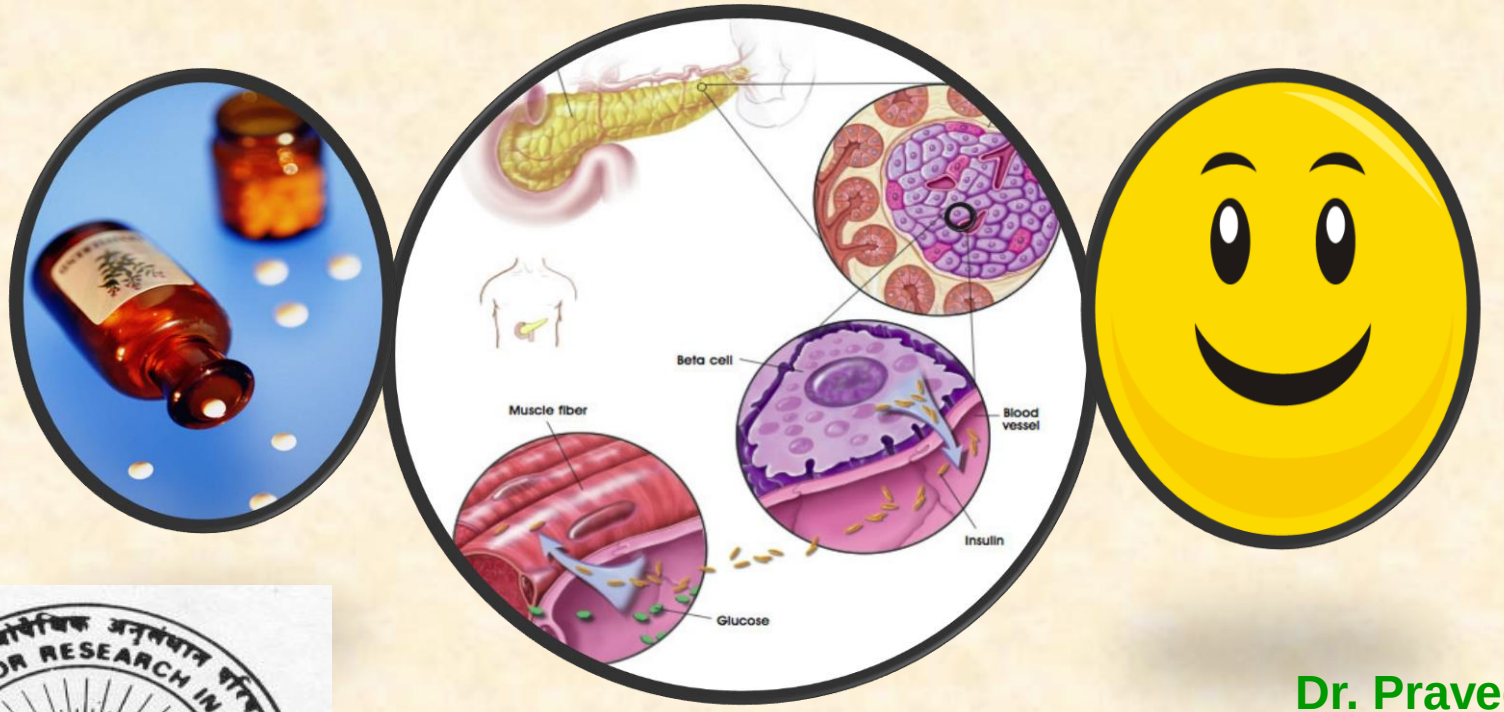
Scope & limitation in the treatment of diabetes mellitus and its complications, outcome of a few clinical research studies through Homoeopathy



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Scientist-4
Central Council for Research in Homoeopathy,
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New Delhi- 110 058

Origin Of Homoeopathy

Homoeopathy, compared to other medical practices, has a comparatively recent origin (about 200 years), and has generated considerable interest in health care.

Dr. Christian Friedrich Samuel Hahnemann was a great scholar, linguist and a reputed German physician .

Homoeopathy – An Intro.



- Homoeopathy is a natural system of healing based on the law ‘Similia Similbus Curantur’, which means ‘let likes be treated by likes’.
- This law says that a substance in minimum dose that has the ability to produce a set of symptoms in healthy individuals can be used to cure similar set of symptoms in a diseased individual.

