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THE ROLE OF LESSER KNOWN HOMOEOPATHIC MEDICINE AZADIRACHTA INDICA 3X AND INDIVIDUALIZED HOMOEOPATHIC MEDICINES WITH AID OF KENT REPERTORY AS ADD ON TREATMENT IN CASES OF TYPE 2 DIABETES MELLITUS - RANDOMISED COMPARATIVE TRIAL

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ABSTRACT

Diabetes Mellitus is recognized as most important public health problem and more than 170 million people worldwide suffer from disease. Diabetes Mellitus comprises a group of metabolic disorders characterized by chronic hyperglycemia secondary to absolute or relative deficiency in insulin secretion and/or insulin action. The incidence of Diabetes Mellitus in India as well as in Rajasthan is increasing due to change in lifestyle i.e. eating habit, sedentary life and increasing stress. Considering the rising incidence of Diabetes Mellitus, India is the top-ranked country in incidences of diabetes mellitus. Blood sugar level also not improving inspite of conventional medicines & side-effects of the same, the efforts is to control blood sugar with Homoeopathic medicines in conjunction with conventional medicines as well as to prevent complications.

OBJECTIVES

To assess the improvement with Azadirachta indica 3X in comparison to Individualized Homoeopathic Medicines prescribed with the aid of Kent Repertory in cases of type 2

Diabetes Mellitus as add on treatment.

To asses the improvement pre and post t/t with levels of FBS, HbA1c. To asses the change in Waist Hip ratio pre and post t/t.

To observe the clinical symptoms of Azadirachta Indica.

Study Design

A Randomised Comparative trial.

METHOD

100 individuals were randomly allocated in to 2 groups. One group of 50 patients were given Azadirachta indica 3X and another 50 patients were given individualized homoeopathic medicine from Kent repertory. Follow up of the patients conducted periodically as specified in the protocol. Conventional medicine continued during the treatment in both groups.

STUDY SETTING

The present study was undertaken at M.N. Homoeopathic Medical college, and Research Institute, Bikaner. The cases were taken from the OPD/IPD.

STUDY DURATION

The study was undertaken for a period of 12 months, pre preparation was done for 2 months, cases were registered in first 3 months and each case was followed up for a period of minimum 3 months (each follow up at 15 days interval) and analysis & observation was done in last 4 months.

INTERVENTION

Patients were enrolled from O.P.D./ I.P.D. as and when they came, after confirmation of their inclusion criteria as per protocol, till such time that the target is achieved. These 100 individuals were randomly allocated to 2 groups. One group of 50 patients was given individualized homoeopathic medicine repertorise from Kent Repertory and another 50 patients was given Azadirachta Indica 3X follow up of thepatients conducted periodically as specified in the protocol. Allopathic medicine continued during treatment in both groups.

STATISTICAL TECHNIQUE AND DATA ANALYSIS

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- 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 Mean= 7.82 (Pre-treatment) to7.51(post- treatment) P value 0.0001.

While the Pre-treatment and 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- 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) P value 0.0001.

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 Azadirachta indica 3X. Prescription done according to the susceptibility can effectively and safely relieve the T2DM symptoms. Since the duration of this study was for one year only and a 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 T2DM.

KEYWORDS: AZADIRACHTA INDICA, INDIVIDUALIZED HOMOEOPATHIC MEDICINE, KENT REPERTORY, T2DM.

INTRODUCTION

Diabetes mellitus is the widest spread affection of mankind. Diabetes Mellitus comprises a group of metabolic disorders characterized by chronic hyperglycaemia secondary to absolute or relative deficiency in insulin secretion or insulin action.[1]

"Mother of all diseases – Diabetes" - W.H.O.

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.[2]

Diabetes consists of 3 types
Type I- Previously called insulin dependent mellitus. Type II- Previously called non-insulin dependent diabetes and Gestational diabetes mellitus.[2]

Diabetes is reaching as epidemic proportion across the globe. Today, there are 382 million people affected with diabetes around the globe. It is estimated that, 316 million people with impaired glucose tolerance are at high risk from the disease–an alarming number that is set to reach approximately 471 million by 2035. Diabetes is on the rise all over the world and countries are struggling to keep up with the progression of this metabolic disorder. Although diabetes is often not recorded as the cause of death, globally, it is believed to be the fifth leading cause of death in 2000 after communicable diseases, cancer and injury India ranked first with 31.4 million people followed by China (20.8 million) and United State (17.7 million). The statistical data is going to be double by 2030 with expected number of 79.4 million people in India, 42.3 million people in China and 30.3 million people in USA Preliminary study conducted by the Indian Council of Medical research (ICMR) revealed the statistical data, that the lower proportion of the population of Chandigarh (0.12 million), Jharkhand (0.96 million) and Uttar Pradesh (4.23 million) was affected in states of Northern India as compared to 9.2 million in Maharashtra and 4.8 million in Tamil Nadu.[2]

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".[3]

Azadirachta indica (Neem) is a medicinal plant, used in Ayurveda for treating various diseases, one of which is diabetes mellitus. It is known to possess antiinflammatory, antipyretic, antimicrobial, antidiabetic and diverse pharmacological properties. However, the molecular mechanism underlying the effect of *A. indica* on insulin signal transduction and

glucose homeostasis is obscure.[4]

Doctrine of signature – According to Doctrine of signature Azadirachta Indica work bitter with its taste in cases of Diabetes Mellitus.

