

DRUG ORIENTED CLINICAL RESEARCH ON DIABETES MELLITUS

Abstract

Background- Lack of cure and progressive nature of the Diabetes Mellitus has prompted Central Council for Research in Homoeopathy to undertake a research study.

Aims- To evaluate the efficacy of a group of drugs of known pathogenetic action or those partially proved and lesser-known drugs for Diabetes mellitus.

Setting and design- This study was undertaken at Clinical Research Unit (Tribal) at Pondicherry (1988), Vijayawada (1990) & Salem (1993). It was concluded in March 2003.

Materials and Methods - Clinically diagnosed cases of Diabetes mellitus were selected out of patients reporting in general O.P.D. for treatment. The prescriptions were made based on the symptom similarity of the disease presented by the patients with that of the known pathogenetic symptoms of the assigned drugs.

Results- The analysis of the data suggests a good response of patients to *Chimaphila* and *Thyroidinum* but the number of subjects studied under these 2 drugs was very less to draw any definite conclusion. A moderately effective response was observed in case of *Lactic acid*. The response to *Syzygium jambolanum*, *Cephalandra indica*, *Insulinum*, *Lactic defloratum*, *Glycerinum*, *Chionanthus* was not very encouraging. *Uranium nitricum* was not found to be effective.

Conclusion- No valid conclusion can be drawn from the study. It requires further trial on larger samples with strict guidelines of the protocol including laboratory parameters.

Introduction

'Diabetes mellitus' is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar into energy needed for daily life. Type I diabetes mellitus is due to β -cell destruction and absolute insulin deficiency. Because of lack of endogenous insulin production, administration of insulin is essential. Type II diabetes is associated with variable degree of Insulin resistance, impaired insulin secretion and increased glucose production. Although the prevalence of both Type 1 and Type 2 DM is increasing worldwide, the prevalence of Type II DM is expected to rise more rapidly in the future because of increasing obesity and reduced activity levels.

The incidence of Type II diabetes mellitus, a life style disorder has increased markedly over the last few decades due to changing scenario of living conditions. In the absence of a definitive cure for this condition, the management relies on controlling the blood sugar levels to as near as normal. Lack of cure and progressive nature of disease has prompted Central Council for Research in Homoeopathy to undertake a research study on Type II diabetes mellitus.

The literature of Homoeopathy and the Materia Medica reports of usefulness of Homoeopathic medicines in maintaining/ controlling blood sugar levels in cases of Diabetes mellitus. The council therefore decided to conduct a clinical trial to explore the efficacy and role of Homoeopathic drugs of known pathogenetic action or those partially proved and lesser-known drugs for Diabetes mellitus.

This study was started in the year 1988 (Pondicherry), 1990 (Vijayawada), 1993 (Salem) and concluded in March 2003.

Objective

The objective of the study was to evaluate the efficacy of drugs of known pathogenetic action or those partially proved and lesser-known drugs for Type II diabetes mellitus.

Materials & Methods

Literature survey- was done to collect information (whatever available) on rare and lesser-known drugs (mostly of indigenous origin) showing signs and symptoms similar to diabetes mellitus or having traditional use for diabetes mellitus. Out of these, *Abroma augusta*, *Cephalandra indica*,



Cephalandra indica



Abroma augusta



Syzygium jambolanum



Chimaphila



Chionanthus

Glycerinum, Insulinum, Inula, Lactic acid, Lac defloratum, Syzygium jambolanum, Uranium nitricum, Thyroidinum, Chimaphila umbellate were approved and short listed. Their indications were compiled and sent to the concerned Clinical Research Units for further verification as well as collection of additional symptoms (clinical symptoms) of assigned medicines during study.

Sample size fixed - 2325

Study population- Patients reporting in Unit's O.P.D.

Inclusion criteria - Clinically diagnosed cases of Type II diabetes mellitus (with symptoms/signs mentioned below and increased sugar level) with symptomatic indications for the assigned drugs were the chief criteria for inclusion.

