A Comparison of the Efficacy of Gymnema Sylvestre 6 CH and Gymnema Sylvestre Mother Tincture in Cases of Type 2 Diabetes Mellitus

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ABSTRACT
Diabetes Mellitus is a metabolic disorder characterized by hyperglycemia resulting from inadequate insulin secretion, insulin action or both and insulin resistance. Gymnema sylvestre have reported beneficial effect for treating in type 2 diabetes mellitus.

Objective: A comparison of the efficacy of homoeopathic medicine gymnema sylvestre 6 CH and gymnema sylvestre mother tincture in the treatment of type 2 diabetes mellitus cases.

Material and method: 30 cases of type 2 diabetes mellitus were selected and gymnema sylvestre mother tincture and 6 CH were prescribed for these cases and follow up was every one month, three months and six months.

Results: Over a period of 6 months, there was significant reduction in blood sugar levels (fasting and post prandial blood sugar) in both groups. ANOVA repeated measures also showed significant difference P = 0.001.

Conclusion: There is significant reduction in fasting blood sugar, post prandial blood sugar levels both groups (gymnema sylvestre 6 CH and gymnema sylvestre homoeopathic mother tincture) in type 2 diabetes mellitus cases. The results suggested that gymnema sylvestre 6 CH and gymnema sylvestre mother tincture has beneficial anti diabetic effective and warrants future investigation.

INTRODUCTION
Gymnema Sylvestre is accessible all through the India. This plant homeopathic tincture is produced using the leaves. It is utilized treated in diabetes, toxic snake nibles and wound recuperating.

Diabetes mellitus is a metabolic disorder and increase glucose levels/hyperglycemia because of the either a ↓ of insulin secretion or to a combination of insulin resistance and inadequate insulin secretion to redress. Type 2 diabetes mellitus group comprising milder type of diabetes that happen predominantly in adults but occasionally in juveniles/childrens. More than 75% of Indian individuals are under this order. India is second higher individuals enduring with this disease in the worldwide. In United Kingdom, Sri Lanka, Bangladesh, United States of America, Australia and golf nations have been found to lot higher prevalence of diabetes than the local populations of the particular nations. Untimely coronary heart disease is because to excessive fat in intra abdominal area/region and insulin resistance/opposition.

Tissue lack of care of insulin has been noted in most type 2 diabetes mellitus patients irrespective of weight and has been credited to few interrelated variables. These include a putative hereditary factor, which is exacerbated in time by additional enhancers of insulin resistance, for example, a sedentary life style/ inactive way of life style and central visceral obesity and lack in the response of pancreatic B cells to glucose.

Hyperglycemia because of resistance to insulin and impaired B cell reaction to glucose appear.

Epidemiologic information strong genetic impact, since in monozygotic twins more than 40 years of old, concordance creates in over 70% of cases inside a year whenever one twin creates type 2 diabetes mellitus. 60 ~ 70% central obesity patients of North Americans, Europeans or Africans are suffering with type 2 diabetes, 30% cases are from Chinese and Japan patients’ suffering with type 2 diabetes mellitus. 7 research studies had been published detailing the predominance of the diabetes by the end of the 1960s 6-11, Transient Asian Indian more prone to get type 2 diabetes mellitus and metabolic disorder in different parts of the world wide such as Fiji, United Kingdom and mauritius. This Indian individuals have more fasting insulin levels compared to the white individuals. 21,22, Diabetes increased due to junk/low quality food and excessive eats of sweets in Indian young students 22-25.

CLINICAL FEATURES
Type 2 diabetes mellitus clinical features are Polyuria, thirst, weakness or fatigue, polyphagia with weight loss, recurrent blurred vision, vulvovaginitis or pruritus, peripheral neuropathy, nocturnal enuresis. Mild hypertension is often present in obese diabetics. Eruptive xanthomas on the flexor surface of the limbs and on the buttocks and lipemia retinalis due to hypechyomicronemia can occur in patients with
uncontrolled type 2 diabetes mellitus who have a familial form of hypertriglyceridemia.

INVESTIGATIONS
Glucosuria, Ketonuria, blood testes (glucosetolerance test, glycosolated hemoglobin, fasting and post prandial) and lipoprotein abnormalities in diabetes.