Homoeopathy is based on natural law of healing "Similia Similibus Curantur" (let likes be treated by likes). It is a complete system of therapeutic medication made up of laws, rules, methods and processes, Life force, single remedy, totality of symptoms, infinitesimals minimum dose etc –all are integral to system.[5] Fundamental principle of Homoeopathy is that it treats the patient as a whole and as an individual.[6]

Kent‟s repertory was based on philosophy of deductive logic that is from generals to particular. Dr. Kent divides the symptoms in the higherarche as General Symptoms, which is dived into Mind and Physical; particular symptoms; Common symptoms. The repertory is constructed in such a way that every case can be worked out from general to particular. The advantage of such a process is that the remedies, which have a particular symptom, may not have a specific modality, which is neededfor the case.

Type-2 diabetes is a major, non-communicable disease with increasing prevalence at a global level. Type-2 diabetes results when the body does not make enough insulin or the body cannot use the insulin it produces. Type-2 diabetes is the leading cause of premature deaths. Improperly managed, it can lead to a number of health issues, including heart diseases, stroke, kidney disease, blindness, nerve damage, leg and foot amputations, and death. Type-2 diabetes or adult-onset diabetes is most common type of diabetes, usually begins when a person is in his or her mid-50s, but diabetes is not inevitable.[7]

Thus, this study was an attempt to compare the effectiveness of Azadirachta Indica & individualized homoeopathic medicine with aid of Kent Repertory in cases of type 2 diabetes mellitus.

EPIDEMIOLOGY

Diabetes mellitus is a chronic metabolic disorder the prevalence of which has continued to evolve with time. The worldwide prevalence of DM has risen dramatically over the past two decades. In 2000, according to WHO at least 170 million people worldwide suffer from diabetes or 2.8% of population. Its incidenceis increasing rapidly and it is estimated that by the year 2030, this number will be almost triple.[7] There are 35 million adults with diabetes

in India, and 13.3 million cases remain undiagnosed, up to Aug 2017[3] Type 1 diabetes is growing by 3% per year in children and adolescents. The average age of onset of type 2 diabetes is 42.5 years.[8]

In India studies have shown a rising prevalence of type 2 diabetes mellitus.[9] Prevalence of diabetes in more in urban than in rural areas. Prevalence of impaired glucose tolerance is also high. Considering the high rate of conversion of IGT to diabetes, there may be further increase in the amount of diabetes in the future.

MODERN VIEW

Diabetes is a metabolic disorder in which the body does not produce enough, or do not respond to insulin, a hormone produced in the pancreas.

Function of Pancreas

The pancreas has both exocrine and endocrine functions. The exocrine pancreas forms the bulk of the gland. The acinar cells of the gland secrete the pancreatic juice containing digestive enzyme. This secretion passes through the pancreatic duet, which opens, into the duodenum. The endocrine functions are served by the islets of langerhans.[10]

Classification *of Diabetes*[11]

Primary diabetes

Type I: (Insulin dependent diabetes mellitus)

This form of diabetes is present in only 5 -10% of total diabetes. Type 1diabetes is due to cellular mediated autoimmune destruction of beta cells. Classical symptoms of diabetes like polyuria, polydipsia, nocturia and weight loss are prominent in type 1 diabetes.

Type II: (Non –insulin dependent diabetes mellitus)

Which account for about 90% of diabetes cases, it is not common in adult over age 50. This form of diabetes is strongly linked with obesity, inactivity and a family history of diabetes. It is due to insulin resistance or reduced insulin sensitivity, combined with relatively reduced insulin secretion which in some cases becomes absolutes. It is also called as noninsulin dependent diabetes is NIDDM.

Secondary diabetes

Pancreatic diseases, hormonal, drug induced, insulin receptor abnormalities, specific genetic syndrome, gestational diabetes (GDM), and genetic defects of the insulin receptor.

AETIOLOGICAL CLASSIFICATION[12]

Diseases of Exocrine Pancreas

Trauma Pancreatitis Cystic fibrosis Hemochromatosis

Fibro calculus pancreatopathyNeoplasm

Pancreatectomy

Due to other endocrinopathies

Acromegaly Cushing syndrome Hypothyroidism Pheochromocymota Glucogonoms Aldasterenoma Somatostaninoma.

Drug or Chemical Induced

Thiazides diuretics

Corticosteroids

Nicotinic acid

Environmental

Cytomegalo virus

Congenital rubella

Life Style

Lazy personality with stress, strain, tension, and worries of various kind.

Sedentary life style

Prolonged deprivation of exercise

Prolonged deprivation of fresh air, healthy atmosphere.

Prolonged ill maintains of proper dietary habits with obesity.

Personal with other risk factors as, smoking, mal nutrition, high lipid profile etc.

PATHOPHYSIOLOGY AT CELLULER LEVEL[12]

DM type II = Progressive

B cell damage + Insulin resistance.

INSULIN RESISTANCE[13]

The decreased ability of insulin to act effectively on peripheral target tissues is a prominent feature of type 2 DIABETES MELLITUS and results from a combination of genetic susceptibility and obesity.

