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A COMPARATIVE STUDY FOR EFFECTIVENESS OF *LAC CAMELI* WITH SYNTHESIS 9.1 REPERTORY AS ADJUVANT IN CASES OF TYPE 1 DIABETESMELLITUS– A SINGLE BLIND RANDOMISED TRIAL

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ABSTRACT

Background:- Type 1 diabetes mellitus is also called insulin-dependent diabetes. It used to be called juvenile-onset diabetes, because it often begins in childhood. Type 1 diabetes mellitus is an autoimmune condition. It's caused by the body attacking its own pancreas with antibodies. In people with type 1 diabetes mellitus , the damaged pancreas doesn't make insulin. The right constitutional similimum arrived by the help of mental generals, physical generals, characteristic particulars, causation, modalities and concomitants helps in removing the underlining susceptibility and bring out the cure. It can also managed by diet regimen and life style modification along with homoeopathic treatment.

OBJECTIVES

1. To compare the reduction in HbA1c values with the help of *Lac cameli* andindividualized homoeopathic medicines with aid of synthesis 9.1 repertory in cases of type 1 diabetes mellitus.
2. To compare the reduction in Fasting blood glucose values with the help of *Lac cameli* and individualized homoeopathic medicines with aid of synthesis 9.1 repertory in cases of type 1 diabetes mellitus.

STUDY DESIGN

A Single blind prospective randomised comparative trial.

MATERIALS AND METHODOLOGYMETHOD

100 individuals were randomly allocated in to 2 groups. One group of 50 patients were given individualized homoeopathic medicine repertorised from synthesis 9.1 repertory and another 50 patients were given *Lac cameli*. Follow up of the patients conducted periodically as specified in the protocol. Conventional medicine continued during the treatment in both groups. The present study was undertaken at M.N. Homoeopathic Medical college, and Research Institute, Bikaner. The cases were taken from the OPD/IPD. The study was undertaken for a period of 12 months, out of which in first three months pre-trial and selection of cases done, after that next 6 month follow up, each follow up at 15 days interval .In last 3 month analysis of result. Individualized homoeopathic medicine repertorise from synthesis 9.1 repertory in one group (50 patients) and Homoeopathic medicine *lac cameli.3X* in second group (50 patients). The statistical technique used was paired t-test and independent t-test. Paired t-test was used to assess the before and after values of FBS, HbA1c and anthropometric values in each patient.

RESULTS

Statistical analysis Paired t - tests calculated for comparing the Pre-treatment and Post-treatment in the group A there was significant change in the FBS, HbA1c and anthropometric measurements in the group A that is FBS change from Means- 199 (Pre-treatment) to 166.66(Post-treatment) P value .0001(less than .05) and the anthropometric measurements changed Mean=.95(pre-treatment) to .90(post- treatment) P value .0009 and HbA1c change M= 7.85(pre-treatment) to 7.45(post- treatment) Pvaluve0.0001.

While comparing the Pre-treatment a1nd Post-treatment in the group B there was significant change in the FBS, HbA1c and anthropometric measurements in the group B that is FBS change from Means- 200.02 (pre-treatment) to 169.92(post-treatment) P value .0001(less than .05) and the anthropometric measurements changed Mean=.88(Pre-treatment) to .84(post-treatment) P value .0002 and HbA1c change M= 7.82(Pre-treatment) to 7.51(post-treatment) P valuve0.0001. It is concluded that individualized homoeopathic medicines and *Lac cameli* are both effective in reducing the FBS, HbA1c and anthropometric measurements but significantly individualized homoeopathic medicines are more effective then *Lac cameli.*

CONCLUSION

It is evident from the results that Individualized Homoeopathic medicines are more effective in reducing the FBS, HbA1c and anthropometric measurements as compare to *Lac cameli*.

Prescription done according to the susceptibility can effectively and safely relieve the T1DM symptoms. Since the duration of this study was for one year only anda small sample size was taken, further research and studies of longer duration and large sample size are required to establish its efficacy for case of T1DM.

KEYWORDS: LAC CAMELI, INDIVIDUALIZED HOMOEOPATHIC MEDICINE, SYNTHESIS 9.1REPERTORY, T1DM.