COMPLICATIONS OF DIABETES
In micro vascular complications are diabetic cataracts, diabetic retinopathy,26,27, glaucoma, diabetic neuropathy include micro albuminuria, progressive diabetic nephropathy28-30(Indian people have less rates compared to the white individuals31), gangrene of the feet, diabetic neuropathy include with peripheral neuropathy (distal symmetric poly neuropathy, isolated peripheral neuropathy, painful diabetic neuropathy), autonomic neuropathy (management of autonomic neuropathy, management of erectile dysfunction), skin and mucous membrane complications. In macro vascular complications are coronary artery disease32 and peripheral vascular disease. The coronary artery disease also higher in Indian people compared to the western countries33. Peripheral vascular disease is rare in Indian patients compared to USA and UK.34,35. More than 25% of Indian peoples suffer with diabetic foot ulcer during their life time36 and 8% of Tuberculosis.37 The Research trials showed that type 2 diabetes mellitus can be prevented in peoples at high risk of developing the disease using lifestyle modification, drugs or a combination of the two.38-41.

Gymnema Sylvestre is excellent medicine for diabetes mellitus also efficacious in poisonous snake bites, urinary profuse loaded with sugar. After passage of wine patient examines, this passing of urine in large quantity has made me very weak. Urine colour is white copious and specific gravity,42 Gymnema sylvestre is used for albumin urea, sleeplessness, debility and diabetes insipidus. Absent mind, depression, morose, anxious, unable to moody, face is pale, itching eruption on the face with burning sensation, furuncles of the face, hungry feeling of the stomach with drinks large quantities of cold water at a time yet dryness persists, dry, great thirst and clean tongue, weakness of sexual power. It is also efficacious in poisonous snake bites 43. Traditional plants oral therapy World Health organization has recommended that effective work on diabetes mellitus without side effects.44 Several reviews showed that medical plants had anti diabetic activities.45,46.

MATERIAL AND METHODS
Period of study
The study was conducted on the cases available from January 2019 to June 2019.

Sample size
The sample consisted of 30 cases of type 2 diabetes mellitus visited to department of practice of medicine Out Patient Department (O.P.D) and peripheral centers of Bharatesh Homoeopathic Medical College, Hospital and Research center, Belagavi, Karnataka, India during the specified period.

Type of Study
This was comparison study of Gymnema sylvestre 6 CH and mother tincture in type 2 diabetes mellitus patients with three months and six months follow up and comparison before, after with gymnema sylvestre homoeopathic 6 CH and mother tincture.

Inclusion Criteria
- Both sexes and aged between 30 to 65 years.
- Cases of type 2 diabetes mellitus complaints.
- Blood glucose levels less than 9 mmol/L in fasting blood sugar, less than 11 mmol/L in post prandial blood sugar.
- Cases of type 2 diabetes mellitus where gymnema sylvestre is indicated and prescribed the same in mother tincture.

Exclusion criteria
- Patients who were on homoeopathic medicines other than gymnema sylvestre.
- Taking medicines for diabetes mellitus complications.
- Allergic to herbal medicines.
- Chronic complications of type 2 diabetes mellitus.
- Pregnancy.

METHOD
30 patients (gymnema sylvestre 6 CH group 15 patients and gymnema sylvestre mother tincture group 15 patients) were enrolled by simple non random method. Diagnoses of the cases were made based on relevant clinical history and laboratory values obtained during the first visit according to current medical diagnosis and treatment guidelines.47. Thirty potency of gymmena sylvestre 6 CH and mother tincture were prescribed for the above cases and was followed for a period of three months and six months. Each selected case was recorded on the standardized case record with a special attachment evolved particularly for this study. Diet and exercise were given instruction clearly for minimum 30 days to selected patients. Approximately 60% carbohydrates, 20% proteins and 20% fats were allowed during study period.

REMEDY USED
6 CH Mother tincture of homoeopathic remedy Gymnema sylvestre brought from homoeopathy pharmacy, Belagavi, Karnataka, India. Gymnema sylvestre 6 CH and mother tincture (30 drops in a quarter glass of water 30 minutes after a meal) was given twice daily for a period of study. Follow up was watched and analyzed as per criteria set up in each case according to standard guideline of homoeopathy using the symptomatology of the patient.
FOLLOW UP AND SYMPTOMATIC ASSESSMENT

Each follow up was taken on special follow up sheet of examination findings e.g. blood pressure, weight, investigations, diet and exercise. Each case was evaluated by the homoeopathic physician, dietician, general physician and pathologist. Baseline investigations done in each case were fasting and post prandial blood sugar, glycosylated haemoglobin, urine examination, serum creatinine, lipid profile, electrocardiogram, ultra sound abdomen and ophthalmic check up. Each follow up was one month, three months, six months, nine months and assessed according to the guidelines given in standardized case record follow up sheet. A diabetes complaint was graded according to the intensity, aggravation, presence and absence. Blood glucose values of each patient were estimated again, minimum twice, which after one month, three months, six months and nine months.

