 milisimal potency and in mother tincture on diabetes mellitus type 2 patients.Primary Objective of study to understand the efficacy of homoeopathic medicine gymnemasylvestre in various form vis. Mother tincture and renewed dynamized forms. Secondary Objectives of study to explore the utility of LM scale.To obtain the various clinical aspects of DM patients.

Reseach question: was there any sinificant difference between *Gymnema sylvestre* mother tincture and *Gymnema sylvestre* LM potency in management of Diabetis mellitus type 2.

Hypothesis H0 (Null Hypothesis)

There is no association (Significant difference) between efficacy of GSMT and LM in Case of Type II Diabetes Mellitus.

H1 (Alternative Hypothesis)

GSMT is more efficacious than LM in case of Type II Diabetes Mellitus

H2 (Alternative Hypothesis)

LM is more efficacious than GSMT in case of Type II Diabetes Mellitus

Materials and Method

This prospective, open label, comparative, randomized study was designed to compare effect of *Gymnema sylvestre* in LM (fifty millesimal) and MT (mother tincture) on Type-2 DM patients. The study was conducted at G.H.M.C, Bhopal, Madhya Pradesh over a duration of one year. The data was collected from OPD of the institute along with different camp organized by the institute. A total 60 cases enrolled based on the inclusion and exclusion criteria and patients were randomly allocated to two groups viz. GSMT group (*Gymnema sylvestre* mother tincture) and LM group (fifty millesimal). The patient inclusion criteria were patients of both genders, aged between 30 to 60 years having complaints of Type-2 DM, of any socio-economic status and who consented to participate in the study whereas the patients who were taking medicines for diabetes mellitus complications, having chronic complications of Type-2 diabetes mellitus, Pregnant and lactating women, history of smoking and alcohol consumption, Patients requiring emergency medical intervention, Immuno-compromised patients, refused to provide consent of participation were excluded from study. Out of 60 patients enrolled 40 patients followed up regularly and were finally analyzed.

The patients were divided into two interventional group. Twenty patients were allocated into each group. Group GSMT received Gymnema Sylvester Mother Tincture as a homoeopathic medicine and Group LM received Gymnema Sylvester LM as a homoeopathic medicine. This study was open level study, so patients were aware about the medicines. Each case was followed up for the period of six moths at the interval of one month or as required. HBA1c of each patient were recorded at 3rd and 6th month from the onset of treatment. The quality of life of each patient were assessed by 'Quality of Life Instrument for Indian Diabetes

Patients (QOLID)' at baseline and 6th month. QOLID is a questionnaire developed by Nagpal *et al*., which comprises of 8 domains and 34 items is valid tool to assess the quality of life of Indian patients with diabetes. The domains which are included in this questionnaire are: Role Limitation Due to Physical Health, Physical Endurance, General Health, Treatment Satisfaction, Symptom Botherness, Financial Worries, Emotional/Mental Health, and Diet Satisfaction. In this questionnaire each item/ question (except one) graded with rating of 1 to 5, with minimum score 27 and maximum score 135 [15].

Data were recorded on case proforma, and entered Microsoft® Excel worksheet 2019, and exported into SPSS v21.0 (IBM, USA) for statistical analysis. Categorical variables were expressed as frequency, percentage, and compared using Chi square test with or without Yate's correction. Normality of data was determined using Shapiro-Wilk test. Normally distributed variables were compared between two groups using independent t-test. Comparison within a group at two time-intervals was made using paired t-test. P value<0.05 was considered statistically significant.