INTRODUCTION

Diabetes mellitus is a chronic systemic disease characterized by either a deficiency of insulin or a decreased ability of the body to use insulin. Diabetes mellitus is sometimes referred to as "high sugar" by both clients and care providers.[1]

Diabetes mellitus consists of 3 types 1. Type I- Previously called insulin dependent mellitus, 2. Type II- Previously called Non-insulin dependent diabetes,3.Gestational diabetes mellitus.[1] The World Health Organization (WHO) has recently acknowledged that India has the maximum number of diabetic patients than does any given country (around 35 million). This is projected to increase to 57 million by the year 2025. India is thus the „Diabetic Capital of the World" [2]

The Homoeopathic medicines are prescribed on the basis of similar symptoms with the help of Homoeopathic Materia Medica. Synthesis 9.1 repertory helps in selection of similar medicines which are helpful in cases of type 1 diabetes mellitus.. This study was an attempt to compare the effectiveness of *Lac cameli* & individualized homoeopathic medicine with aid of synthesis repertory in cases of type 1 diabetes mellitus

MATERIALS AND METHODS

The present study was undertaken at OPD /IPD of Mangilal Nirban Homoeopathic Medical College & Research Institute, Bikaner, Rajasthan**.** The study was undertaken for a period of 12 months, out of which in first three months pre-trial and selection of cases done ,after that next 6 month follow up, each follow up at 15 days interval .In last 3 month analysis of result. The effective sample size for each group is 50 and total samples to be taken is 100 cases.

- Group A- Individualized homoeopathic medicine with allopathic treatment-50cases.
- Group B- *Lac Cameli* 3X with allopathic treatment-50cases.

Inclusion / Exclusion criteria

Inclusion criteria

Screening- Screening done on the basis of presenting complaints.

- Cases of both sex with age group 5-60 years were included in the study irrespective of their caste, religion.
- Patients who gave consent for the study.
- Fasting Blood sugar level 160 mg/dl to 400mg/dl.[3]
- Insulin dependent patients.
- Freshly diagnosed cases with in period of 3 to 6 months.

Exclusion criteria

- Co-morbidites like liver disease, arthritis, tuberculosis.
- Pregnant and lactating women.
- Patients suffering from other auto-immune diseases, HIV patients.

INTERVENTION

Group A:- Synthesis 9.1 repertory with adjuvant treatment.

- Potency-Selection of potencies will be done according to patient's susceptibility and homoeopathic principles.
- Doses and repetition-According to patient's susceptibility and homoeopathic principles.
- Manufacturer- Medicine will be obtained from a good manufacturer practice certified company.
- Form- Globules No. 30.
- Route of administration- Oral
- Dispensing- This will be done by the college dispensary.

Group B:- Lac cameli 3x with adjuvant treatment.

- Doses and repetition- Lac cameli 3x potency.
- Manufacturer- Medicine will be obtained from a good manufacturer practice certified company.
- Doses and repetition-According to patient's susceptibility and homoeopathicprinciples.
- Form- tablet form
- Route of administration- Oral
- Dispensing- This will be done by the college dispensary.

Outcome Assessment

According to the before and after scores obtained from the

1. HbA1c
2. Fasting blood sugar
3. Anthropometric measurement(waist-hip ratio)

For HbA1c, FBS

Before score – after score ×100% Before score

- 100% to 75% marked improvement
- 74%- 50% moderate improvement
- 49%- 25% mild improvement
- < 25% not significant
- 0% status quo
- Aggravation-worse

Statistical Technique and **Data analysis**

Paired t-test and independent t –test were used to compare means.

RESULTS

Table 1: Baseline Characteristics of patients studied under modified intention-to-treat (n=100).

Baseline demographic data		
	Group A(Individualized homoeopathic Medicines) No. of Cases (n = 50)	**Group B (Lac cameli 3x) No. of Cases (n = 50)**
Age ± SD		
5-20years	11(22%)	10(20%)
21-35 years	24(48%)	19(38%)
36-50 years	12(24%)	17(34%)
51-65 years	3(6%)	4(8%)
Gender (%)		
Male	28(56%)	25 (50%)
Female	22(44%)	25 (50%)
SOCIOECONOMIC STATUS (%)		
Lower	3 (6%)	8 (16%)
Middle	40 (80%)	36 (72%)
Upper	7(14%)	6(12%)
OCCUPATION (%)		
BANKER	5 (10%)	1 (2%)
BUSINESS	4(08%)	3(6%)

