

A Randomized Clinical Trial To See The Role Of Homoeopathic Medicine Cephalandra Indica Q In The Case Of Diabetes Mellitus Type-II: A Case Report

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Abstract

One of the leading causes of morbidity and mortality is diabetes mellitus. However, controlling and treating it remain major worldwide challenges. Homoeopathy is considered to be helpful for diabetes, particularly type 2 diabetes mellitus. Many homoeopathic medicines are said to be effective against it. This study was carried out at the Shringi Homoeopathic clinic and research Centre in Bhilwara, Rajasthan, to assess how well the homeopathic drug Cephalandra indica Q treats type 2 diabetes mellitus. This study demonstrates that Cephalandra Indica, a homoeopathic remedy, significantly lowers blood sugar levels in people with type II diabetes.

Keywords:-Diabetes, Polyphagia, Polydipsia, Polyuria, Cephalandra Indica.

Introduction

One of the major pandemics of the twenty-first century is diabetes. More than half of adult members of specific groups who exhibit signs of impaired glucose tolerance, impaired fasting glycaemia, or metabolic syndrome either currently have metabolic syndrome or are at high risk of getting it in the future. With 8.3% of people having diabetes in 2014, it is a major global health concern¹. Furthermore, the numbers are increasing at an astonishing rate every day. In India, diabetes is quickly becoming recognized as a "Potential Epidemic".²

Diabetes mellitus is a metabolic disorder that can have many different causes. It is typified by consistently elevated blood sugar levels and irregularities in the metabolism of lipids, proteins, and carbohydrates as a result of inadequate insulin action, secretion, or both. Diabetes mellitus can lead to long-term harm as well as organ failure and malfunction, including the pancreas, liver, and kidneys. The three "P's" of diabetes mellitus are polyphagia (increased appetite), polydipsia (increased thirst), and polyuria (frequent urination). There are other symptoms that could exist, such as visual problems and weight loss. When non-ketotic hyperosmolar syndrome, also known as ketoacidosis, reaches its most advanced stages, it can cause stupor, coma, and, in the event that treatment is not received, death.²

Diabetes mellitus is now one of the biggest public health problems facing any country, having more than doubled in prevalence over the past few decades. Pre-diabetes and type 2 diabetes mellitus are conditions that are more prevalent in younger adults, adolescents, and kids. In 2015, 415 million persons (83% in low- and middle-income countries, or LMIC) had diabetes, according to data provided by the International Diabetes Federation (IDF); by 2040, it is anticipated that this figure will increase to 642 million. It is especially troubling as over 50% of individuals with diabetes are unaware that they have the illness. Individuals who are unaware of their diabetes or do not receive a diagnosis will not be able to manage it well, which raises the risk of various problems. Oral hypoglycemic medications and injectable or oral insulin are two common pharmacotherapies used to treat diabetes in the current system. Ayurveda, Siddha, Unani, homoeopathy, and other traditional Indian medical systems all employ natural treatments for diabetes.

Still, there are differences between the traditional and modern systems. The treatments utilized in the existing system have a number of negative impacts in addition to being expensive and having negative physiological effects. Nowadays, homoeopathic doctors diagnose many illnesses by identifying the distinct mental and physical symptoms.

Consequently, homoeopathic medicine is presently the second most popular form of treatment in the world. An effective homeopathic physician also has access to a wide variety of medications. Because they are thought to be extremely safe, effective, and to have few to no adverse effects when taken orally, traditional herbs have also been suggested by the World Health Organization (WHO) to be investigated for the treatment of diabetes.⁴ There are also many reviews available of traditional medications made from medicinal herbs that have anti-diabetic properties. One of them is *Cephalandra indica*, a member of the Cucurbitaceae family and also referred to as Telakucha or Kundru. According to Hahnemann, diabetes is a complicated chronic condition that has advantages at both higher and lower potencies. However, since this is a disease characterized by the dissolution of pancreatic tissues, we might conclude that lesser potencies, such as mother tincture, work better in situations like this.

