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Effectiveness of *Cephalandra indica* mother tincture as an anti-diabetic in type 2 diabetes mellitus

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Abstract
Diabetes Mellitus is one of the common metabolic disorders in today's Indian population. Etiological factors such as genetic, dietary, drugs etc., are accountable for the occurrence of diabetes. Homoeopathy being a system of holistic approach, there are remedies based on the individualizing characteristic symptoms. Mother tinctures by virtue of their physiological action may be used to remove the physical and physiological obstacles to cure and palliate. In homoeopathic system *Cephalandra indica* is one among the antihyperglycemic medicine. Aqueous and ethanolic extract of *Cephalandra indica* showed a hypoglycemic effect in one research study. In our protocol, a total number of 50 -100 cases were screened and a minimum of 32 among them was selected based on the formula. Each patient's blood sugar level was analyzed before the trial. Data from the sample is collected and is subjected to paired "t" test to determine the efficacy. P value after the paired (t) test was found $5.13008X10^{-13}$ which is >0.001 that shows significant variation in fasting blood glucose level before and after treatment

Keywords: *Cephalandra indica*, mother tincture, anti-diabetic, 2 diabetes mellitus

Introduction
As a result of advancement of civilization, the intensity of stress and strain is also increased in society which in turn is affecting the individual and causing a number of diseases. Diabetes Mellitus is one of the common metabolic disorders in today's Indian population. Etiological factors such as genetic, dietary, drugs etc., are accountable for the occurrence of diabetes. No matter what, the condition is a result of insulin hormone deficiency, which may be complete absence, or partial or relative deficiency, when observed pertinent to co-existing insulin resistance. Insufficient production of insulin plays the major role in the abnormal metabolism linked in diabetes and hyperglycemia. Also, it plays a pivotal role in the emergence of complications of the said condition.

There is substantial escalation in the incidence of diabetic patients from the last two centuries. In a survey conducted, this condition remains in the 4th position where patients seek a doctor for treatment in daily practice. It accounts for major premature disability and death. Complications such as blindness, end stage renal disease (ESRD), non-traumatic limb amputations pose a threat to the quality of life in a person. Researchers suggest seven-fold raise in the cardiovascular, cerebral and peripheral vascular diseases. It is also a prime contributing factor to neonatal morbidity and mortality.

Data from the literature indicate the prevention of various complications of diabetes, when blood glucose levels and other risk factors are controlled. Lasting intent of Diabetic care includes reducing blood vessel and nerve complications and sustaining a sense of wellness. These aims are best achieved by early detection and management [1].

Type 1 diabetes mellitus is due to ß cell damage caused by an autoimmune mechanism usually sudden, progressing over a few days to weeks. Above 95% of affected individuals with this type, manifest the symptoms before 25 years of age, and it affects men and women equally with a preponderance to white population.

Type2 Diabetes mellitus is due to Insulin resistance in peripheral tissue and failure in the beta cell to secrete insulin. Type 2 DM is most common and is highly connected to history of diabetes in the family, old age, obesity, and lack of exercise. It is observed more in women, especially with gestational diabetes in blacks, Hispanics and Native Americans. Insulin resistance and hyperinsulinemia disturbs the glucose tolerance ability. Altered beta cells gets exhausted and further deteriorates the cycle of glucose intolerance and hyperglycemia.

Yet, etiology of type 2 DM is multifactorial and probably genetic [1, 2].

Homoeopathy being a system of holistic approach, there are remedies based on the individualizing characteristic symptoms. The prospective approach is also possible and amply proved by homoeopathy using the constitutional and organ specific remedies which has played a great role in postponing complications and general sense of well-being experienced by the patients whose mind and intellect are touched by dynamic medicines. In Type 1 diabetes mellitus (IDDM) insulin needs to be administered and homoeopathy has no much scope. But in Type 2 diabetes mellitus (NIDDM) homoeopathy has got beneficial effects, which has played a great role in postponing complications and gives a general sense of well-being to the patients mind and intellect are also touched by dynamic medicines. Above all cost effectiveness is one of the major benefits for the patients.

Mother tinctures by virtue of their physiological action may be used to remove the physical and physiological obstacles to cure and palliate. The physiological actions of mother tinctures are to be utilized. In homoeopathic system of medicine more and more detailed evidence based clinical study is required on diabetes mellitus especially to bring down glucose levels with the help of mother tinctures. In homoeopathic system *Cephalandra indica* is one among the antihyperglycemic medicine [3].