CLERK	4 (08%)	1(2%)
STENOGRAPHER	6 (12%)	1(2%)
HOUSEWIFE	9(18%)	10(20%)
LABOUR	2(4%)	12(24%)
SHOPKEEPER	5(10%)	1(2%)
STUDENT	13(26%)	15(30%)
TEACHER	2(4%)	6(12%)
RISK FACTORS (%)		
Not specific	19 (38%)	15 (30%)
Alcohol	5(10%)	4 (8%)
Sedentary	5(10%)	3 (6%)
Obesity	6(12%)	10 (20%)
Smoking	3 (6%)	4(8%)
Stress	12 (24%)	14(28%)
HABITAT %		
RURAL	21 (42%)	22 (44%)
URBAN	29 (58%)	28 (56%)
FAMILY HISTORY %		
PRESENT	25(50%)	19(38%)
ABSENT	25(50%)	31(62%)
COMMON RUBRIC %		
Frequency of micturation	2(4%)	1(2%)
Obesity	6(12%)	10(20%)
weakness	42(84%)	39(78%)
PRESENT COMPLAINTS		
Anxiety	1	0
Boil	5	4
Backache	1	3
Burning during micturation	2	1
Carbuncle	1	1
Cough	3	1
DM	5	9
Pain during micturation	1	4
Fever	15	20
Frequency of micturation	3	1
Gangrene	1	0
Obesity	1	0
Weakness	11	5
Abscess	0	1

Table 2: Distribution of 50 cases of T1DM According to 'Indicated Medicine.

Sr. No.	Medicine	No. of Patients	Percentage
1	*Acid Phos*	4	8%
2	*Calc Phos*	5	10%
3	*Insulinum*	5	10%
4	*Iodum*	4	8%
5	*Lachesis*	3	6%
6	*Medo*	3	6%
7	*Nat phos*	3	6%
8	*Nat sulph*	5	10%
9	*Nux Vom*	4	8%
10	*Phosphorus*	4	8%
11	*Sulphur*	6	12%
12	*Syz*	4	8%
	Total	**50**	

Table 3: Status.

	Group A	Group B
FBS parameter		
Mild improvement	14	13
Not significant	30	34
Worse	6	3
HbA1c parameter		
Not significant	31	33
Status quo	5	6
worse	6	11
Anthropometric measurement parameter		
Mild improvement	2	1
Not significant	26	29
Status quo	5	11
Worse	17	9

Table 4: Paired Samples Statistics Group A.

	Group A	Mean	N	Std. Deviation	Std. ErrorMean
Pair1	FBS_ Beforetreatment	199.00	50	34.92222	4.91046
	FBS_After treatment	166.66	50	41.70235	5.89760
Pair	HbA1c_ before				
1	treatment	7.8520	50	.91724	.12972
	HbA1c_ after	7.4540	50	.93726	.13255
	treatment				
Pair	Anthropometric_				
1	beforetreatment	.9588	50	.21859	.03091
	anthropometric_ after	.9082	50	.21480	.03038
	treatment				

Table 5: Comparison of clinical parameters in group A Paired Samples Test.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	fbs_btA - fbs_atA	32.2400 E1	27.58039	3.90046	24.50174	40.17826	8.291	49	.000
Pair 1	Hbac_btA -hbac_atA	.39800	.55714	.07879	.23966	.55634	5.051	49	.000
Pair 1	ant_btA - ant_atA	.05060	.10133	.01433	.02180	.07940	3.531	49	.001

Paired t-test calculated for group A showed mean= 166.66±41.70(SD) as after score compared to mean=199.00±34.92(SD) as before score in FBS for patients suffering from type 1 Diabetic mellitus with significance =0.000, which shows that individualized homoeopathic medicines are effective in reducing the FBS levels in patients suffering from type 1 Diabetes mellitus.

Paired t-test calculated for group A showed mean= 7.45±.93(SD) as after score compared to mean=7.85±.91(SD) as before score in HBA1C for patients suffering from type 1 Diabetic mellitus with significance =0.000, which shows that individualized homoeopathic medicines are effective in reducing the HBA1Cscore in patients suffering from type 1 Diabetes mellitus.

Paired t-test calculated for group A showed mean= .90±.21(SD) as after score compared to mean=.95±.21(SD) as before score in Anthropometric measures for patients suffering from type a Diabetic mellitus with significance =0.000, which shows that individualized homoeopathic medicines are effective in reducing the Anthropometric measurement in patients suffering from type 1 Diabetes mellitus.