The Central Council for Research in Homoeopathy examined the effects of *Cephalandra indica* Mother tincture on pancreatic beta cell regeneration using an albino rat model.⁵ *Cephalandra indica* is the medication that homoeopathic physicians typically recommend as a mother tincture. It's occasionally referred to as the "Indian insulin substitute." In 1952, Dr. S.C. Ghose introduced this medication to homoeopathy by demonstrating its effectiveness and providing case studies of its application in the mother tincture form for the treatment of diabetes mellitus⁶. No research has indicated whether *Cephalandra Indica* performs best in its mother tincture or in other potencies, with the exception of a study conducted on diabetic rats and published in the journal "Antidiabetic effect of *Cephalandra indica*-Q in diabetic rats" by Arindam Pal, S. Gauri, Moumita Patra, and others. This study demonstrated a significant reduction in blood sugar levels using the mother tincture form.⁵ Thus, the current study's objective is to assess *Cephalandra indica* mother tincture's effectiveness in treating patients with type II diabetes.

Material And Methods

Case Definition

Patients with type II diabetes were recruited for the trial using the randomization technique, and they were treated using the specific homoeopathic treatment *Cephalandra Indica* Q after signing a consent form.

Study Design

Type of Method: *Cephalandra Indica* is being tested in a phase 2, single blind, randomized clinical trial to determine its impact on individuals with type II diabetes. The study was conducted for approx. 6 months in the outpatient department of the Shringi Homeopathic clinic and research center in Bhilwara. Based on inclusion and exclusion criteria, one case was chosen from among individuals who voluntarily desire to participate in research. We followed up on this case for roughly six months. Ideally, follow up every fifteen days. The patient is free to call at any time with complaints.

Allocation: -: Patients who meet the eligibility requirements have been enrolled, and part of the patient randomization process involves assigning subjects at random to obtain Homeopathic remedy.

Condition: - Diabetes mellitus type-II

End point- Effectiveness.

Masking/Blinding: Single blinding was carried out where in the participant was blinded.

Mode of intervention: - Oral route.

Primary goal: To assess changes in reduction of blood glucose level before and after treatment by using A.D.A. (American Diabetes Association) diagnostic criteria.

Study Setting

The study was carried out in OPD of Shringi Homoeopathic clinic and Research Centre, Bhilwara (Rajasthan).

Duration of study-

The study was undergone for a period of 6 months.

Criteria for follow-up -

- i. The patient was closely monitored, and information about the clinical, investigative, and symptomatic changes was documented and the prognosis was examined.
- ii. A follow-up was typically conducted every 15 days.
- iii. Based on the severity of the condition for a minimum of six months, plus an additional two months for observation, or at least six follow-ups.
- iv. A detailed Standard Follow-Up was created.

v. The foundation was homoeopathic theory.

Sampling procedure

Selection of cases/case definition: Since this is a case report, only one patient with type II diabetes who had a blood sugar level below 400 mg/dl after a meal, or a HbA1c below 8% without any issues was randomly assigned to the study.

Selection of remedy: Remedy is Select on the basis of therapeutics of Diabetes in Homeopathy.

Dose and strength of drug: Drug was administered in liquid form.

Drug administration: Drug administration was done through oral route. Doses were given in Liquid form 30 drops in ¼ cup of normal water BD. Repetition of dose was done as per the need of the patient.

Drug dispensing: Was done in Mother Tincture (liquid) form.

Declaration: was informed that the medication being utilized here is safe for people to use. The aforementioned medicine is already available in homoeopathic literature, has been thoroughly tested on human subjects in good health, and is safe and free of adverse effects.

Inclusion criteria -

- i. A patient with type II diabetes who does not have any significant systemic problems
- ii. Patient with a HbA1c below 8% or a random blood sugar level below 400 mg/dl.
- iii. The capacity to follow study protocol and provide informed consent.
- iii. Legal capacity.