Homoeopathy: Global scenario



- Homoeopathy is the second leading system of medicine for primary health care in the world.
- Holistic and Individualistic approach: Homoeopathy believes in treating the patient as a whole, and not only his/her diseased body part.
- Single, Simple remedy

Merits of Homoeopathy

- ✓ Principles of treatment based on Nature's Laws (Likes cure likes)
- ✓ Effects of medicines known by proving on healthy human beings.
- ✓ Most cost – effective treatment: affordable by all sections of People
- ✓ No adverse drug reactions
- ✓ Simple method of application of medicines
- ✓ Medicines palatable, hence better acceptability
- ✓ Medicine can be selected on the basis of symptoms & signs of patients, without waiting for cumbersome & costly diagnostic procedures



CENTRAL COUNCIL FOR RESEARCH IN HOMOEOPATI

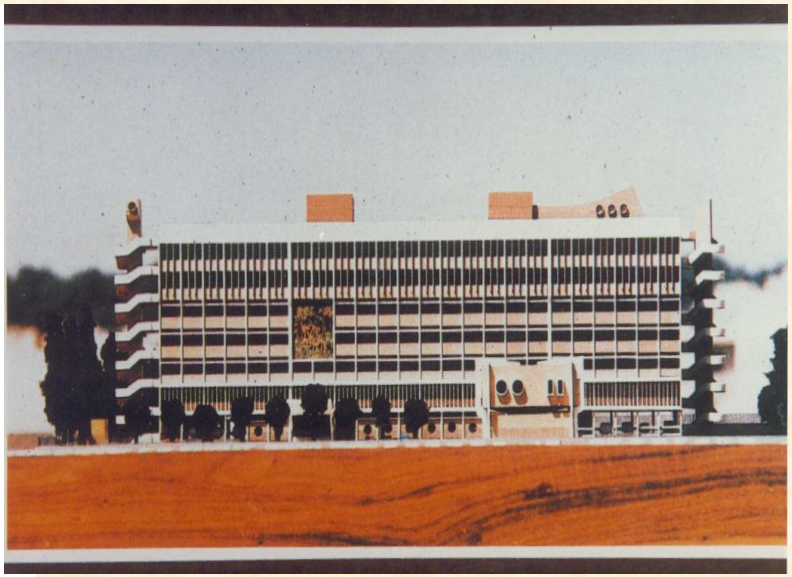
An autonomous body under Ministry of Health and Family Welfare, Department of AYUSH, Govt. of India

CCRH was established on 30.03.1978 as a Premier Research Organization in India

OBJECTIVES

- **Promotion**
- **Development**
- **Co-ordination and**
- **Dissemination**

of Research in Homoeopathy



SCIENTIFIC VALIDATION

To scientifically validate the results by:

- **Formulating protocols in conformity with the guidelines of WHO/ICMR**
- **Involving experts of modern medicine, experts in Homoeopathy in protocol making**
- **Approval by protocols by SAC & ethical committee**
- **Conducting all the sophisticated laboratory tests required as per provisions of protocols**
- **Involving experts of modern medicine for diagnosis, follow up and outcome assessment**
- **Involving bio-statisticians in protocol making and interpretation of results**
- **Scrutiny of studies by Data Review Board/Screening Committee**

Complementary system & Diabetes

Globally, there has been a revival of interest in complementary system of healthcare especially in the prevention and management of chronic lifestyle-related non-communicable diseases for which there are no effective/curative drugs in the modern system of medicine and most of the patients are on lifelong drugs with side effects.

Why Evidence-based medicine (EBM)

- Aims to apply the best available evidence gained from the scientific method .
- To assess the strength of evidence of the risks and benefits of treatments(including lack of treatment) and diagnostic tests.
- Using techniques from science, engineering, and statistics, such as the systematic review of medical literature, meta-analysis, risk-benefit analysis, and randomized controlled trials (RCTs)
- It also aims to Overcome the challenge that homoeopathy is acting like placebo.

Classification of EBM

Two types of evidence-based practice :

- Evidence-based guidelines:

  Evidence-based guidelines (EBG) is the practice of evidence-based medicine at the organizational or institutional level.

- Evidence-based individual decision making

  Evidence-based individual decision (EBID) making is evidence-based medicine as practiced by the individual health care provider.

Limitations of EBM

Although evidence-based medicine is regarded as the "gold standard" for clinical practice there are a number of limitations and criticisms of its use.

Ethics

- In some cases, such as in open-heart surgery, conducting randomized, placebo-controlled trials is commonly considered to be unethical, although observational studies may address these problems to some degree.

Cost:

- The types of trials considered "gold standard" (i.e. large randomized double-blind placebo-controlled trials) are expensive.

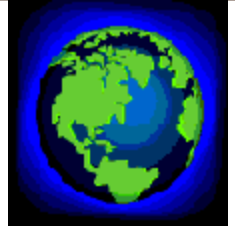
Time:

- The conduction of a randomized controlled trial takes several years until being published, thus data is restricted from the medical community for long years and may be of less relevance at time of publication.

Others:

- Unfortunately, there is a large information gap between research and clinical practice. Because so much research is published all the time, clinicians are unaware of most of it, or do not have the 'tools' to assess its quality.
- Researchers, on the other hand, do not understand the information needs of clinicians and continue to present their work in a way that is not easily accessible to busy practitioners.

Prevalence of diabetes



Source: Wild et al, 2004

The top 10 countries, in numbers of people with diabetes, are:

1. India
2. China
3. USA
4. Indonesia
5. Japan
6. Pakistan
7. Russia
8. Brazil
9. Italy
10. Bangladesh

Year		2000	2030
Ranking	*Country*	*People with diabetes (millions)*	
1	India	31.7	79.4
2	China	20.8	42.3
3	United States of America	17.7	30.3

Classification of Diabetes

Type I

Diabetes is also known as Insulin Dependent Diabetes Mellitus (IDDM) or Juvenile Diabetes.