Table 6: Paired Samples Statistics Group B.

	Group B	Mean	N	Std. Deviation	Std. ErrorMean
Pair 1	fbs_btB fbs_atB	200.00 169.92	50 50	39.40604 48.14639	5.57286 6.80893
Pair 1	hbac_btbhbac_atb	7.8220 7.5100	50 50	.91077 .90447	.12880 .12791
Pair 1	Ant_btBant_atB	.8862 .8496	50 50	.14032 .14553	.01984 .02058

Table 7: Comparison of clinical parameters in group B Paired Samples Test.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	fbs_btB - fbs_atB	30.1000 E1	26.78429	3.78787	22.48799	37.71201	7.946	49	.000
Pair 1	hbac_btb - hbac_atb	.31200	.47751	.06753	.17629	.44771	4.620	49	.000
Pair 1	Ant_btB - ant_atB	.03660	.06517	.00922	.01808	.05512	3.971	49	.000

Paired t-test calculated for group B showed mean= 169.92±48.14(SD) asafter score compared to mean=200.02±39.40(SD) as before score in FBS for patients suffering from type 1 Diabetes mellitus with significance =0.0001, which shows that *Lac cameli* is effective in reducing the FBS score in patients suffering from type 1 Diabetes mellitus.

Paired t-test calculated for group B showed mean= 7.51±.90(SD) as after score compared to mean=7.82±.91(SD) as before score in HBA1C for patients suffering from type 1 Diabetes mellitus with significance =0.000, which shows that lac cameli medicine is effective in Reducing the HBA1C score in patients suffering from type 1 Diabetes mellitus Paired t-test calculated for group B showed mean= .84±.14(SD) as after score compared to mean=.88±.14(SD) as before score in Anthropometric measures for patients suffering from type 1 Diabetes mellitus with significance =0.000, which shows that lac cameli is effective in Reducing the Anthropometric measures score in patients suffering from type 1 Diabetes mellitus.

Table 8: Pre & Post treatment changes in FBS, HbA1c, Anthropometric measures in Group A &B of T1DM.

Clinical Parameters	Group				Mean- difference (95% C.I.)	p-value	
	A		B				
	Baseline	Follow-up	Baseline	Follow-up		p1	p2
FBS	199 (34.92)	166.66 (41.70)	200.02 (39.40)	169.92 (48.14)	3.26 (-14.61, 21.131)	0.89	0.71
HbA1c	7.85 (0.91)	7.45 (0.93)	7.82 (0.91)	7.51(0.90)	0.05 (-0.30,0.42)	0.87	0.76

Anthropometric measurement	0.95 (0.21)	0.90 (0.21)	0.88 (0.14)	0.84(0.14)	-0.05 (-0.13,0.01)	0.05	0.11

DISCUSSION

Among 100 cases of type 1 Diabetes Mellitus, 21 patients (21%) cases were of age group 5-20 years followed by 43(43%) cases in the 21-35 years age group, 36-50 years age group 29(29%) cases whereas minimum cases were observed in age group above 51-65 years i.e only 7(7%) cases. Previous studies shows that the peak age at diagnosis was 12 years. Onset of diabetes before the age of 15 years constitute about 1%–4% of the total diabetic population. India had reported a prevalence of juvenile diabetes (onset below 15 years) <1% to 3.61%.[4]

Another study shows that the prevalence of diabetes increased with age and reached the peak at 70–89 years of age in Chinese and Japanese subjects but peaked at 60–69 years of age followed by a decline at the 70 years of age in Indian subjects. At 30–79 years ofage, the 10-year age-specific prevalence of diabetes was higher in Indian than in Chinese and Japanese subjects. Indian subjects also had a higher prevalence of impaired glucose regulation in the younger age-groups (30–49 years) compared with that for Chinese and Japanese subjects.[5]

In this study among 100 cases of Type 1 Diabetes Mellitus showed 53 patients (53%) male and 47 patients (47%) female. Previous studies shows that it was higher in male then female. there is no gender difference although there is high prevalence in women at age of 30-39 years of age.[5]Another study shows that male:female ratio was1.3:1.[6]