Results

In this study, we observed that there was no significant difference in mean age of the patients between group GSMT and LM (53.25±6.62 years vs. 52.95±6.73 years; P=0.888). Age-group based distribution also showed a non-significant difference between the groups (P=0.596). In this study, in GSMT group, 60% were male and 40% female while there were 45% male and 55% female patients in LM group. There was no statistically significant difference in gender distribution between both groups (P=0.342). In this study, in GSMT group, 40% patients were non-vegetarian, and 60% patients were vegetarian while 25% patients were non-vegetarian, and 75% patients were vegetarian in LM group. (P=0.311). In this study, in GSMT group 65% patients eating a junk food and 35% patients eating a healthy food while LM group 45% eating a junk food and 55% patients eating a healthy food. (P=0.204). In this study, there was no significant different in mean duration of the diabetes of the patients between group GSMT and LM (10.30±3.40 years vs. 8.30±3.51 years; P=0.075). Duration of diabetes distribution also showed 15% patients had 3-5 years duration, 20% patients had 6-9 years duration, 35% had 10-12 years duration and 30% patients had 13-15 years duration in a GSMT group while 20% patients had 3-5 years, 45% patients had 6-9 years, 30% patients had 10-12 years and 5% patients had 13-15 years duration in a LM group. (P=0.126). In this study, 30% of GSMT and 25% of LM had a family history while 70% of GSMT and 75% of LM had no family history of diabetes mellitus. We did not observe a significant difference in family history between both groups (P=0.723). In socioeconomic status study, 35% of lower, 20% of middle and 45% of upper-class patients were in GSMT group while 45% of lower, 5% middle and 50% upper class patients in LM group (P=0.349). In this study, there was no significant different in mean weight of the patients between group GSMT and LM (67.45±6.04 Kg vs. 64.45±6.53 Kg; P=0.140).In this study, there was no significant different in mean BMI of the patients between group GSMT and LM (23.24±2.03 Kg/m^2 vs. 23.20±3.04 Kg/m^2; P=0 966). BMI distribution also showed 35% were normal, 20% of obese and 45% of overweight in GSMT group while 25% of normal, 30% of obese, 35% of overweight and 10% of underweight in LM group. In this study, there was no significant different in mean BMI of the patients between group GSMT and LM (23.24±2.03 Kg/m2 vs. 23.20±3.04 Kg/m2; P=0 966). BMI distribution also showed 35% were normal, 20% of obese and 45% of overweight in GSMT group while 25% of normal, 30% of obese, 35% of overweight and 10% of underweight in LM group (P=0.394).In this study, 40% of GSMT and 45% of LM were from rural area while 60% of GSMT and 55% of LM group from urban area (P=0.749).In this study, 40% of GSMT and 10% of LM had CVD, 25% of both GSMT and LM were hypertensive, and 35% of GSMT and 65% of LM had no comorbidities. We found a non-significant difference in co-morbidities distribution between both groups (P=0.067). At baseline, there was no significant difference in HbA1c levels between GSMT and LM group (7.76±0.18vs. 7.73±0.19; P=0.678).Our study also observed a significant HbA1c levels in GSMT compared to LM group at 6-month (6.77±0.41 vs. 7.13±0.27; P=0.003). We also observed a significant decrease in HbA1c levels in both groups (p<0.0001). At baseline, there was no significant difference in QOLID between GSMT and LM group (84.55±3.10 vs. 83.95±3.23; P=0. 553. Our study also observed a significant QOLIB in GSMT compared to LM group at 6-month (127.90±7.15 vs 115.20±3.38; P=<0.0001). We also observed a significant improvement in QOLID in both groups (p<0.001).