Type II

Diabetes is also known as Non-Insulin Dependent Diabetes Mellitus (NIDDM) or Adult-onset Diabetes.



Gestational Diabetes mellitus (GDM):

GDM is a prodromal form of type 2 DM being unmarked by pregnancy.

Others

genetic, drug induced etc.

THE TRIAD OF TREATMENT



Aims of treatment

Early detection and Prevention of complication

- Annual Screening procedure
- Early detection
- Pharmacological intervention
- Target for Control

	Very good	Acceptable	less than ideal
BMI(kg/m2)	<25	<27	>27
Hb AIC	<6.5	6.5-7.5	>7.5

PLAN OF TREATMENT

Non Medicinal Management:

- Patients would be advised on diabetes self care, dietary restrictions, care of feet, and prevention of injuries.
- Appropriate advise regarding alcohol or tobacco abuse/addiction would be given.
- Life style modifications, physical exercise etc.

Medicinal Management:

The indicated medicine along with the general supportive care shall be followed by a periodic check-up to assess the progress in the case.

- Constitutional/holistic/individualized
- Palliative/ Organopathic
- Symptomatic

Who are to be screened for early diagnosis?

- A strong family history
- Obesity
- Age ≥ 45 years
- Previously identified Impaired fasting glucose (IFG) or Impaired Glucose Tolerance (IGT)
- History of GDM
- Hypertension (Blood pressure = or more than140/90 mmHg)
- HDL cholesterol level = or less than 35 mg/dl
- Triglyceride level more than 250 mg/dl
- Polycystic ovarian syndrome

Steps for Primary prevention in high risk population

- structured programs that emphasize lifestyle changes
- moderate weight loss (7% body weight)
- regular physical activity (150 min/week)
- dietary strategies including reduced calories and reduced intake of dietary fat
- dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake)

Role of Cephalandra indica Q in the management of Diabetes Mellitus as an add on medicine along with conventional anti-diabetics



Objective	To ascertain the role of Cephalandra indica Q, in the management of patients suffering from DM (type I or type II) continuing on anti-diabetic treatment and to identify its reliable indications.
Study design	Prospective observational study (1992 – 2000)
Inclusion criteria	Post-prandial blood sugar level more than 160 mg/dL even after taking anti-diabetic medicine.
Dose	One drop/ kg body weight → divided in 3 parts, mixed with one ounce of water →3 times a day
Outcome measures	FBS, PPBS
No. of patients	96 (treated averagely for a period of 42 months)

Hafeezullah Baig, K Singh, Anita Sharma, Praveen Oberai, S Kaushik, Debadatta Nayak, Alok Mishra. Role of Cephalandra indica Q in the management of Diabetes Mellitus as an add on medicine along with conventional anti-diabetics. CR Series II. 2009

Results	**88 patients were followed up**
Allopathy	**Dosage of allopathic medicines was reduced in maximum number of patients but, it was completely withdrawn in 17 patients.**
Recurrence	**No recurrence in 9 patients, recurrence with less intensity in 55 patients.**

Changes in blood sugar level after treatment

	Before treatment	After treatment	Difference	p-value
	(Mean ±SD)			
FBS	**138.90 ± 24.38**	**115.86 ± 26.36**	**23.03 ± 27.62**	**0.0001**
PPBS	**265.08 ± 44.67**	**204.75 ± 39.96**	**60.33 ± 53.40**	**0.0001**

A prospective multi-centric open clinical trial to evaluate the usefulness of homoeopathic medicines in the management of diabetic distal symmetric polyneuropathy

Design	**Prospective observational study (2005 – 2009)- 5 centers**
Primary objective	**To evaluate the role of homoeopathic medicines in the management of DPN and assessing the degree of intensity of symptoms amenable to homoeopathic treatment.**
Secondary objectives	**To determine and verify characteristic symptoms of medicine(s) used,** **to check the progression of disease and to consider the clinical findings like control of blood sugar levels,** **changes in symptoms & signs of peripheral neuropathy and changes in symptoms and signs of occlusive arterial disease.**
Inclusion criteria	**Age over 30 years with diagnosed IDDM or NIDDM, HbA1c, less than 8%** **Sensory Loss** **Written informed consent**