IMPAIRED INSULIN SECRETION

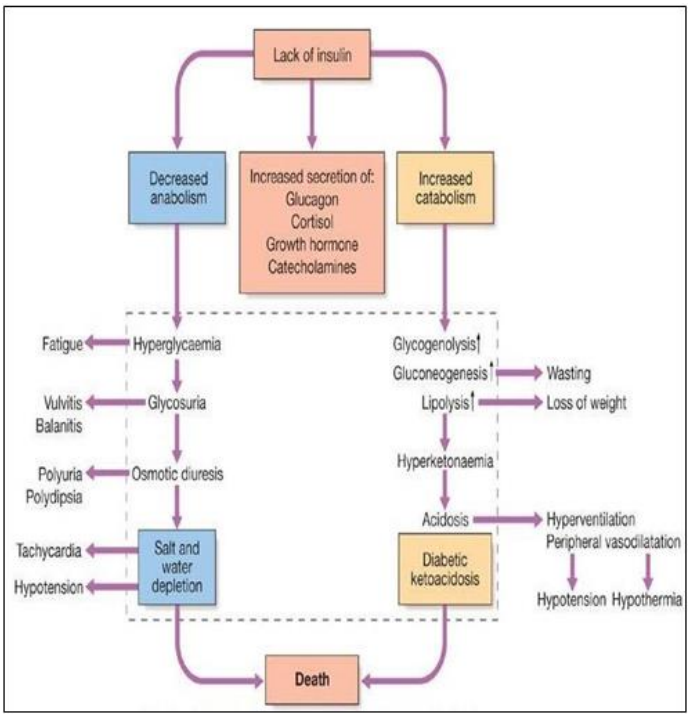

FIGURE 1.

Insulin secretion and sensitivity are interrelated. In type 2 diabetes mellitus, insulin secretion initially increases in response to insulin resistance to maintain normal glucose tolerance. Initially, the insulin secretary defect is mild and selectively involves glucose-stimulated insulin secretion.

INCREASED HEPATIC GLUCOSE PRODUCTION[11]

In type 2 diabetes mellitus, insulin resistance in the liver reflects the failure of hyperinsulinemia to suppress to gluconeogenesis, which results in fasting hyperglycemia & decreased glycogen storage by the liver in the post of prandial state. Increase in hepatic glucose production occurs early in the course of diabetes, though likely after the onset of insulin secretary abnormalities and insulin resistance in skeletal muscle.

Clinical Features of DM

The clinical feature depends upon on extent of pathology, age of patient, treatment given / not given, etc.

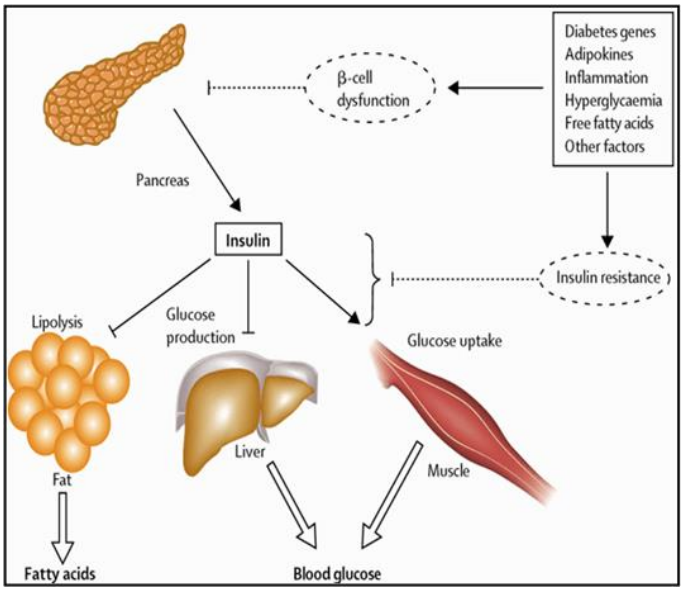

FIGURE 2.

CLINICAL FEATURES OF DIABETES MELLITUS[15]

Commonest clinical features are due to osmotic change.

Polyphasia: As low insulin / low glucose utilization / State of cell fasting / hunger stimulation.

Polydipsia: Due to resulting loss of water & electrolytes.

Polyuria: It is due to osmotic diuresis as blood glucose level exceeds the renal threshold.

Weight loss: Due to muscle wasting because of gluconeogenesis [wasting due tolipolysis, fluid depletion & electrolyte loss].

Easy fasting, giddiness, blurring of vision, muscle pains, cramps & aches all due to fluid depletion & electrolyte loss.

Opportunistic Infection: Furuncles, Carbuncles, Upper respiratory track infection, Vulvo vaginitis, Balanoprosthitis, Balanitis.

COMPARISON OF TYPE-I AND TYPE-II DIABETES

Table 1: Comparison of Type 1 and Type 2 Diabetes mellitus.

	TYPE 1	TYPE 2
AGE OF ONSET	Juvenile Onset < 30 Yrs	Adult Onset > 40 yrs
BODY WEIGTH	Non Obese	Mostly Obese
KETOSIS	Common	Uncommon
INSULIN SECRETION	Severe Deficiency	Moderate Deficiency
INSULIN RESISTANCE	Occasional	Almost Always
ISLET CELLS ANTIBODIES	Frequont	Absent
F/H OF DIABETES	Absent	May be present

DIAGNOSIS[29]

Blood sugar Monitoring

Fasting PGL more than 7 mmol/ lit. i.e. >126mg /dl

Random PGL >11mmol/lit i.e. > 180 mg /dl.

Oral Glucose Tolerance Test (O.G.T.T.)

Preparation for OGTT

Unrestricted carbohydrate diet for 3 days.

Fasting overnight, at-least for 8 hrs

Rest for 30 min.

When random PGL is between 7 -11 mmol /lit.

Impaired Glucose Tolerance: Fasting <110 mg / dl After 2 hrs. Glucose load 120 to 180mg/ dl	Diabetes mellitus Fasting > 110 mg/ dl After 2 hours of glucose loadmore than 180 mg/dl

Inference

PLASMA INSULIN LEVEL

Fasting blood insulin concentration is 10 µ/ml (multi higher in portal blood).