- Polyuria
- Polydypsia
- Polyphagia
- Weight loss
- Recurrent UTI
- Vaginitis and Itching
- General weakness.

Exclusion criteria - Type II diabetes mellitus with severe complications

Diagnostic criteria -

- Random blood glucose = 200 mg/dL or more
- Fasting plasma glucose = 126 mg/dL or more

Assessment criteria (Improvement) -

- Marked : When a patient is asymptomatic and blood sugar touches the normal level.
- Moderate : Symptomatic relief with more than 50% reduction in increased blood sugar level but persisting above normal range.
- Mild : When a patient has symptomatic relief with less than 50% reduction in increased blood sugar level (Never touching normal)
- No improvement : No response after treatment for a sufficient period.
- Worse : Aggravation of subjective and objective symptoms.
- No Reported : The patient does not report back after first, second or third visit.
- Dropped out : The patient does not fulfill the requirements of the project.
Or
Attending physician does not want to keep the patient under study on valid reasons.

Observations and Results

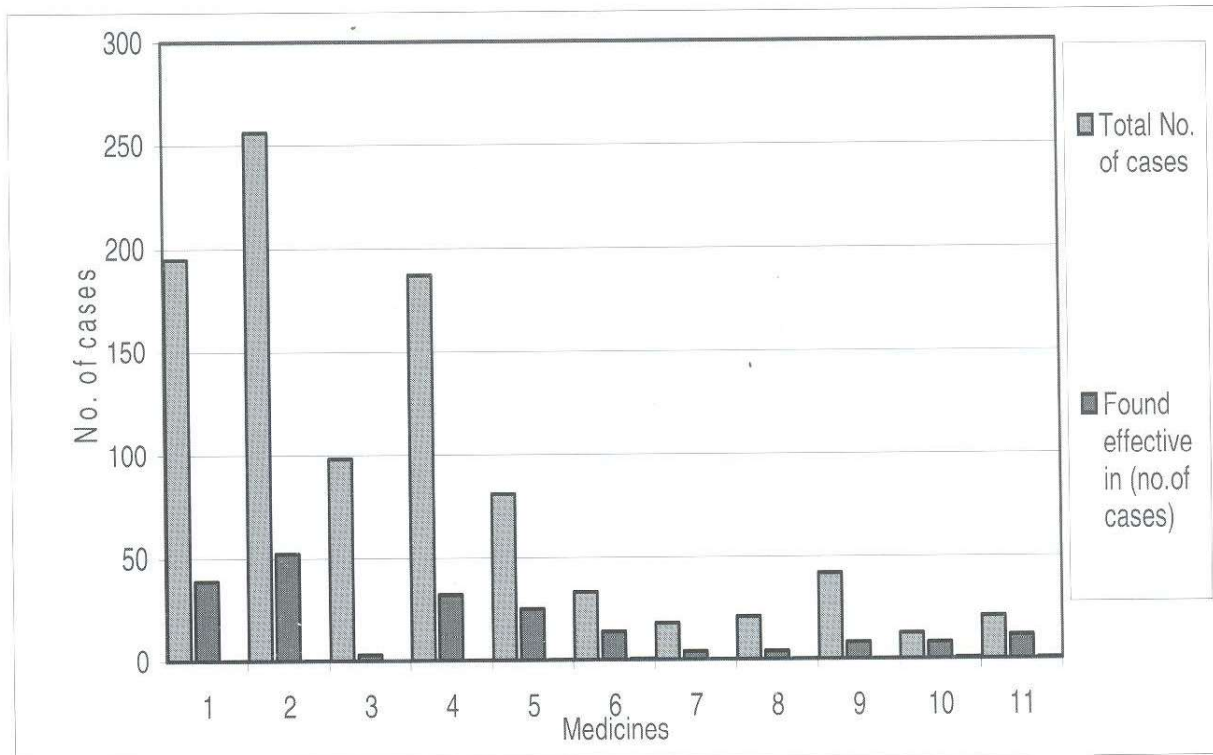
Target achieved - 2132 number of cases were studied.