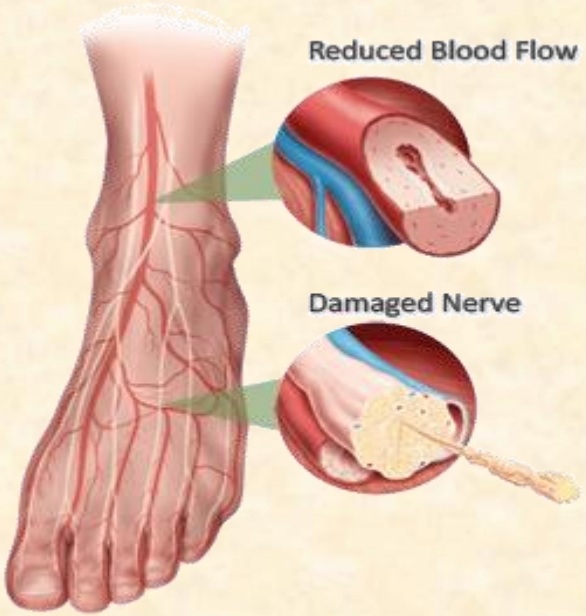
C.Nayak, Vikram Singh, V.P. Singh, Hari Singh, Praveen Oberai, Varanasi Roja, Shashi Shekhar Shitanshu, H.Baig, Ch.Raveendar, G.R.C.Reddy, Pratima Devi, S. Bhubaneshwari. A prospective multi-centric open clinical trial to evaluate the usefulness of homoeopathic medicines in the management of diabetic distal symmetric polyneuropathy .

Exclusion criteria	• Diabetic Mononeuropathy, Polyradiculopathy, amyotrophy, autonomic Neuropathy • Abnormalities of gait, Absent stretch reflexes • Wrist drop, Foot drop • Development of typical Charcot joints, particularly in the feet , Paralysis of III, IV or VI Cranial Nerves • Loss of arch with multiple fractures of tarsal bones • Neuropathy due to other causes • Myocardial infarction less than 6 months , Unstable angina • Complication of diabetes (retinopathy, renal involvement or with history of recurrent acute complications like hypoglycemia, ketoacidosis) • HbA1c more than 8%
Pre-identification of trial medicines	15 medicines were identified →repertorizing the main diagnostic symptoms of DPN (Numbness, Insensibility foot; Formication; Delusions senses of; Prickling; Senses hyper-acute, painlessness of complaints usually painful) →Complete Repertory→3 marks →were selected as trial medicines viz. ***Sulph., Lyco., Rhus tox., Nux vom., Phos. ac., Phos., Ars.alb., Con., Cocc., Op., Sec. Rhod., Plat., Graph.*** and ***Stram..***

Outcome measures	• Distal Diabetic Symmetric Polyneuropathy symptom score (DDSPSS) • Nerve conduction studies • FBS, PPBS, HbA1c
Treatment period	• 12 months
No. of patients	247 (123 males and 124 females)

Formula= {(score AT ENTRY– score AT END) / score AT ENTRY} x100.

- Cured (100% improvement),
- Marked improvement (75 to <100 %),
- Moderate improvement (50 to<75 %),
- Mild improvement (25 to <50 %),
- Not significant (< 25%),
- Not improved (no change) and
- Worse (increase in symptoms score).

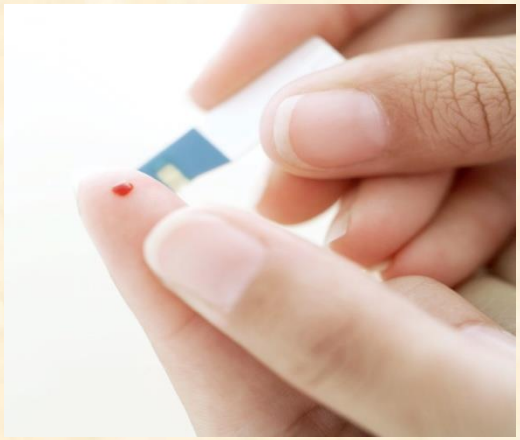


OUTCOME STATUS

Intensity of disease	Patients before Rx	No. of patients after Rx				
		Positive(%)				Negative (%)
		Cured	Marked	Moderate	Mild	Not significant + Not Improved
Mild	77	1 (1)	17 (22)	36 (47)	12 (16)	11 (14.2)
Moderate	162	9 (6)	48 (30)	86 (53)	14 (9)	5 (3.08)
Severe	8	0 (0)	1 (13)	4 (50)	3 (38)	0
Total	247	10 (4.04)	66 (26.7)	126 (51)	29 (11.7)	16 (6.47)