Exclusion criteria-

- i. If a patient has severe co-morbidities or needs emergency medical attention.
- ii. The patient doesn't have signed consent.
- iii. Poor communication skills.
- iv. Any patient suffering from a systemic ailment.
- v. A pregnant or nursing mother who is a patient.
- vi. Patient with a HbA1c above 8% or a random blood sugar level exceeding 400 mg/dl.
- vii. The using of sedative drugs.
- viii. Individuals taking any kind of medication, including homeopathic, allopathic, Ayurvedic, or diabetic drugs.
- ix. Concurrent enrollment in other clinical trials or having finished a study less than six months ago (patients are specifically questioned about this).
- x. When a patient requires immediate medical attention or has serious co-morbidities.
- xi. There is no signed consent from the patient.
- xii. Communication deficiencies.
- xiii. Any individual with a systemic illness.
- xiv. A patient who is a nursing or pregnant mother.
- xv. A patient whose random blood sugar level is more over 400 mg/dl or whose HbA1c is higher than 8%.
- xvi. Administering sedative medications.
- xvii. People using any type of medication, such as allopathic, homeopathic, Ayurvedic, or diabetic medications.
- xviii. Having completed a study less than six months ago or concurrent enrollment in other clinical studies (patients are particularly questioned about this).

Withdrawal Criteria

- The cases that did not receive appropriate follow-up or therapy cessation during the study were excluded.
- The patient may stop receiving treatment if they are not getting better.
- Any patient who refuses to cooperate with the study is discovered.
- Any Participant who desires to revoke their agreement to participate in the study.

Intervention

Certain homeopathic remedies After a thorough case was taken in accordance with the case report form, *Cephalandra Indica* was dispensed from the dispensing unit of Shringi Homeopathic Clinic & Research Centre under the supervision of the Investigator or her designated nominee, or from any licensed homoeopathic pharmacies. *Cephalandra Indica*, an interventional medicinal product (IMP), was given to the patient in the form of a mother tincture. 30 drops BD were administered with a ¼ cup of water, based on the patient's needs.

Medicine: *Cephalandra Indica*.

Doses: Specific homoeopathic remedy *Cephalandra Indica* was prescribed in mother tincture form. Each dose consists of 30 drops in ¼ cup of normal water; to be taken orally on clean tongue in empty stomach. Along with medicine, the patient was received standard psychosocial intervention.

Duration of treatment: 4months for patient.

Potency:Medicine prescribed in Mother tincture form.

Risk management plan: - Risk in cases -

1. When the patient did not respond to my medication or when their blood sugar level did not change for almost a year following treatment.
2. Should I discover that the patient's blood sugar is rising and that complications are developing.
3. When the patient's condition continued to worsen despite receiving therapy in every way.
4. A patient whose blood sugar unexpectedly increased.
5. Patient experiencing severe side effects despite taking homeopathic medication (mother tincture of Cephalaria indica).

Management Plan:

After excluding the patient from my research study due to the aforementioned circumstances, I attempted to cure the patient's diabetes mellitus type II using alternative constitutional or homeopathic therapeutic treatments. I described all the risks associated with type II diabetes to the patient and sent them to a higher center if they did not improve with that treatment.

Case Report

On 02 February 2023, a 45-years-old male Hindu businessman who is non-vegetarian and comes from a middle-class household in an urban location came to our outpatient department (OPD) with the following problems.

1. Weakness and occasionally dizziness.
2. Losing weight.
3. Increased micturition frequency, particularly at night.
4. Polydipsia (Excess Thirst)
5. Polyphagia (Excess Hunger).
6. A leg wound that hasn't healed in four months.

Treatment History: After receiving allopathic care for six months, he saw a brief improvement in symptoms.

Family History – Mother suffering from DM type-II. Father and all siblings are healthy.

Patient as whole:

Appetite: Sufficient, three meals a day and four chapattis per meal.

Thirst: Ten to fifteen glasses a day.

Aversion: fatty foods

Stool: Constipation.

Urine: yellow-colored, slightly foul, and more lustful; worse when lying down. Intermittent burning micturition.

perspiration: Minimal, inoffensive, and non-staining

Tongue: Clean and Moist

Mind:Suppressed wrath and irritability are signs of a thermal reaction in hot minds.

General examination: The patient appeared to be in good health.