Cephalandra indica commonly called as little gourd and locally as 'Kovai', grows abundantly and wildly in India. Natives used this plant to relieve diabetic symptoms. Juice of the tuberous roots and leaves has been expansively used in Ayurvedic and Unani practice [4, 5, 6, 7]. In the first scientific research on cephalandra, the researchers failed to demonstrate any hypoglycemic effect [5]. But the aqueous and ethanolic extract of *Cephalandra indica* had a hypoglycemic effect in another study [8]. Several years ago, a work on the plant identified the action of leaf preparation on rats depressing the activity of the enzyme glucose-6-phosphatase [9]. Insulin stimulatory effect has also been demonstrated on existing ß cells in diabetic rats [10, 11]. Ayurvedic treatment includes the bitter variety to reduce blood sugar, bloody dysentery and other cutaneous manifestations [4, 12, 13, 14, 15].

Hence this study is a modest attempt to highlight the effectiveness of *Cephalandra indica* Q in the treatment of type 2 diabetes mellitus, along with the intake of diabetic diet, life style changes and with the gradual reduction in other drugs.

Homoeopathic USES

- Diabetes mellitus, bilious complaints, boils and carbuncles, generalized burning pains, increased urination, giddiness, weakness and exhaustion after urination, extreme dryness of mouth associated with excessive thirst. Not inclined to do work [3].

So, this study was undertaken to evaluate *Cephalandra indica* mother tincure as a possible antidiabetic drug

Aims and Objectives

To evaluate the effectiveness of *Cephalandra indica* mother tincture in treatment of Type 2 Diabetes Mellitus patients.

Materials and Methods

Hypothesis

- H0 = No difference in blood sugar level after administering *Cephalandra indica* Q in type 2 diabetes mellitus patients
- H1 = There is significant difference in blood sugar level after administering *Cephalandra indica* Q in type 2 diabetes mellitus patients

Detailed Research Plan

Sample Design

1. This study was conducted in patients who attend the outpatient, in patient departments and peripheral centers of Fr. Muller Homoeopathic Medical College and hospital, Deralakatte, Mangalore.
2. A total number of 50 -100 cases was screened and a minimum of 32 among them was selected.
3. $N= (Z_\alpha + Z_\beta)^2 (d/s)^2$
4. $\alpha = 1.96$, $\beta = 0.84$, at 5% level of significance and 80% power (d/s) = 0.5 (acc cohen)
5. Asymptomatic patients with elevated plasma glucose were also selected.
6. All the patients were treated with *Cephalandra indica* mother tincture.

Inclusion Criteria

1. The patients between the age group of 30- 75 years of both sexes were selected for the study.
2. Diagnostic criteria is mainly based on elevated fasting blood sugar >110mg/dl

Exclusion Criteria

1. Cases with advanced pathological conditions like diabetic nephropathy, diabetic retinopathy, diabetic ketoacidosis and diabetic foot were excluded.
2. Patients with major illness like bronchial asthma, COPD, Blood disorders, malignancies, cardiovascular diseases and hepatobiliary diseases were excluded.

Research Setting

- Purposive sampling was followed in this study. Patients who belong to the above category of inclusion criteria are taken up and were subjected to screening study so as to confirm hyperglycemic.
- Each patient's blood sugar level was analyzed before the trial.
- Each patient was treated for 6 months with *Cephalandra indica* mother tincture, and attended once in a month. At each attendance there was an assessment of fasting blood sugar level.

Research Methodology and Statistics

- Criteria for deciding the efficacy of Homoeopathic drug is based on
- Change in fasting blood glucose level.
- Data from the sample is collected and is subjected to paired "t" test to determine the efficacy.