Among 100 cases of Type 1 Diabetes Mellitus i.e. 43(43%) were observed from rural areas whereas 57(57%) observed from urban areas. Previous studies shows that there is high prevalence in urban areas. A study from southern India in subjects showed that diabetes was prevalent in 3.7% of the urban population and in 2.1% of the rural population.[7] Another study shows prevalence of diabetes increased from 18.6% to 21.9 in the city, 16.4 to 20.3 in the town, and 9.2 to 13.4 in the periurban villages. The Prevalence ratio showed a non significant 8% rise in diabetes in the city, while significant increases had occurred in the town (39%) and periurban villages(34%).[8]

In the present study among 100 cases of Type 1 Diabetes Mellitus were from lower socioeconomic status 11 (11%) & upper socioeconomic status 13 (13%) whereas observed maximum cases middle socioeconomic status 76(76%). Where as previous studies shows that prevalence is high in lower socioeconomic status.[9] It is a contradiction in which the prevalence is high in lower socioeconomic group. Another study shows prevalence in middle socioeconomic status.[10]

In this study among 100 cases of Type 1 Diabetes Mellitus risk factor of life style were not significant in 34% cases, where as in 9% cases alcohol were risk factor, in 8% sedentary, 16% obesity, 7% smoking and 26% stress factor. A previous study shows that high prevalence in obesity and hypertensive people.[11] Another study also shows high prevalence in cases of hypertension and there were no prevalence of smoking and alcohol.[12]

In the present study among 100 cases of Type 1 Diabetes Mellitus have present family history of T1DM i.e. 44% and 56% cases there were no any family history. Previous study contraindicate in which shows that the prevalence of diabetes among individuals who have a first-degree relative with diabetes (14.3%) was significantly higher than that of individuals without a family history (3.2%).[13] Another study also shows high prevalence of T1DM who have a first-degree relative with diabetes.[14]

Among 100 cases of Type 1 Diabetes Mellitus have maximum number of T1DM in student that is 28%, where as 6% in banker, 7% business, 5%in clerk, 7% in stenographer, 19% housewife, 14% were in labour, 6% were shopkeeper and 8% were teacher. Where as a previous studies shows that their are three broad occupation groups with the highest adjusted prevalence of diabetes were protective services (8.9%), farming, fishing, and forestry (8.8%), and community and social services (8.4%).[15] Another previous study shows 12% in manual workers, 7% in managers, and 6% in office workers.[16]

In the present study most frequently prescribed Homoeopathic medicines were S*ulph. (n=6),Calc.p. (n=5), Insulinum (n=5), Nat.sulph. (n=5), Acid phos. (n=4),Iodum (n=4),Nux v. (n=4), Phosphoorus (n=4), Syz (n=4), Lachesis (n=3), Medo.(n=3), Nat. phos. (n=3)* previous studies shows that *Lycopodium clavatum*, *Phosphorus* and *Sulphur* were the medicines most frequently prescribed.[17] Another study shows Lycopodium, Phosphorous and Silicea are the most frequently indicated.[18]

In group A(n=50) pre-treatment mean of FBS improved from 199(34.92) to 166.66(41.70) post-treatment. While in group B(n=50) pre- treatment mean of FBS improved from 200.02(39.40) to 169.92(48.14) post- treatment. In group A(n=50) pre- treatment mean of HbA1c improved from 7.85(0.91) to 7.45(0.93) post-treatment. While in group B(n=50) pre-treatment mean of HbA1c improved from 7.82(0.91) to 7.51(0.90) post-treatment. As shown in table 6 in group A(n=50) pre-treatment mean of Anthropometric measurement improved from 0.95(0.21) to 0.90(0.21) post-treatment. While in group B(n=50) pre-treatment mean of Anthropometric measurement improvedfrom 0.88(0.14) to 0.84(0.14) post-treatment.

CONCLUSION

This was a prospective, single blind, randomised, comparative trial with positive results and these results need further validations by conducting clinical trials.

From the above study it is concluded that individualized homoeopathic medicines and *Lac cameli* are helpful in cases suffering from T1DM. No adverse effect were recorded when individualized homoeopathic medicine and lac cameli was prescribed. It is concluded that individualized homoeopathic medicines and *Lac cameli* are both effective in reducing the FBS, HbA1c and anthropometric measurements. But significantly individualized homoeopathic medicines are more effective then *Lac cameli* Thus, this study helps in improving clinical practice of homoeopathic physicians.

This study also has some limitations such as small sample size, comparison with another drug not present, single blinding, used only one scale for assessment.

A double blind, large sample size and a longer study duration can be planned for such studies. A better statistics can be applied for generalizations of the results.

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