After meal – 50 – 70 µ/ml of blood.

GLYCOSURIA

Test for sugar: Benedict‟s qualitative test.

Test for Ketone bodies: Rothra‟s test

Gerhardt‟s test.

Blood lipids

Concentration of serum lipids is another important index of overall metabolic control in

diabetic patients and should be monitored regularly.

Glycated Haemoglobin

Glycated haemoglobin refers to the products of chemical reaction between glucose and Hb.

It is cumulative estimate of the mean blood sugar concentrations over the proceeding 9-12 week. The normal value of glycated haemoglobin is in the range of 4-6% of total Hb. A rise in HbA1c level, more than 6.5% indicate diabetes mellitus.

COMPLICATIONS OF DIABETES MELLITUS

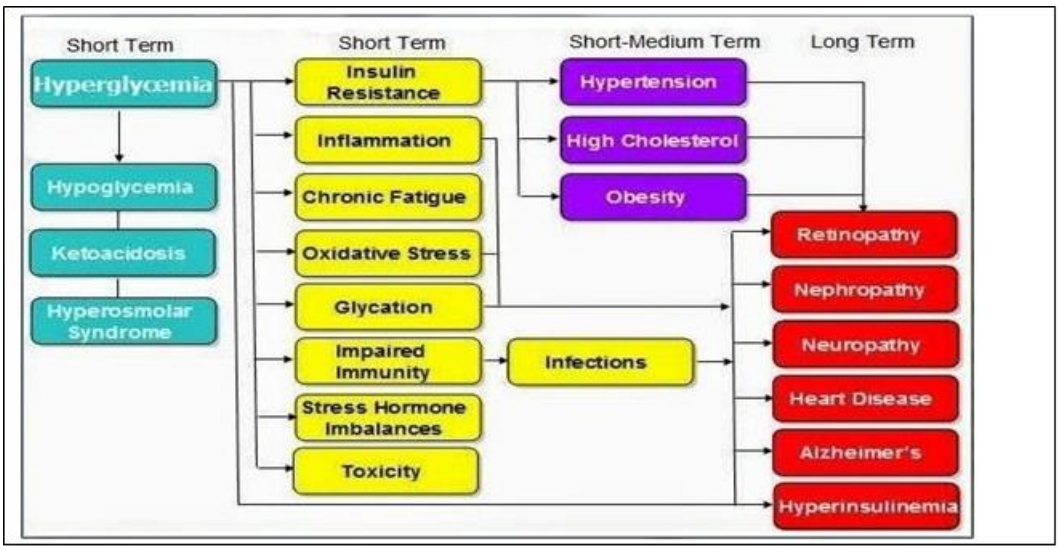

FIGURE 3.

Acute Complications

Hypoglycaemia

Diabetic Ketoacidosis

Non- Ketotic Hyperosmolar diabetic coma

Lactic acidosis

Acute circulatory failure.

Long term complications of Diabetes[11]

Diabetic Retinopathy

Diabetic neuropathy

The diabetic Foot

Diabetic Nephropathy.

THERAPEUTICS APPROACH

Conventional Medicine

Oral hypoglycemic agents Sulphonyl urea Biguanides Alpha – Glucosidase Meglitinides Insulin sensitizer as thizolidinedion	Insulin supplementations Short acting – Human actrapid Intermediate acting – NPH Mixtard Long acting – Insulin zinc suspension

DIET FOR DIABETES MELLITUS

Calories monitoring: Calories in individual food items & injection per day should be monitored.

Judicious selection: Moderation of protein, restriction to fat, proper selection of carbohydrate.

Maintaining ideal body Weight: (Height in centimeter- 100) x 0.9 = IBW.

Weight reduction in Obese: An energy deficit of 500Kcal daily will help to reduce 500gm weight/week.

Optimal calorie Intake: Sedentary work – 20 to 25/ kg ideal body weightModerate – 26 to 30kcal / kg I.B.W.
Strenuous – 31 to 35 kcal/kg I.B.W.

More Age – low calories: 10 % less calories for each above 50 years.

More natural less refined: As apple – low glycemic peak + dietary fibers.
Apple juice has high glucose peak without dietary fibers.

FIGURE 4.

HOMOEOPATHIC VIEW

Homoeopathy is based on natural law of healing ―*Similia Similibus Curantur*‖(let likes be treated by likes). It is a complete system of therapeutic medication madeup of laws, rules, methods and processes, Life force, single remedy, totality of symptoms, infinitesimals minimum dose etc –all are integral to system.[16] Fundamental principle of Homoeopathy is that it treats the patient as a whole and as an individual. There is no medicine for any particular disease, but there is a medicine for the patient suffering from the disease.[17]

Dr. Kent *states in his lesser writing* "To cure any condition we must base the prescription on the totality of the signs and symptoms and not on the pathology".[18]

Dr. H.A. Roberts states similar remedy or the similar disease satisfies susceptibility and establishes immunity.[19]

Disease is in truth a "spiritual, dynamic derangement of our spirit-like vital principle in sensation and function [or] immaterial derangements of our state of health.[20]

Dr. Hahnemann says that "the chronic diseases which spring from miasms cannot be healed unaided, nor can real health be restored by vital force alone". They could not be properly called illness but rather dyscrasia or diathesis states which conditioned the birth of the illness or the syndromes. Miasm is an invisible, inimical, dynamic principle, which permeates into the system of a living creature, creating a groove or stigma in the constitution and which can only be eradicated by a suitable antimiasmatic treatment.[21]