Pathological findings

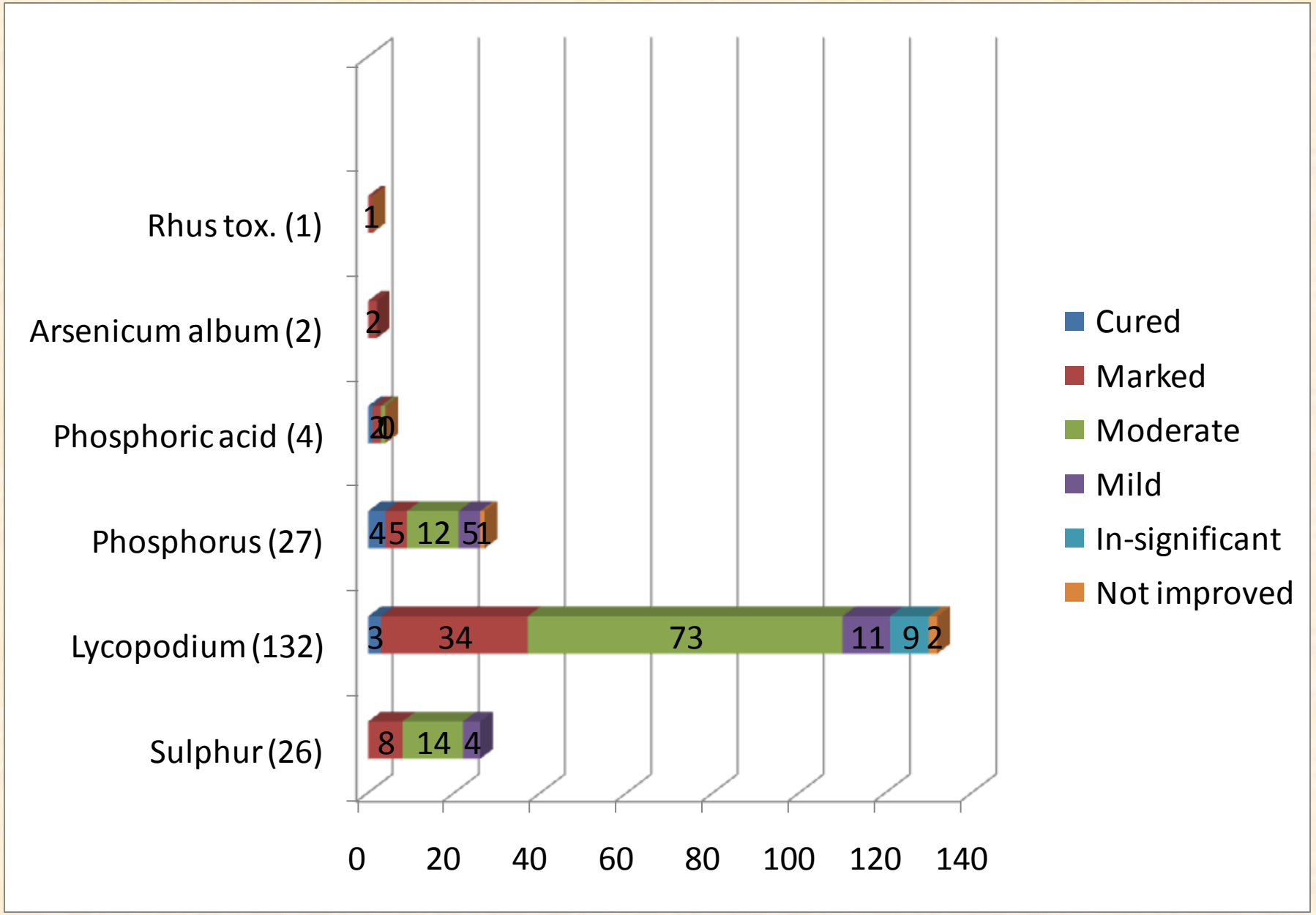
Blood parameters	Mean ± SD		Change	p value
	At entry	At end		
FBS (mg/dL)	124.81± 40.5	114.65 ± 30.2	10.6± 10.3	0.0001
PPBS(mg/dL)	204.86± 68.05	178.34 ± 47.37	26.5 ±20.68	0.0001
Hb%	12.15 ± 1.5	12.37 ± 1.57	0.22 ± 0.07	0.005
HbA1c (gm%)	7.37± 1.27	6.78 ± 0.87	0.59 ± 0.4	0.0001



Nerve conduction studies of peripheral nerves

Investigations		(Mean±SD) at entry	(Mean±SD) at end	p-value
Right Tibial Nerve	Distal Motor Latency in millisecond	4.54 ± 0.97	4.58 ±1.31	0.635
	Compound muscle action potential amplitude in millvolt	7.34 ± 4.16	6.92 ±3.94	0.033
	Motor nerve conduction velocity in millisecond	43.51 ± 7.82	44.12 ±7.91	0.196
Right Peroneal Nerve	Distal Motor Latency in ms	4.32 ± 0.89	4.26 ±0.81	0.388
	Compound muscle action potential amplitude in mV	4.29 ± 2.23	4.74 ±3.1	0.021
	Motor nerve conduction velocity in ms	44.51± 6.04	44.27±6.31	0.551
Right Sural Nerve	Distal Sensory Latency in ms	4.69 ± 4.47	3.87 ±2.42	0.001
	Sensory nerve action potential amplitude in microvolt	8.99 ± 8.91	9.58 ±9.26	0.134
	Sensory nerve conduction velocity in ms	40.06 ± 14.72	40.3 ±11.26	0.738

Outcome assessment of trial medicine



Diabetic Foot Ulcer – A Clinical Study (From 2005-2008) at DSU (Extn. Unit), Hyderabad
Salient features of the study

- Study is conducted with predefined protocol parameters viz. screening, inclusion and exclusion criteria, detailed case recording proforma, assessment by score criteria, prescription as per to the homoeopathic principles
- 63 cases of Diabetic Foot Ulcer cases have completed 6 months follow up
- Out of 63 cases 57 cases showed marked improvement, 4 cases moderately, 1 case mild and 1 case did not show significant improvement
- Drugs frequently found useful are Silicea, Sulphur, Lycopodium, Ars. Alb, Phosphorus etc.