STATISTICAL ANALYSIS

The collected data was analyzed by mean, standard deviation, P value and ANOVA

Research hypothesis

There is a significant decrease in blood sugar levels in type 2 diabetes mellitus before and after homoeopathic treatment with gymnema sylvestre 6 CH and mother tincture.

Null Hypothesis

There is no significant decrease in blood sugar levels in type 2 diabetes mellitus before and after homoeopathic treatment with gymnema sylvestre 6 CH and mother tincture.

RESULTS

Among 30 type 2 diabetes mellitus patients with mean ± SD, maximum cases were observed in age group of 30-40 years in 10 (33.33%) cases, 40-50 years in 11 (36.66%) cases, 50-60 years of age group had 05 (16.66%) cases, 60 – 65 years in 4 (13.33%) (Table 1 - A) and patients were in the male 15(50.00%) and 15 (50.00%) patients were females out of 30 cases. In verification research Gymnema sylvestre 6 CH and mother tincture was prescribed to the patients according to the intensity, aggravation, presence and absence. Blood glucose values of each patient were estimated again, minimum twice, which after one month, three months, six months and nine months.

The study of 30 patients showed a ration of male to female subjects was 15 and 15 (Table 1 - B). Baseline data for Gymnema sylvestre 6 CH group and Gymnema sylvestre mother tincture groups were analyzed on a subject wise basis which has been shown in Mean ± Standard deviation (SD) baseline Gymnema sylvestre 6 CH group, Fasting Blood Sugar was 8.46± 0.28, Gymnema sylvestre 6 mother tincture group base line was 8.38± 0.30. P value showed that 0.70577. After 3 months in the Gymnema sylvestre 6 CH group base line was 7.2± 0.31 and Gymnema sylvestre mother tincture group base line was 7.37± 0.33, P value showed after three months duration of the study was 0.0001.After six month duration in the Gymnema sylvestre 6 CH group base line was 6.38± 0.32 and Gymnema sylvestre mother tincture group was 6.58 ± 0.21. P value showed after six months was 0.0001 (Table 2). 30 diagnosed cases of diabetes were studied for a period of baseline, 3 months and 6 months, fasting blood sugar and post prandial blood sugar levels were checked in every 3 month and 6 months (before, during and after the treatment) in mmol/L.

The following observation was made in Mean ± SD baseline Gymnema sylvestre 6 CH group, post prandial blood sugar was10.5± 0.26 Gymnema sylvestre mother tincture group base line was 10.4± 0.31, P value showed that 0.7. After 3 months in the Gymnema sylvestre 6 CH group base line was 9.34± 0.50 and Gymnema sylvestre mother tincture group base line was 9.52 ± 0.37, P value showed after three months duration the study 0.0001. After six months duration in the Gymnema sylvestre 6 CH group base line was 8.4 ± 0.30 and Gymnema sylvestre mother tincture group was 8.45 ± 0.32, P value showed after six months was 0.0001 (Table 2). Repeated measures ANOVA was performed comparing data obtained at baseline, at three months and six months, which also revealed significant difference between the two groups, Gymnema sylvestre 6 CH group in fasting blood sugar was F= 151.646 and Gymnema sylvestre mother tincture group fasting blood sugar F= 15.056; fasting blood sugar of Gymnema sylvestre 6 CH and Gymnema sylvestre mother tincture P value was 0.0001 and Gymnema sylvestre 6 CH group of post prandial blood sugar was F value 131.192 and Gymnema sylvestre mother tincture P value showed after three months duration the study 0.0001.

Tab 1: Baseline Characteristics

| Gender | No. of Cases | Percentage (%) |
|--------|--------------|----------------|
| 30-40  | 10           | 33.33          |
| 40-50  | 11           | 36.66          |
| 50-60  | 5            | 16.66          |
| 60-65  | 4            | 13.33          |
| Total  | 30           | 100            |
(B) Distributions of cases according to gender Levels

| Age Group | No. of Cases | Percentage (%) |
|-----------|--------------|----------------|
| Male      | 15           | 50             |
| Female    | 15           | 50             |
| Total     | 30           | 100            |

(C) Distributions of cases according to Blood Glucose

| Blood Glucose | No. of Cases | Percentage (%) |
|---------------|--------------|----------------|
| FBS           | 15           | 50.00          |
| PPBS          | 15           | 50.00          |
| Total         | 30           | 100            |