Homoeopathy offers a comprehensive treatment as it goes to of the problem by helping build up immunity. Health implies the complete physical, social and mental well-being. A disease is individual manifests its state of ill-health by subjective, objective and organic symptoms. Homoeopathy believe in giving a singleholistic remedy which will cover person as a whole to achieve this the patient is analyzed on various aspects of mental, physical and familial attributes and also a complete study on the psychological environment of the patient has gone through in his life.[21,22]

Dr. Hahnemann described this theory of miasms in his book „The Chronic disease". The threemiasms (Psora, syphilis and sycosis) given in that work are held to be responsible for all diseases of a chronic nature and to form the foundation or basis for all disease in general. miasm are "Infectious principle".[20]

Concept of totality of symptom through different aphorism of Organon of Medicine

Aphorism 7-The totality of symptom is outwardly reflected picture of the internal essence of the disease, that is of the affection of the vital force it must be the sole means where the disease can be make known what medication it requires the only thing that can find out the selection of the most appropriate remedy.

Aphorism 18- The totality of symptom must be the sole guide to direct in the choice of a remedy.

Aphorism 70-Toatality is nothing but the essence of the medicine to select the similar remedy and facilitate a cure.[23]

Homoeopathic Medicines

SYZYGIUM JAMBOLANUM

Jambol Seeds - Enlexing, active principle.

Has an immediate effect of increasing the blood sugar, glycosuria results.

A most useful remedy in diabetes mellitus. No other remedy causes in so marked degree the diminution and disappearance of sugar in the urine. Prickly heatin upper part of the body; small red pimples itch violently. Great thirsts, weakness, emaciation. Very large amount of urine, specific gravity high. Old ulcers of skin. Diabetic ulceration. The seeds powdered, ten grains three times a day; also the tincture.

Relationship -Compare: Insulin-An aqueous solution of an active principle from pancreas which affects sugar metabolism. If administered at suitable intervalsin diabetes mellitus, the blood sugar is maintained at a normal level and the urine remains free of sugar. Over dosage is followed by weakness and fatigue and tremulousness and profuse sweating.

Miasmatic Classification

Miasmatic classification of symptom of diabetes mellitus: - Classification according to Dr. Hahnemann– Diabetes, which with allopathic remedies is usually so fatal, has probablynever any other origin then this remedy.[24]

Table 2: Miasmatic classification according to Dr. Hahnemann.

S.No.	Symptom	Miasm
1	Pressure on the bladder as if from urging to urination afterdrinking	Psora
2	Sugar in blood (functional disturbance)	Psora
3	excessive thirst in short interval	Psora
4	Sugar in urine (functional disturbance)	Psora
5	Polyuria	Psora
6	Polydipsia	Psora
7	Insatiable hunger then again want appetite	Psora
8	Weight gain	Psora
9	Weight loss	Psora
10	Recurrent UTI	Psora

REPERTORIAL VIEW

KENT: PREFACE[26]

This Repertory was used as a general Repertory of the Homoeopathic Materia Medica. It is a compilation of all the useful symptoms recorded in the fundamental works of our Materia Medica, as well as from the notes of our ablest practitioners. Many unverified symptoms have been omitted.

KENT: CONTENTS[27]

Table 3

Pageno.	CONTENTS	Pageno.	CONTENTS	Pageno.	CONTENTS	Pageno.	CONTENTS
541	Abdomen -	235	Eye	1	Mind	476	Stomach
884	Back	355	Face	397	Mouth	635	Stool
645	Bladder	1278	Fever andHeat	324	Nose	430	Teeth
822	Chest	1341	Generalities	1293	Perspiration	448	Throat
1259	Chill	693	Genitaliamale	667	Prostategland	669	Urethra
778	Cough	714	Genitaliafemale	762	Respiration	645	Urinaryorgans
285	Ear	107	Head	606	Rectum	680	Urine
812	Expectoration	321	Hearing	1303	Skin	96	Vertigo
471	Externalthroat	662	Kidneys	1234	Sleep	271	Vision
952	Extremities	746	Larynx andtrachea	349	Smell	758	Voice

USE OF THE REPERTORY[28]

By J. T. Kent, A.M., M.D.

As homœpathy includes both science and art, Repertory study must consistof science and art.

The scientific method is the mechanical method; taking all the symptomsand writing out all the associated remedies with gradings, making a summary with grades marked, at the end.

There is an artistic method that omits the mechanical, and is better, but allare not prepared to use it. The artistic method demands that judgment be passed on all the symptoms, after the case is most carefully taken. The symptoms must be judged as to their value as characteristics, in relation to the patient; they must be passed in review by the rational mind to determine those which are strange, rare, and peculiar.

Gradation of Remedies[28]

Table 4: Gradation of remedie.