Duration of study- Duration of the study was not fixed. It was a continuous study, reviewed every year by the Scientific Advisory Committee.

Assessment of Results:-

S.No.	Name of the drugs found effective	Total No. of cases	
		administered in	Found effective in
1.	Abroma augusta 6, 30, 200	187	32
2.	Cephalandra indica 6, 30, 200	256	52
3.	Chimaphila 6, 30, 200	13	8
4.	Chionanthus 6, 30, 200	42	8
5.	Glycerinum 6, 30, 200	21	4
6.	Insulinum 6, 30, 200	81	25
7.	Lac defloratum 6, 30, 200	18	4
8.	Lactic acid 6, 30, 200	33	14
9.	Syzygium jambolanum 6, 30, 200	195	39
10.	Thyroidinum 6, 30, 200	21	12
11.	Uranium nitricum 6, 30, 200	98	3

Figure-1
Drugs found effective



Signs/ symptoms ameliorated during study

1. *Thyroidinum* 6, 30, 200

Tiredness, weakness, anaemia, falling of hair mentally inactive, irritable, restless, desire for sweets, cold water, dry burning skin with eczema

2. *Chimaphila* 6, 30, 200

Puffiness of face, swelling of the lower limbs, pitting on pressure, loss of weight, ulcerations, excessive urination with turbid urine, all complaints are worse in damp weather

3. *Lactic acid* 6, 30, 200

Excessive appetite with nausea and vomiting, tongue very dry with thirst, pain in shoulder joint, wrist joint, and elbow joint with severe weakness, burning pain in the stomach ameliorated by vomiting

4. *Cephalandra indica* 6, 30, 200

Diabetes mellitus with hypertension, excessive

dryness of mouth with thirst, thirst for large quantity of water, frequent urination, profuse perspiration with weakness & giddiness, tingling & numbness of palms & soles, burning sensation all over the body

5. *Syzygium jambolanum* 6, 30, 200

Excessive thirst, profuse urination, weakness, emaciation, diabetic pruritus & ulcers.

6. *Abroma augusta* 6, 30, 200

Dryness of mouth with thirst for large quantity of water, excessive unnatural appetite, flatulence, constipation, profuse urination, dysmenorrhoea with scanty menses, severe nervous debility and impotency in male patients

7. *Insulinum* 6, 30, 200

Diabetes with skin affections, eruptions with itching aggravated after taking food, excessive thirst and excessive appetite.

Discussion

The goal of the therapy mainly was:

1. Amelioration /elimination of symptoms related to hyperglycaemia.
2. Effective blood sugar control
3. To enable the patients to maintain as normal a life style as possible.

Apart from medical therapy, appropriate health education, motivation, maintenance of nutrition, physical activity and self-care etc. were suggested.

The results of the study suggest a good response of patient to Chimaphila and Thyroidinum but the number of subjects studied under these 2 drugs was very less. Hence, more controlled study with a larger study population would be needed to fully appreciate the hypoglycemic action of these 2 drugs.

A moderately effective response was observed in case of Lactic acid which also relieved pains and

weakness commonly associated with Type II Diabetes mellitus.

Syzygium jambolanum, Cephalandra indica , Abroma augusta, Insulinum, Lac defloratum, Glycerinum and Chimaphila were helpful in amelioration of certain symptoms of Diabetes mellitus.

Conclusion

Although the initial results of these studies have confirmed a positive role of a number of homoeopathic drugs in potencies such as 6, 30, 200 in mitigating the symptoms of Diabetes mellitus yet further clinical trials of homoeopathic medicines in variable potencies are required to explore their therapeutic effect in Diabetes mellitus and to draw a definitive conclusion.

Reference

Concluding reports of CRU(T) at Pondicherry, Vijayawada & Salem.