Response to treatment

Improvement status	No. of patients	Percentage
Marked	57	90.5%
Moderate	04	6.3%
Mild	01	1.6%
Not significant	01	1.6%

MEDICINES PRESCRIBED & FOUND USEFUL

Name of medicine	No. of cases prescribed	Percentage %	Improvement assessment			
			Marked	Moderate	Mild	Not significant
Sulphur	11	17.5	10	01	-	-
Silicea	22	34.9	21	01	-	-
Lycopod.	10	15.9	10	-	-	-
Ars. Alb	08	12.7	08	-	-	-
Sepia	01	1.6	01	-	-	-
Secale cor	01	1.6	-	01	-	-
Calc. carb	01	1.6	01	-	-	-
Plumbum met.	01	1.6	-	01	-	-





AFTER HEALING



1. Arsenic alb 30 – repeated twice during the study period
2. Ulcer healed up completely within 6 months of time
3. No recurrence within the study period

RESEARCH CASE NO. 13

At entry





During treatment





After treatment





1. Arsenic alb 30 – two doses during the study period
2. Ulcer healed up within six months
3. No recurrence within the study period





AFTER HEALING



1. Silicea 30 – repeated thrice during the study period
2. Ulcer healed up completely within 3 months of time
3. No recurrence within the study period





After treatment



1. Secal cor 30 – three doses during the study period
2. Ulcer showed marked healing within in one year
3. As the ulcer is on the sole of the foot, the most pressure and tough skin area, healing took more than one year

Effects of Homoeopathic intervention in pre-diabetes (EHIP): An open label randomized controlled exploratory trial

Pre trial phase

STUDY DESIGN: An Open Label Randomized Controlled exploratory trial.

Two groups:

- Group 1: Individualized homoeopathy plus life style modifications (IH+LSM).
- Group 2: Control (Placebo +LSM)

The intervention will be for a period 6 months.

Interim Analysis Results

Variables	Homoeopathy + TLC		Placebo + TLC		P value
	Mean	SD	Mean	SD	
FBS	17.70	25.05	20.63	29.62	0.57
OGTT	20.59	45.42	12.96	37.59	0.34
HBA1c	-0.43	2.67	-0.29	1.48	0.81
LDL	3.23	26.10	-2.47	24.40	0.24
VLDL	-0.10	9.30	1.94	15.18	0.42
HDL	-0.25	6.44	1.80	11.02	0.23
TGL	0.52	52.71	1.06	44.61	0.95
Physical Activity Score	-3.28	4.44	-3.53	6.70	0.82

ROLE of Homoeopathy in National Programme for Control and prevention of Diabetes Cardiovascular diseases and Stroke(NPCDCS)

- As per the NPCDCS programme, integration with AYUSH is a part of the strategy
- Homoeopathic doctors can play an important role :

  - **health promotion through behavior change,**
  - **counseling of patients for healthy lifestyle including meditation, yoga**
  - **Opportunistic screening**
  - **Prevention, control and treatment of NCDs**

TARGET GROUP

The program aims to cover all vulnerable age groups who may be prone to NCDS.

STRATEGIES

In lines with the operational guidelines of NPCDCS :

1) Prevention through behavior change
2) Early Diagnosis
3) Treatment
4) Capacity building of human resource
5) Surveillance, Monitoring & Evaluation

Methodology of AYUSH (Homoeopathic intervention) in NPCDCS

SCREENING OF POPULATION (Krishna and Darjeeling District)
Treatment at CHC

Cohort I

- Preclinical Hypertension and Stage I Hypertension
- Pre Diabetes
- Dyslipidemia: Borderline high risk lipid levels

Randomization

GROUP IA → Homoeopathy + TLC including Yoga

GROUP IB → TLC including Yoga

- Follow up regularly on predesigned format for 6months
- Routine monitoring of HbA1C and FBS at 3rd, , 6th , 9th and 12th month. OGTT, LFT, Lipid profile at 6th and 12th month
- WHO QOL Bref at 6th and 12th month

Cohort II

- Hypertension on standard care,
- Diabetes/ Complications of Diabetes on standard care;
- Dyslipidemia on standard care
- High risk lipid level on standard care

Randomization

GROUP IIA → Allopathy +Homoeopathy + TLC including Yoga

GROUP IIB → Allopathy +TLC including Yoga

- Follow up regularly on predesigned format for 6 months
- Routine monitoring of HbA1C and FBS at 3rd, , 6th , 9th and 12th month. OGTT, LFT, Lipid profile at 6th and 12th month
- WHO QOL Bref at 6th and 12th month
- Reduction in dosage of standard care

Scope of Homoeopathy in diabetes mellitus

- Different levels of evidence is found.
- Homoeopathy has some scope in managing complications of diabetes.
- No. of anti-diabetic medications can be tapered/withrawn.
- Timely-administered homoeopathic medicines may assist in preventing long-term complication through day-to-day diabetes management.