Sr. No	Typography	Grades	Marks
1	BOLD CAPITAL	First	3
2	*Italics*	Second	2
3	Roman	Third	1

Rubric Related to Diabetes Mellitus

Generalaties:- Diabetes Mellitus: abroma-a., adren, aether, all-s allox, aloe, alumn, am-act, anthraco, apoc, arg-met, arist-m, ars *Ars-br*, asc-c, aspar, aur, aur-m-n, *Bor- ac*, bov, calc, calc-p, calc-sil, canth, carb-ac, carb-v,carc, card-m, *Carl* caust, cephd-I, chel, chim, chion, chlol, chlorpr, cod coff coloc, con, cop, cortico, cortiso, cub, cupr,cupr-ar, cur, eup-pur, ferr-i, ferr-m, ferr-p, fl-ac, flor-p, gal-ac, galeg, glyc, *Gymne*, hed, helon, hydrang, hygroph-s, indgf-a, ins, *Inul*, iod, iris, kali-act, kali-br, kali-chl, kali-p, kiss, kreos, *Lac-ac*, lac-d, lach, lyc, lycps-v, mag-act, mag-o, mag-p, mag-s, mang-act, med, meny, merc, merc-d, moni, morph, mosch, murx, nat-ch, nat-lac, nat- m, nat-p, Nat-s, nep, nit-ac, nux-v, Op, orthos-s, oxyg, pancr, peps, perh, ph-ac, *Phase*, phlor, phos, Pilo, plan, plb, podo, rad-br, rad-met, ran-b, rat, *rhus-a*, rhus-t, sacch-I, sal-ac, sanic, sarcol-ac, saroth, sep, *Ser-ang*, sil, spong, *Squil*, stict, stront-c, stry-ar, sul-ac, sulfonam, sulph, syph, Syzyg, tarent, Ter, *Terebe*, term-a, thuj, thyr, *uran-m, Uran-n, Urea*, vanad, vichy-g, vince.[29]

MATERIALS AND METHODS

Study Setting

The present study was undertaken at OPD /IPD of M.N. HomoeopathicMedical College & R.I. Bikaner, Rajasthan.

Study Duration

The study was undertaken for a period of 12 months, pre preparation was done for 2 months, cases were registered in first 3 months and each case was followed up for a period of minimum 3 months (each follow up at 15 days interval) and analysis & observation was done

in last 4 months.

Selection of Sample Size and Sampling Technique

Sample selection was done on the basis of table of standard margin of error andrandom sampling techniquo was used.[13]

100 cases were included in the studyGroup A = 50 Azadirachta Indica 3X

Group B = 50 Individualised Homoeopathic Medicine

Inclusion / Exclusion Criteria

Inclusion Criteria

All patients irrespective of age, sex, occupations and socioeconomic status included in the study.

Patient with fasting plasma glucose more than 126 mg/dl.[23]

Only those patients who testify to the diagnostic criteria of HbA1c for Type2DM were considered for the clinical trial.[30]

Patient who gave consent for the study.

Exclusion Criteria

Patients with any complications due to Diabetes or suffering from associated co-existing systemic disorder were excluded from the trial.

Pregnant and lactating women Immunocompromised Patient.

Study Design

A Randomised Comparative trial.

Intervention Model

Patients were enrolled from O.P.D./ I.P.D. as and when they came, after confirmation of their inclusion criteria as per protocol, till such time that the target is achieved. These 100 individuals were randomly allocated to 2 groups. One group of 50 patients were given individualized homoeopathic medicine repertorise from Kent Repertory and another 50 patients were given Azadirachta Indica 3X follow up ofthe patients conducted periodically as specified in the protocol. Allopathic medicine continued during treatment in both groups.

Group A – Azadirachta Indica 3X

Doses and repetition- Azadirachta Indica

Potency - 3X potency.

Manufacturer- Medicine was obtained from a good manufacturer practice and certified company

Doses and repetition- 1 Pellet BD

Form- Pellet form

Route of administration for group A with add on t/t - Oral

Dispensing- This was done by the college dispensary from a certified pharmacist.

Group B - Individualized homoeopathic medicine

Potency-Selection of potencies were done according to susceptibility and homoeopathic principles.

Doses and repetition- According to patient‟s susceptibility and homoeopathic principles.

Manufacturer- Medicine were obtained from a good manufacturer practice and certified company.

Form- Pellet form

Route of administration- Oral

Dispensing- This was done by the college dispensary.

Selection of Tools

A detailed case taking Proforma, especially designed for study was used.

Patient Consent form with information sheet Biochemical parameter FBS and HbA1C.

Waist-Hip ratio, Kent Repertory through RADAR 10 software for Repertorization.

SPSS Software version 21.

Data Collection

A detailed case taking Proforma, especially designed for study was used.

Recording of Data

Data were recorded in approved Case Report Format.

Centralized data was collected in approved master chart in proper excel format.

Confidentiality

All the evaluation forms, reports and other records were kept in locked file cabinet.

Any information about the patient was not leaked out until required.

Maintenance

There were forms that were completed by for each subject recruited, including two consent form for the patients information and his/her written consent for the enrolment in the study. These were updated from time to time.

Follow Up

Patients enrolled in this study visited every 15 th day for follow up & assessment done. In acute exacerbation state, frequency of visit on alternate day or earlier. Atleast 6 follow ups of patient was finally assessed the case.

Outcome Assessment

According to the before and after scores obtained from the 1. HbA1cFasting blood sugar Anthropometric measurement (waist-hip ratio).

For HbA1c, FBS: -

Base line score – After score X 100.

Baseline score

100 – 75% = Marked Improvement

74 – 50 % = Moderate Improvement

49 – 25 % = Mild Improvement

< 24% = Not Significant

0% = Status Quo

<0% = Worse

HbA1C and FBS was assessed with statistical techniquos.

Statistical Techniques & Data Analysis

Data analysis was done using SPSS and excel

Paired t-test were used to assess the before and after scores in each group.

Before treatment- [mean± SE_m]

After treatment- [mean± SE_m]

Independent test – were used to assess improvement between both groups.

Investigation

Fasting plasma glucose was done fortnightly while HbA1c was done once atthe begning of the trial and then after 3 month at the end.