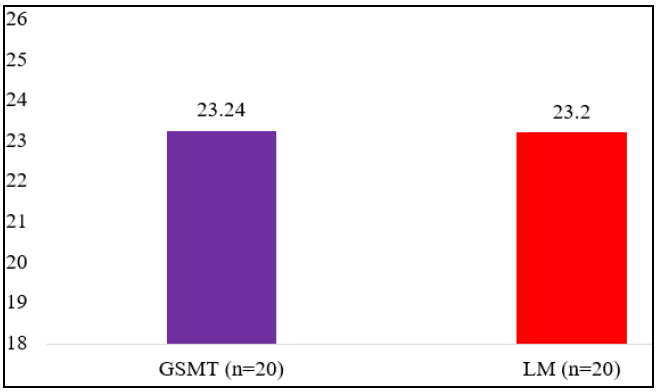

Fig 14: Bar diagram showing the comparison of BMI

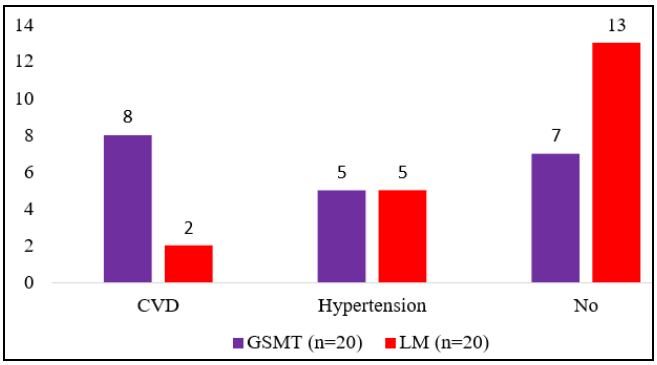

Fig 17: Bar diagram showing the comparison of comorbidities

Table 1: Comparison of demographic characteristics of the study subject (n=40)

Sr. No.	Variable	GSMT (n=20)	LM (n=20)	χ^2or t-value	P value
1	Age (Years)	53.25±6.62	52.92±6.93	0.142	0.888
2	Age Group				
	≤40	2	1	1.887	0.596
	41-50	4	6		
	51-60	14	12		
	>60	0	1		
3	Gender				
	Male	12	9	0.902	0.342
	Female	8	11		
4	Diet				
	Veg	12	15	1.025	0.311
	Non-veg	8	5		
5	Duration of Diabetes	10.30±3.40	8.30±3.51	1.829	0.075
6	Duration Group				
	3-5	3	4	5.714	0.126
	6-9	4	9		
	10-12	7	6		
	13-15	6	1		
7	Family History	6	5	0.125	0.723
8	Socio Economic Status				
	Lower	7	9	2.102	0.349
	Middle	4	1		
	Upper	9	10		
9	Weight	67.45±6.04	64.45±6.53	1.507	0.140
10	BMI	23.24±2.03	23.20±3.04	0.043	0.966
11	BMI Group				
	Normal	7	5	2.983	0.394
	Obese	4	6		
	Overweight	9	7		
	Underweight	0	2		
12	Lifestyle				
	Junk Food	13	9	1.616	0.203
	Healthy Food	7	11		
13	Comorbidities				
	CVD	8	2	5.4	0.067
	Hypertension	5	5		
	No	7	13		
14	Dwelling Place				
	Rural	8	9	0.102	0.749
	Urban	12	11		

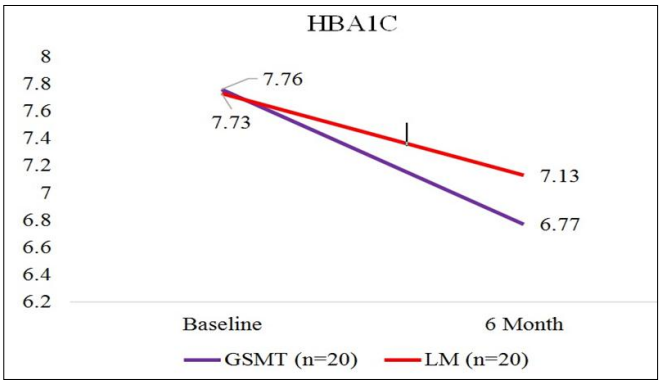

Fig 3: Line diagram showing the comparison of HbA1c

Table 2: HbA1c

HbA1c	GSMT (n=20)	LM (n=20)	P value
Baseline	7.76±0.18	7.73±0.19	0.678
6 Month	6.77±0.41	7.13±0.27	0.003
P value	<0.0001	<0.0001	