F.B.S: Fasting Blood Sugar; PPBS: Post Prandial Blood Sugar

Tab 2: Blood Sugar (mmol/L) changes in the two groups over different points in time

| Groups                                | Baseline       | 3 Months       | 6 Months       | F value\(^v\) | P value\(^v\) |
|---------------------------------------|----------------|----------------|----------------|--------------|--------------|
| Fasting blood sugar                   |                |                |                |              |              |
| Gymnema sylvestre 6 CH (n=15)         | 8.46 ± 0.28    | 7.2 ± 0.31     | 6.38 ± 0.32    | 151.646      | <0.00001     |
| Gymnema Sylvestre mother tincture (n=15) | 8.38 ± 0.30    | 7.37 ± 0.33    | 6.58 ± 0.21    | 185.056      | <0.00001     |
| P Value                               | 0.70577        | 0.0001         | 0.0001         |              |              |
| Post prandial Blood Sugar             |                |                |                |              |              |
| Gymnema sylvestre 6 CH (n=15)         | 10.58 ± 0.26   | 9.3 ± 0.50     | 8.4 ± 0.30     | 131.192      | <0.00001     |
| Gymnema Sylvestre mother tincture (n=15) | 10.40 ± 0.31   | 9.52 ± 0.37    | 8.45 ± 0.32    | 149.307      | <0.00001     |
| P Value                               | 0.07           | 0.0001         | 0.0001         |              |              |

\(^v\)Repeated measures ANOVA was carried out with time as factor versus group for showing difference between the groups, and independent t test was carried out for showing the difference between the groups at each time point, i.e. at 3 months and 6 months.

DISCUSSION

Out of 30 type 2 diabetes mellitus patients with mean ± SD, maximum cases were observed in age group of 30-40 years in 10 (33.33%) cases, 40-50 years in 11 (36.66%) cases, 50-60 years of age group had 05 (16.66%) cases, 60 – 65 years in 4 (13.33%) (Table 1 – A) and patients were in the male 15(50.00%) and 15 (50.00%) patients were females out of 30 cases. In comparison research Gymnema sylvestre 6 CH and gymnema sylvestre mother tincture was prescribed to the patients according to the totality of symptoms and similarity. The observations were made Gymnema sylvestre mother tincture and gymnema sylvestre 6 CH is the most effective medicine for the comparison study. It was observed that there was a significant reduction in Fasting Blood Sugar (FBS) and Post Prandial Blood Sugar (PPBS) values in base line, three months, six months of Gymnema sylvestre 6 CH and gymnema sylvestre mother tincture. Up to now gymnema sylvestre 6 CH and gymnema sylvestre mother tincture has not been compared in maintenance patients with type 2 diabetes mellitus. In this comparison study we examined a dentifrice form containing Gymnema sylvestre 6 CH and gymnema sylvestre mother tincture homoeopathy drug to evaluate its effects on type 2 diabetes mellitus. The results of this comparison study suggest that the
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The study demonstrates a significant reduction in the mean of Fasting Blood Sugar (FBS) and Post Prandial Blood Sugar (PPBS) of gymnema sylvestre 6 CH and gymnema sylvestre mother tincture.

The diabetes mellitus cause serious complications to human body. It leads to acute complications (micorvascular) as well as chronic complications (macrovascular). Therefore, it is suggested that more studies must be designed to find out the exact antidiabetic effects of Gymnema sylvestre on type 2 diabetes mellitus. The research concluded positive outcome in controlling in diabetes mellitus (type two) with allopathic drugs (antidiabetic). But Homoeopathic medicine Gymnema sylvestre 6 CH and gymnema sylvestre mother tincture was not prescribed in none of the comparison studies.

CONCLUSION

The research showed that significant reduction in blood glucose levels with gymnema sylvestre 6 CH and gymnema sylvestre mother tincture. Gymnema sylvestre plays an important role in the treatment of type 2 diabetes mellitus. There was no side effective during the treatment and it can be concluded that homoeopathic Gymnema sylvestre 6 CH and gymnema sylvestre mother tincture can be help the diabetic (type 2) patients to take a new lease on life. During the comparison study it was observed that in almost all the cases the homoeopathic medicine gymnema sylvestre 6 CH and gymnema sylvestre mother tincture responded well. There is a significant reduction in fasting blood sugar, post prandial blood sugar levels in both groups (gymnema sylvestre 6 CH and gymnema sylvestre mother tincture). Thus, we can conclude that gymnema sylvestre mother tincture and gymnema sylvestre 6 CH used with holistic approach is very effective in treating the cases of type 2 diabetes mellitus.

LIMITATIONS

Duration was six months only.

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CONFLICT OF INTEREST

None declared.

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