Limitations of homoeopathic system

- IDDM due to the nature of the disease;
- Acute complications requiring emergency treatment SCOPE;
- Effective in the management of early NIDDM and limiting the complications due to Diabetes mellitus;
- Homoeopathic treatment along with intake of hypoglycemic drugs and/or insulin can prevent the progress and the complications associated with this condition.
- In most urgent cases where danger of life & imminent death allow no time for the action of homoeopathic remedy.

WE USE HOMOEOPATHY

- **NON SURGICAL CHRONIC DISEASES**
- **RECURRENT ILLNESS**
- **PROPHYLAXIS & MANAGEMENT OF EPIDEMICS**
- **PALLIATION**
- **ACUTE DISEASES**
- **MEDICAL EMERGENCIES**
  (WHEN DOCTOR TELLS TO PRAY)
- **IMPOSSIBLE HOPELESS CASES**
  (TRIAL OF HOMOEOPATHY)

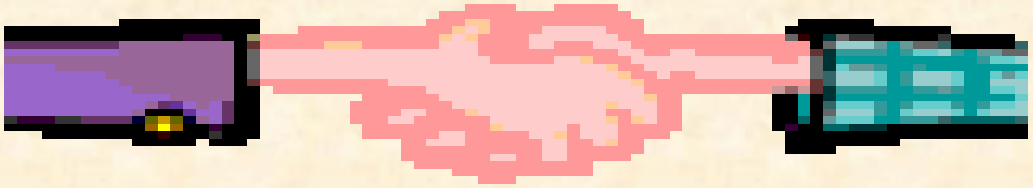
SUMMARY

- T2DM is an epidemic of dangerous proportions
- The epidemic is growing continuously
- India is at the epicenter of this epidemic
- Early diagnosis with routine screening should be mandatory
- Early and sustained glycemic control can prevent or minimize future complications
- Consultation of diabetologist is mandatory periodically
- There is no substitute to insulin in homoeopathy

Need of the hour

- All systems have their limitations and should join hands to face the epidemic of diabetes to contribute in delivering their best.
- Conduct studies jointly to have effectiveness in emergent conditions too.
- Conduct studies to arrest the disease in preclinical stage.