Results

Table 1: FBS levels of 32 subjects before and after treatment

Sl. No	Name	Before treatment	After treatment(months)					
			1	2	3	4	5	6
1	Mrs.a	390	260	291	262	279	253	271
2	Mrs. B	282	180	160	170	189	130	136
3	Mrs. C	332	226	230	215	250	262	230
4	Mrs. D	241	170	150	134	126	104	101
5	Mrs. E	370	253	222	280	291	270	282
6	Mrs. F	184	181	163	160	180	132	90
7	Mrs.g	122	80	89	75	79	88	84
8	Mrs. H	168	79	82	92	101	112	124
9	Mrs. I	329	180	197	192	181	188	171
10	Mrs. J	332	298	270	235	205	184	188
11	Mrs. K	298	190	186	166	169	141	106
12	Mrs. L	470	365	340	300	335	232	220
13	Mrs.m	185	106	120	106	107	85	112
14	Mrs.n	222	164	172	131	113	116	121
15	Mrs.o	408	232	270	380	296	244	240
16	Mrs. P	200	120	114	122	134	116	120
17	Mrs.q	166	117	131	127	169	128	130
18	Mrs. R	195	116	110	126	144	82	90
19	Mrs. S	219	171	152	178	265	197	166
20	Mrs. T	280	232	206	210	214	180	173
21	Mr. U	282	180	140	163	168	140	139
22	Mr. V	551	292	240	268	238	230	183
23	Mr. W	190	183	174	95	98	101	197
24	Mr. X	262	130	146	143	121	128	142
25	Mr. Y	480	464	380	340	291	260	234
26	Mr. Z	230	180	122	138	132	140	151
27	Mr.ab	360	232	200	150	153	160	175
28	Mr. Ac	224	200	171	178	163	144	151
29	Mr.ad	170	150	135	140	108	101	112
30	Mrs.ae	192	132	121	128	124	130	127
31	Mr. Af	320	162	168	171	188	192	170
32	Mrs.ag	356	211	227	240	252	274	216

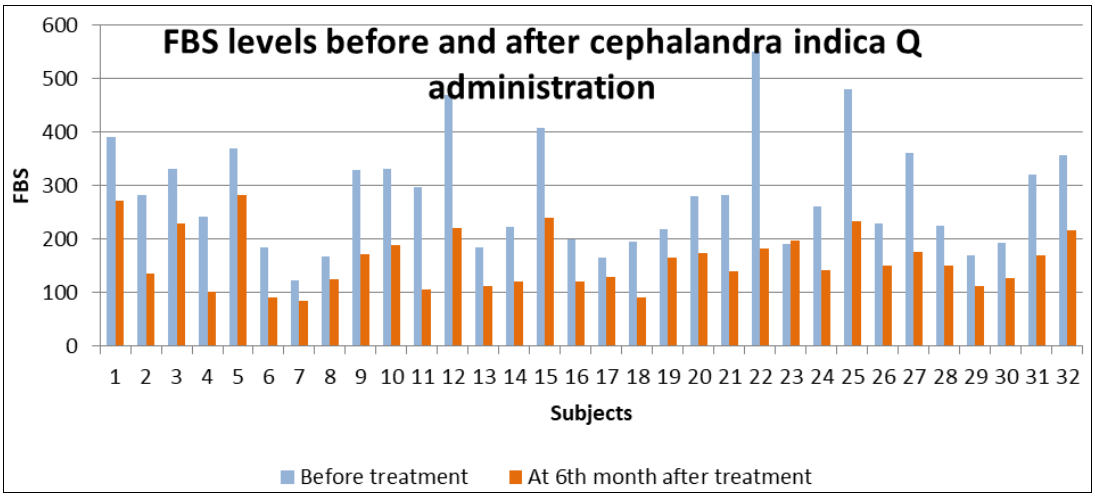

Fig 1: Graphical representation of FBS levels after treatment for 6 months

- Mean before treatment - 276.65
- Mean after treatment - 159.53
- Done paired 't' test
- $P = 5.13008 \times 10^{-13}$
- $p < 0.01$ = significant
- $p < 0.001$ = highly significant
- $P < 0.001$ so the alternative hypothesis is accepted and null hypothesis is rejected.
- H1 = There is significant difference in sugar level after administering *Cephalandra indica* Q in type 2 diabetes mellitus patients.

Discussion

The statistical analysis of the data proves that the drug named *Cephalandra indica* mother tincture is a potent medicine to decrease blood glucose level in Type 2 diabetes individuals.

P value after the paired t test was found $5.13008X10^{-13}$ which is >0.001 that shows significant variation in fasting blood glucose level before and after treatment.

Limitations

- The effect of general management and other allied medications during the period of study could not be ruled out.
- In all the cases studied, the ideal consideration of FBS values could not be possible.
- As the latest investigation to evaluate the prognosis is HbA1C which is not considered in this study due to cost factor.

Recommendations

- A study involving larger sample size and larger time frame could produce more reliable results.
- Study on the effectiveness of *Cephalandra indica* at higher potencies like 6x, 6c can be done.

Conclusion

The above study has given insight into considering *Cephalandra indica* Q as a good alternative to regulate blood glucose level. However, randomized clinical research trials on the effectiveness of *Cephalandra indica* is necessary.

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