Ethical Clearance

Ethical clearance was obtained from the Institutional Ethics Committee.

OBSERVATIONS AND RESULTS

The observations were analyzed as

1. Distribution of Cases of Type 2 Diabetes Mellitus According to ―AgeGroup‖.
2. Distribution of Cases of Type 2 Diabetes Mellitus According to ―Gender‖.
3. Distribution of Cases of Type 2 Diabetes Mellitus According to―Occupation‖.
4. Distribution of Cases of Type 2 Diabetes Mellitus According to ―SocioEconomic Status‖.
5. Distribution of Cases of Type 2 Diabetes Mellitus According to ―PresentComplaints‖.
6. Distribution of Cases of Type 2 Diabetes Mellitus According to ―RiskFactor‖.
7. Distribution of Cases of Type 2 Diabetes Mellitus According to ―Habitat‖.
8. Distribution of Cases of Type 2 Diabetes Mellitus According to ―FamilyHistory of T2DM‖.
9. Fasting Blood Sugar‖, ―HbA1c‖ and ―Waist Hip Ratio‖ Levels in Cases of Type 2 Diabetes Mellitus in both A and B Group.
10. Distribution of Cases of Type 2 Diabetes Mellitus According to ―IndicatedMedicine‖ and Azadiracta Indica 3x.

Statistical Tool

Paired Samples Statistics

Table 5: Comparison of Clinical Parameters in Group A.

	Group B	Mean	N	Std. Deviation	Std. ErrorMean
Pair 1	fbs_btBfbs_atB	200.00 169.92	50 50	39.40604 48.14639	5.57286 6.80893
Pair 1	hbac_btb hbac_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 6.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% ConfidenceInterval 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 A showed mean= 169.92±48.14(SD) as after score compared to mean=200.02±39.40(SD) as before score in FBS for patients suffering from type 2 Diabetic mellitus with significance =0.0001, which shows that Azadirachta indica 3X is effective in Reducing the FBS score in patients suffering from type 2 Diabetic mellitus.

Paired t-test calculated for group A 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 2 Diabetic mellitus with significance =0.000, which shows that Azadirachta indica 3X medicine is effective in Reducing the HBA1C score inpatients suffering from type 2 Diabetic mellitus.

Paired t-test calculated for group A 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 2 Diabetic mellitus with significance =0.000, which shows that Azadirachta indica 3X is effective in Reducing the Anthropometric measures score in patients suffering from type 2 Diabetic mellitus.

Paired Samples Statistics

Table 7: Comparison of clinical parameters in group B.

	Group A	Mean	N	Std. Deviation	Std. Error Mean
Pair1	FBS_ Before treatment	199.00	50	34.92222	4.91046
	FBS_ Aftertreatment	166.66	50	41.70235	5.89760
Pair1	HbA1c_ beforetreatment	7.8520	50	.91724	.12972
	HbA1c_ aftertreatment	7.4540	50	.93726	.13255
Pair1	Anthropometric_before	.9588	50	.21859	.03091

	treatment				
	anthropometric_ after treatment	.9082	50	.21480	.03038

DISCUSSION

In this study, entitled "The Role of Lesser Known Homoeopathic Medicine Azadirachta Indica 3X And Individualized Homoeopathic Medicines With Aid Of Kent Repertory As Add On Treatment In Cases Of Type 2 Diabetes Mellitus – Randomised Comparative Trial" I came with this discussion.

Age

Grp A - 50 cases of type 2 diabetes mellitus 14 patients (28%) cases were from age group 30-40 years followed by 29 (58%) cases in the 41-50 years age group, whereas minimum cases were observed in age group above 51-60 years age group 7 (14%) cases.

Grp B - 50 cases of Type 2 diabetes mellitus 19 patients (38%) cases were from age group 30-40 years i.e followed by 21(42%) cases in the 41-50 years age group, whereas minimum cases were observed in age group above 51-60 years i.e only 10 (20%) 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%.[31]

Indian subjects also had a higher prevalence of impaired glucose regulationin the younger age-groups (30–49 years) compared with that for Chinese and Japanese subjects.[32]

Sex / Gender

50 cases of Type 2 Diabetes Mellitus in group – A, 25patients (50%) female and 25 patients (50%) male.

50 cases of Diabetes Mellitus in group B20 patients (50%) were male and 30 patients (50%) were 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.[33] Another study shows that male female ratio was 1.3:1.[34]

OCCUPATION

50 cases of Type 2 Diabetes Mellitus have 6 (12%) were banker,3 (12%) have their business, 2(4%) were clerk, 2(04%) were in bike mechanic, 20 (40%) were housewife, 8 (16%) were shop keeper, and 09(18%) were teacher in group A.

50 cases of Type 2 Diabetes Mellitus have 5 (10%) were banker, 10 (20%) have their business, 1(2%) were clerk, 19 (38%) were housewife, and 03 (06%) were labor in group A.

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%).[35] Another previous study shows 12% in manual workers, 7% in managers, and 6% in office workers.[36]

Socio Economic Status

50 cases of Type 2 Diabetes Mellitus were from lower socioeconomic status group 04 (08%) & middle socioeconomic status group 39 (78%) whereas observed minimum cases upper socioeconomic status group 7 (14%) in group A As shown in figure 13 among 50 cases of diabetes mellitus were from lower socioeconomic status group 5 (10%) & middle socioeconomic status group 38 (76%) whereas observed minimum cases upper socioeconomic status group 7 (14%) in group B.