Need of the Hour: Joint Endeavour

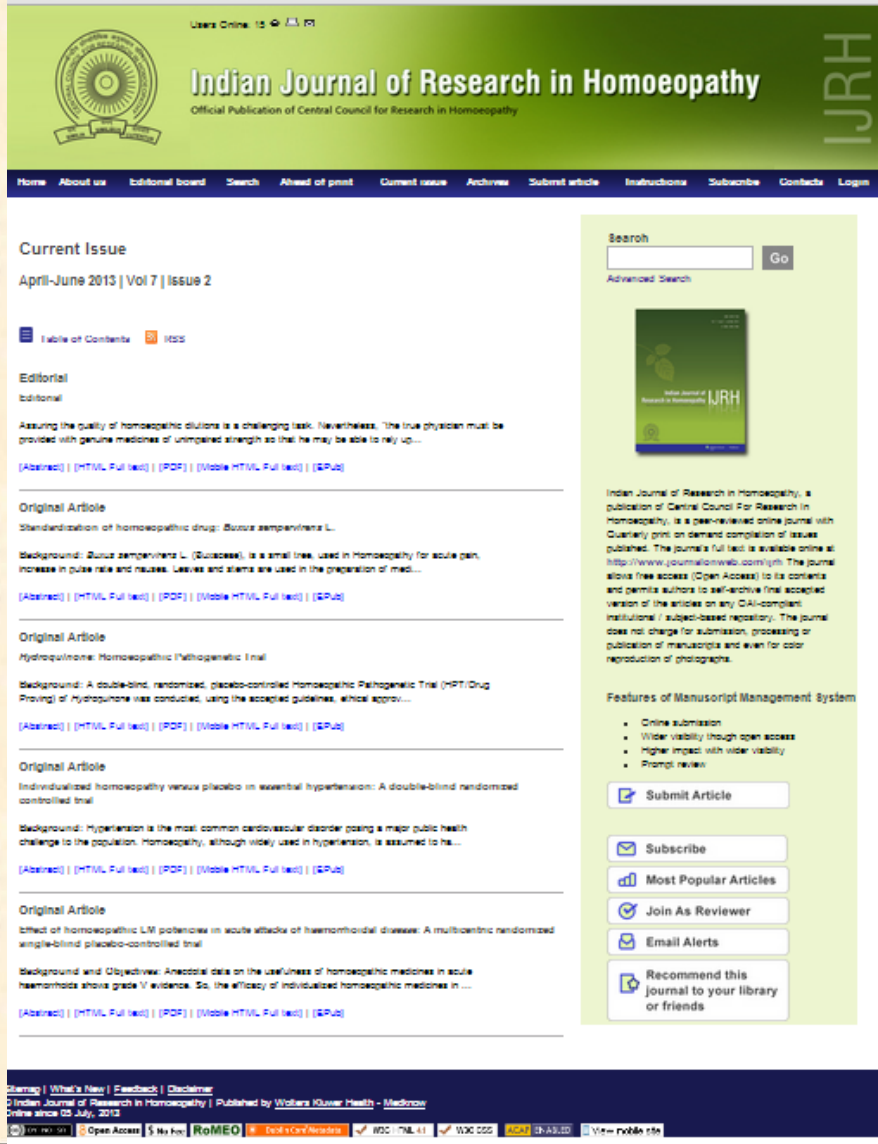


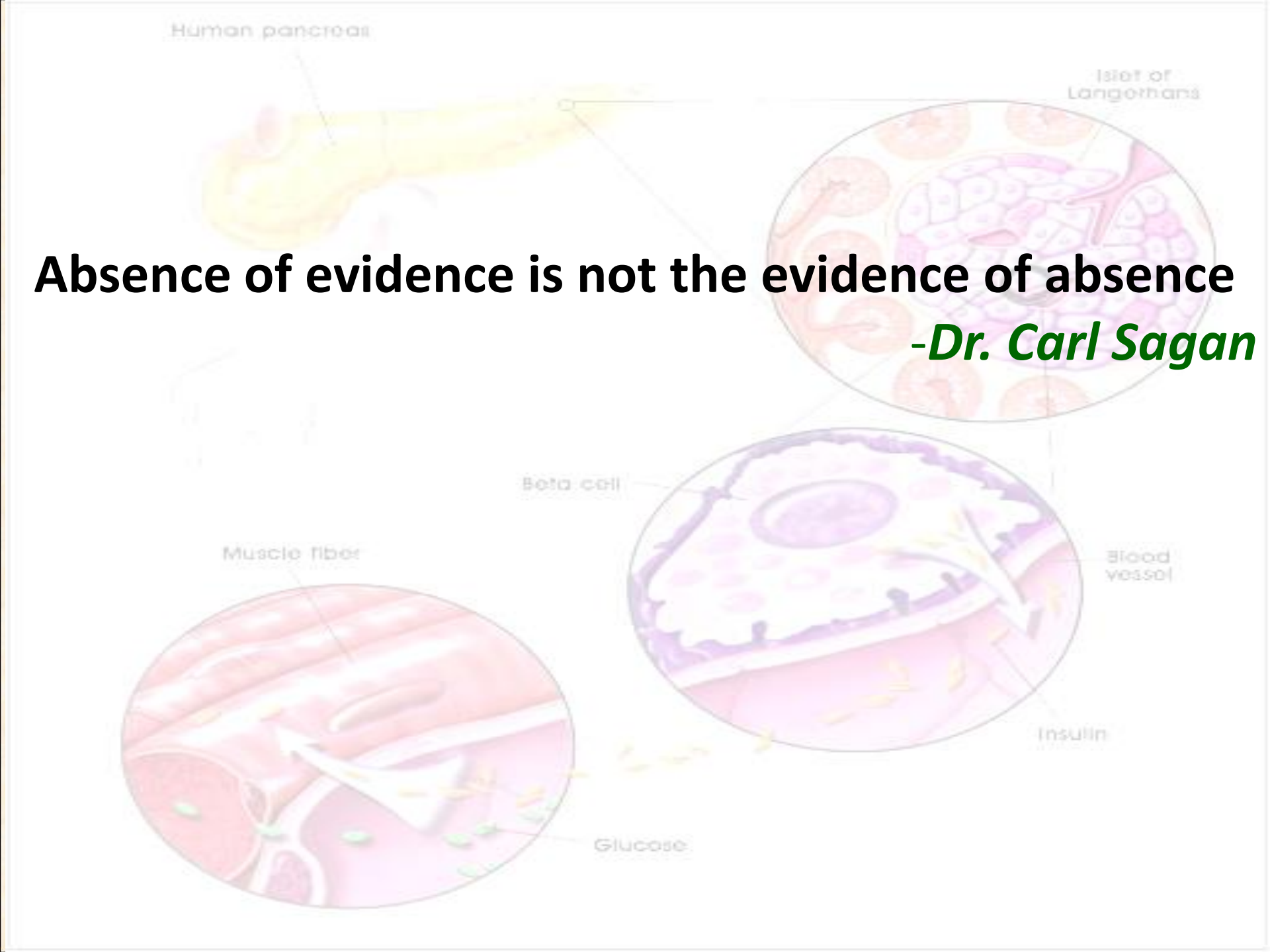
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Indian Journal of Research in Homoeopathy

- **Launched in 2007**
- **First peer reviewed homoeopathic journal in Asia**
- **Sections on**
  - **Fundamental research**
  - **Drug standardization**
  - **Drug proving**
  - **Clinical verification**
  - **Clinical research**
  - **Extra-mural research**
  - **Case studies**

Now IJRH is available as an open access journal online at http://ijrh.org





Absence of evidence is not the evidence of absence

-Dr. Carl Sagan

Thank You