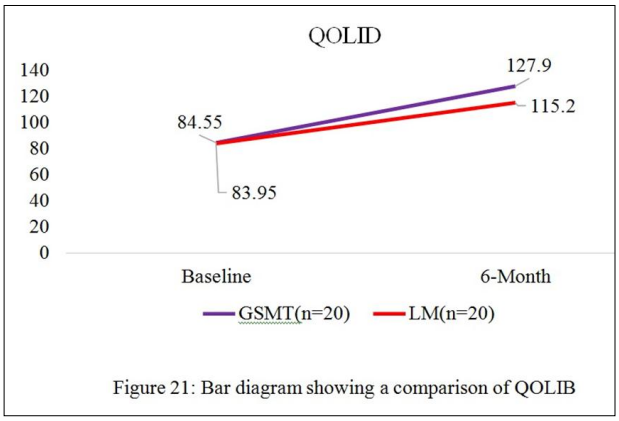

Fig 4: Bar diagram showing a comparison of QOLIB

Table 3: Quality of Life

QOLID	GSMT (n=20)	LM (n=20)	P value
Baseline	84.55±3.10	83.95±3.23	0.553
6 Month	127.90±7.15	115.20±3.38	<0.0001
P value	<0.0001	<0.0001	

Manual Statistical Quality of Life Score In GSMT Group

Table 16: Manual statistical quality of life score in GSMT Group

Baseline	6_month	x-y	(x-y)2	ΣD	ΣD2	(ΣD(x-y))2/n
88	128	-40	1600	-40	1600	80
89	139	-50	2500	-50	2500	125
85	134	-49	2401	-49	2401	120.05
90	129	-39	1521	-39	1521	76.05
80	133	-53	2809	-53	2809	140.45
87	115	-28	784	-28	784	39.2
81	121	-40	1600	-40	1600	80
85	124	-39	1521	-39	1521	76.05
87	134	-47	2209	-47	2209	110.45
83	133	-50	2500	-50	2500	125
83	131	-48	2304	-48	2304	115.2
81	120	-39	1521	-39	1521	76.05
80	128	-48	2304	-48	2304	115.2
85	127	-42	1764	-42	1764	88.2
83	122	-39	1521	-39	1521	76.05
89	137	-48	2304	-48	2304	115.2
85	120	-35	1225	-35	1225	61.25
86	124	-38	1444	-38	1444	72.2
82	119	-37	1369	-37	1369	68.45
82	140	-58	3364	-58	3364	168.2
Sum		**-867**	38565	**-867**	38565	**1928.25**

ΣD is stand for the sum of (x-y)
X stand for the Baseline and Y stand for the 6-Month $\Sigma D^2$is stand for the sum of $(x-y)^2$
N=20
t= -26.98
P value -<0.0001

In LM Group

Table 17: Manual statistical quality of life score in LM Group

Baseline	6_month	x-y	(x-y)2	ΣD	ΣD2	(ΣD(x-y))2/n
81	117	-36	1296	-36	1296	64.8
90	114	-24	576	-24	576	28.8
81	111	-30	900	-30	900	45
88	112	-24	576	-24	576	28.8
87	110	-23	529	-23	529	26.45
81	114	-33	1089	-33	1089	54.45
84	115	-31	961	-31	961	48.05
89	118	-29	841	-29	841	42.05
82	117	-35	1225	-35	1225	61.25
87	112	-25	625	-25	625	31.25
84	120	-36	1296	-36	1296	64.8
84	119	-35	1225	-35	1225	61.25
86	118	-32	1024	-32	1024	51.2
81	118	-37	1369	-37	1369	68.45
81	117	-36	1296	-36	1296	64.8
80	110	-30	900	-30	900	45
80	119	-39	1521	-39	1521	76.05
87	119	-32	1024	-32	1024	51.2
81	111	-30	900	-30	900	45
85	113	-28	784	-28	784	39.2
Sum		-625	19957	-625	19957	997.85

ΣD is stand for the sum of (x-y)
X stand for the Baseline and Y stand for the 6-Month $\Sigma D^2$is stand for the sum of $(x-y)^2$
N=20
t= -29.52
P value -<0.0001

Discussion

The Prospective and comparative study was design to know the effectiveness of case *Gymnema sylvestre* MOTHER TINCTURE and LM potency on DM type 2 patients. The study was done at OPD and IPD of Government Homoeopathic Medical College and Hospital Bhopal and its attenuateunits. For the study 40 patients screened the data was recorded on standard case taking properly. patients were distributed to simple randomization method and medicine was given each group. Statistical method used were chi-square test with or without yate's correction, Shapiro wilk test, independent t-test, pair t test. Two know the significance.