Where are previous studies shows that prevalence is high in lower socioeconomic status.[37] It is a contradiction in which the prevalence is high in lower socioeconomic group. Another study shows prevalence in middle socioeconomic status.[38]

Present Complaints

50 cases of Type 2 Diabetes Mellitus 8 cases with present complaint of UTI, 4 cases with present complaint of Bodyache, 5 cases with present complaint of Fatiquo, 6 cases with present complaint of Polydipsia, 3 cases with present complaint of Dysuria, 7 cases with present complaint of weight Gain, 3 cases with present complaint of Weight Loss, 9 cases with present complaints of Poor Wound Healing, 5 cases with present complaint of Blurred Vision in group A.

50 cases of Type 2 Diabetes Mellitus 7 cases with present complaint of UTI, 5 cases with presents complaint of Blurred Vision, 2 cases with present complaint of Polyuria, 10 cases with present complaint of Poor Wound Healing, 11 cases with present complaint of Fatiquo,

4 cases with present complaint of Polydipsia, 6 cases with present complaint of Weight Loss in group B.

Risk Factor

50 cases of Type 2 Diabetes Mellitus were13 (26%) cases were Stress, 19 (38%) cases are not specific, 04 (08%) are alcoholic, 04 (08%) were sedentary, 10 (20%) obesity history in group A.

50 cases of Type 2 Diabetes Mellitus were 24 (48%) cases were not specific, 3 (6%) alcoholic, 4 (8%) were sedentary, 6 (12%) obesity, and 13 (26%) stress history in group B.

A previous study shows that high prevalence in obesity and hypertensive people.[39] Another study also shows high prevalence in cases of hypertension and there were no prevalence of smoking and alcohol.[40]

Habitat

50 cases of T2DM 18 cases were from rural area and 32 cases from urban area.

50 cases of T2DM 17 cases were from rural area and 33 cases from urban area 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.[41] Another study showsPrevalence 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 nonsignificant 8% rise in diabetes in the city, while significant increases had occurred in the town (39%) and periurban villages (34%).[42]

Family History

50 cases of T2DM 24 (48%) had positive family history and 26 (52%) had negative family history T2DM in Group A 50 cases of T2DM 25 (50%) had positive family history and 25 (50%) had negative family history T2DM in Group B.

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%).[43] Another study also shows high prevalence of T1DM who have a first-degree relativewith diabetes.[44]

Individualized Homoeopathic Medicines

50 cases of Type 2 diabetes mellitus were treated with homoeopathic medicine selected on basis of totality of symptoms.

The most frequently prescribed homoeopathic medicines were Nux Vomica 6 (12%), Nat. Phos 5 (10%), Insulinum 5 (10%), Cal. Carb 5 (10%), Phosphorus 5 (10%), Suphur 4 (8%), Acid Phos 4 (8%), Syzygium 4 (8%), Iodium 4 (8%), Gymnema 3 (6%), Medohrrhinum 3 (6%), Nat Sulph 2 (4%). Nux Vomica was the medicines most frequontly prescribed.[45] Another study shows Lycopodium, Phosphorous and Silicea are the most frequontly indicated.[46]

Improvement

50 cases of T2DM in group-A on the basis of HbA1c assessment parameter 1 case was Marked, 04 were Moderate, 26 were Mild, 13 were not significant, 02 were Status Quo and 1 cases was Worse.

50 cases of T2DM in group-B on the basis of HbA1c assessment parameter 15 cases were Marked, 03 were Mosderate, 11 were Mild, 13 were not significant, 02 cases status quo and 06 cases were Worse.

Statistical Analysis

Group A(n=50) pre-treatment mean of FBS improved from 200.02(39.40) to 169.92(48.14) post- treatment. While in group B(n=50) pre- treatment mean of FBS improved from 199(34.92) to 166.66(41.70) post-treatment. Group A(n=50) pre-treatment mean of HbA1c improved from7.82(0.91) to 7.51(0.90) post-treatment. While in group B(n=50) pre-treatment mean of HbA1c improved from7.85(0.91) to 7.45(0.93) post-treatment. Group A(n=50) pre-treatment mean of Anthropometric measurement improved from0.88(0.14) to 0.84(0.14) post-treatment. While in group B(n=50) pre- treatment mean of Anthropometric measurement improved from 0.95(0.21) to 0.90(0.21) post-treatment.

CONCLUSION

From the study "The role of lesser known Homoeopathic Medicine Azadirachta indica 3X and Individualized Homoeopathic Medicines with aid of Kent Repertory as add on treatment in cases of type 2 Diabetes Mellitus – ARandomised Comparative trial." it is evident that

1. Homoeopathic medicines repertorized with aid of Kent Repertory and Azadirachta Indica

have significant beneficial effect in managing the casesof T2DM, when given as add on treatment with conventional medicines.

2. Homoeopathic medicines selected on the basis of individualization reduce the FBS, anthropometric measurements as well as HbA1c, more effectively as compared to Azadirachta Indica. Thus, this study helps in improving clinical practice of homoeopathic physicians.
3. The most commonly used medicines were Nux Vomica 6 (12%), Nat. Phos 5 (10%), Insulinum 5 (10%), Cal. Carb 5 (10%), Phosphorus 5 (10%), Suphur4 (8%), Acid Phos 4 (8%), Syzygium 4 (8%), Iodum 4 (8%), Gymnema 3 (6%), Medorrhinum 3 (6%), Nat Sulph 2 (4%).

Limitation of Study

Large sample size can be use for better statistical analysis. Blinding and a longer study duration can be planned for such studies. Abetter statistic can be applied for generalization of the results.

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