Facial features absent, anemia/pallor nonexistent,

Lack of cyanosis, absence of deformity, Skin is dry, oedema is absent, Leg abscess.

absence of emaciation or cachexia

65 kg in weight, SpO₂ = 99%

166 cm in height

Temperature: 96.8 F

Heart rate: 130/80 mm Hg

Heart Rate: 80 beats per minute, interim diagnosis Type II diabetes mellitus

Report- Before Treatment

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BIOCHEMISTRY

INVESTIGATION	RESULT	UNIT	NORMAL RANGE
B.SUGAR (R)	270.00	Mg/Dl	<-140Mg/Dl

Signature: [Handwritten Signature]

(Figure-1 Blood sugar Level Before treatment)

General Management –Exercise for weight loss, avoid consuming fast food, packed food and spicy food. Meditation for stress management.

Table 1: Follow Ups during treatment

Date	Change in Symptoms	Prescription	Justification
02/02/2023	Weakness. Weight loss. Increase frequency of Micturition. Polyphagia (Excess Hunger) Polydipsia (Excess Thirst). Wound at leg which is not	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	According to therapeutics of Diabetes Mellitus type-II Homeopathic medicine Cephalandra Indica Q was prescribed.

	healing since 4 months.		
17/02/2023	Weakness relieved. Frequency of Micturition decreased. Polyphagia (Excess Hunger) Polydipsia (Excess Thirst). Wound at leg which is not healing.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.
04/03/2023	Weakness relieved. Frequency of Micturition decreased. Wound at leg which is start healing.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.
19/03/2023	Weakness relieved. Frequency of Micturition decreased. Wound at leg which is start healing. General improvement.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.
03/04/2023	All Symptoms improved. General Wellbeing.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.
18/04/2023	All Symptoms improved. General Wellbeing.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.
03/05/2023	All Symptoms improved. General Wellbeing.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.
19/05/2023	All Symptoms improved. General Wellbeing.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 5 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.
25/05/2023	All Symptoms improved. General Wellbeing. Blood Sugar random level decreased.	Cephalandra Indica Q 30 drops BD with ¼ cup of water x 15 Days	Improvement was observed so no change of medicine and Cephalandra Indica Q was given.

Report- After Treatment

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RegistrationNo : 16888
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ReportDate&Time :

BIOCHEMISTRY

INVESTIGATION	RESULT	UNIT	NORMAL RANGE
B.SUGAR (R)	167.00	Mg/Dl	<140Mg/Dl

Signature: [Handwritten Signature]

(Figure-2. Blood sugar Level After treatment)

Results

After comparing the blood sugar levels before and after the treatment, this study's notable findings were revealed. Following treatment, this patient's blood sugar level dramatically decreased. After examining the data, we draw the conclusion that the homoeopathic medication Cephalandra Indica Q significantly reduces the patient's random blood sugar level in type II diabetes. Therefore, based on this study, we can conclude that homoeopathic treatment helps patients retain their quality of life while also lowering their blood sugar levels.

Discussion

Diabetes mellitus can result in several long-term issues, making it a dangerous medical disease. Moreover, epidemiology suggests that there is a global increase in Type II diabetes patients. Numerous investigations in

homoeopathic, allopathic, and other systems have been carried out worldwide on diabetes mellitus in general and Type II diabetes mellitus in particular. The goal of these studies has been to determine the best ways to control or reduce blood sugar levels. Because of its "holistic" and "individualistic" approach, the homoeopathic system is successful in decreasing diabetic-related issues and complications; numerous outstanding papers and books explore this topic. It is vital to determine if biochemical values improve after the use of well-known homoeopathic drugs. If so, it's imperative to ascertain whether these drugs have any effect on Mother tincture form.

In order to determine the effectiveness of *Cephalandra indica* Q, a homoeopathic medication that is frequently used to manage diabetes mellitus, the study employed a randomized prospective clinical trial methodology.

In this study patient selected on the basis of symptoms of Diabetes Mellitus type-II. Patient came at the outpatient department of Shringi Homeopathic Clinic and Research Center. Patient received medication following a consent form that has been properly signed and agreed upon and Random Blood Glucose Level (BSLR) was analyzed.

This observation indicates that the homoeopathic treatment utilizing *Cephalandra Indica* Q was successful in lowering blood sugar level.

Suggestions for future work

Only case report of a single patient won't provide reliable data and there is a greater risk for bias, future research using this literature advises that further homoeopathy research in this sector is needed, with a large number of patients enrolled and a long study period.

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Conflict of interest: There is No conflict of interest.

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