The present study was aimed to evaluate the effectiveness of GSMT and LM in the management of T2DM. A total of 40 patients were randomized to receive either GSMT and LM. Results of the study have been presented below.

Age

In our study, mean age of all the patients was 53.1 years. 65% patients in the age group of 51-60 years. Approximately 7% patients in age group of ≤40. 25% patients in age group of 41-50. Misra *et al*. although the proportion of patients of age <30 years was low; its prevalence had significantly increased during the study period. The proportion of patients in the age-group of 30-49 years also increased significantly to nearly 30% by 2015. Development of diabetes at a younger age among the South Asian populations is well known [16]. Nanditha *et al*. as the prevalence of diabetes increases in the general population a higher prevalence in lower age group has been documented [17]. Mohan *et al*. the observations of our study support this characteristic feature. Majority of the were aged50- 69 years at all periods of the study. The reason for the reduction observed in the older age-group of patients with 70 years is not clear but may be related to mortality due to co-morbidities or being referred to other centers such as cardiac or renal specialty centers [18].

Gender

In our study, 52.5% inmale patients and 47.5% in female patients affected by Diabetes mellitus in Type-2. In study, 277 (55.4%) were males and 223 (44.6%) were females. Thakkar *et al*. [19] reported prevalence of DM was 58% in males and 42% in females. Santosh YL *et al*. [20] reported prevalence in males of 58.23% and that in females of 41.76%. In our study, 303 (66.6%) patients were in the age group of 41 - 60 years with mean age of 57 yrs. Shah A *et al*. [21] found that prevalence of DM was highest in the age group of 40 - 60 (56.12%) years followed by 60 - 80 (32.31%) years' age group.

BMI

In our study, mean BMI of all the patients was 23.22 years.30% patients of normal, 25% patients of obese, 40% patients of overweight and 5% patients of underweight in a BMI group. Lehar *et al*. there were only a few persons with diabetes who were underweight. An important observation was that only a small proportion of patients (<13%) maintained normal BMI and nearly a quarter of the patients were obese (BMI30 kg/m2). The proportion of patients with obesity consistently increased. This is in accordance with the observations in the epidemiological studies in India that the rate of obesity is increasing particularly in the urban

populations [22]. In the present Ramachandran *et al*. these studies showed a more pronounced increase in abdominal obesity than in BMI among the general population and also in persons withT2D [23]. Ram *et al*. the increase in abdominal obesity is a stronger index of insulin resistance than the overall obesity [24].

Comorbidities

In this study, 25% each patient in CVD and Hypertension, and 50% No comorbidities. In present study, Naing *et al*. in our study 10.7% have hypertension, 6.6% had recurrent skin infection, 1.3% had Pulmonary tuberculosis. Diabetes mellitus is a metabolic disorder that weakens the immune system and also a known risk factor for tuberculosis. The prevalence of tuberculosis is higher in patients with diabetes mellitus in comparison with non-diabetes mellitus and impaired glucose tolerance. Naing NN *et al*. found 14.7% of diabetes mellitus patients with tuberculosis [25].

Duration of Diabetes

In our study, there was no significant different in mean duration of the diabetes of the patients between group GSMT and LM (10.30±3.40 years vs. 8.30±3.51 years; P=0.075). Duration of diabetes distribution also showed 15% patients had 3-5 years duration, 20% patients had 6-9 years duration, 35% had 10-12 years duration and 30% patients had 13-15 years duration in a GSMT group while 20% patients had 3-5 years, 45% patients had 6-9 years, 30% patients had 10-12 years and 5% patients had 13-15 years duration in a LM group (P=0.126). Most of respondents are fall under the category between 1.1 year to 10 years and got DM complications. Under this period,70.12 per cent of sample respondents are suffering from DM complications. The mean age and duration of DM was not significantly different with respect to no. of DM complications in study population [26, 27]. However, in urban group, mean age was significantly higher for those with two or more DM complications (65.4 years) than those with one DM complications (57.1 years). No significant differences were observed between no. of DM complications and i) age, and ii) duration of diabetes among the overall study population (n = 252), and sub populations (urban and rural). Male in rural areas is having more DM complications and it is more significant than other categories. 61 per cent of respondents in urban areas and 63 per cent of respondents in rural areas have got diabetic nephropathy complications [28].

Socio Economic Status

In this study,35% of lower, 20% of middle and 45% of upper-class patients were in GSMT group while 45% of lower, 5% middle and 50% upper class patients in LM group (P=0.349).In the study of Shah *et al*., [29] Mohan *et al*., [30] Rao *et al*., [31] and Anjana *et al*., [32] out of 61 diabetic patients, 9 (14.8%) were in class I, 11 (18%) were in class II, 10 (16.4%) were in class III and remaining 25 (41%) were in class IV and 6 (9.8%) were in class V. There was highly significant association between socioeconomic status and Diabetes mellitus (p=0.0001).

lifestyle

In our study, in GSMT group 65% patients eating a junk food and 35% patients eating a healthy food while LM group 45% eating a junk food and 55% patients eating a healthy food. (P=0.204).Turner *et al*. revealed that regular ingestion of excessive milk, meat, and junk foods has a substantiated effect on the blood glucose levels of the individuals, particularly in case of diabetes mellitus. These results establish the role of the frequency and the type of food an individual consumes in healthy and unhealthy conditions. Ayurveda recommends avoiding milk products to control diabetes [33].

Weight

In our study, the mean weight was 66.12±13.8 kg There were 10.7% undernourished patients. The reviewed studies showed obesity had an impact on insulin resistance [34].

Dwelling Place

In this study, 42.5% from Rural area and 47.5% patients from Urban area. Tripathy *et al*. reported that the overall prevalence of DM among the study participants was found out to be 8.3% (95% confidence interval [CI] 7.3%–9.4%) which was higher in the urban areas (9.4%, 95% CI 7.7%–11.4%) as compared to rural (7.6, 6.4%–9.1%) [35].

Family History

In this study, 27.5% patients' family history in yes and 72.5% patients no family history. In study 187 (37.4%) patients have positive family history. Observed 152 newly detected diabetic patients and reported family history in 63 patients (41.4%). Reported that positive family history was present in 1/3 of newly detected diabetics. According to all these studies, there was strong relationship between family history and diabetes mellitus. Relationship of family history with Type-2 diabetes mellitus is due to strong genetic component.

Diet

In our study, 32.5% patients are non-vegetarian and 67.5% patients are vegetarian. In the study of Schulz *et al*. [36] found that the availability of healthy food influences individual dietary choices. In some instances, it is difficult for patients to comply with the prescription of a diabetic diet, and this is a consequence of social factors such as illiteracy, poverty, and cultural misconceptions about the role of diet in the management of type II DM. The usually recommended daily energy intake for the non-obese diabetic patient is between 1500 and 2500 calories per day, the average allowance being 2000 calories per day. The recommended overweight diabetic patient is between 800 and 1500 calories per day, while the underweight should be allowed at least 2500 calories per day [37].

HbA1C

At baseline, there was no significant difference in HbA1clevels between GSMT and LM group (7.76±0.18vs. 7.73±0.19; P=0.678). Our study also observed a significant HbA1clevels in GSMT compared to LM group at 6-month (6.77±0.41 vs. 7.13±0.27; P=0.003).

QOLID

At baseline, there was no significant difference in QOLID levels between GSMT and LM group (84.55±3.10 vs. 83.95±3.23; P=0.553).Our study also observed a significant QOLIB levels in GSMT compared to LM group at 6-month (127.90±7.15 vs 115.20±3.38; P=<0.0001). Although, it is unknown if homeopathic treatment could improve QoL in diabetic patients. One surgery reported that the patients who

were receiving homeopathic treatment have higher satisfaction with treatment, and a weak but positive QoL with reduced adverse effects.[38]

Conclusion

In this study, we found a significant reduction in HbA1c levels with both forms of Gymnema Sylvestre. *Gymnema sylvestre* plays an important role in the treatment of type2 diabete smellitus. Therewasno adverse effect observed during the treatment and it can be concluded that *Gymnema sylvestre* can help diabetic patients to make their life better. It was also supported by a significant improvement in their quality of life for 6-months.

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