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Observational Case Study

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# Systematic Cross Sectional observational Study on Impact of add on therapy for patients with Type II diabetes mellitus (Madhumegam)

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## ABSTRACT

Type II diabetes mellitus (T2DM) commonly known by its name madhumegam in siddha terminology accounts for around 90% of all cases of diabetes. In T2DM, the response to insulin is diminished, and this is defined as insulin resistance. During this state, insulin is ineffective and is initially countered by an increase in insulin production to maintain glucose homeostasis, but over time, insulin production decreases resulting in T2DM. It is most commonly seen in persons older than 45 years. T2DM accounts for around 90% of all cases of diabetes. In T2DM, the response to insulin is diminished, and this is defined as insulin resistance. During this state, insulin is ineffective and is initially countered by an increase in insulin production to maintain glucose homeostasis, but over time, insulin production decreases resulting in T2DM. T2DM is most commonly seen in persons older than 45 years. Understanding the pathology and occurrence of the disease ensure the proper management through valid therapeutic ailments. The main aim of the present investigation is to carry out the systematic observational analysis on the usage of add on therapy for patients with T2DM and belief on siddha therapy among the study population in the outpatient department of Arignar Anna Government Hospital of Indian medicine, Chennai, Tamil Nadu, India. Results of the present study reveals evidence based data's with respect to etiology, treatment, impact of diet, exercise on adjoining both siddha and allopathic system of medicines. It was observed from the results of the study that weakness, polyuria and parasthesia are more prevailing among other complications. Further 33% of cases who undergone both siddha and other treatments has shown good control on type II diabetes and its complication's. It was observed that there was marked decrease in secondary complication associated with type II diabetes in patients undergoing both siddha and allopathic system of medicines. In conclusion preference of patients towards siddha system has been steadily increasing. Combinatorial approach on treating T2DM offers greater results and better control on clinical symptoms and secondary complications associated with T2DM.

**KEY WORDS:** ***Type II diabetes mellitus, Madhumegam , Complications., Combinatorial approach, Etiology, Treatment, Siddha, Allopathy***

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## 1. Introduction

Prevalence of diabetes type II diabetes was increasing across the world. Studies showed that more than 220 million suffer from diabetes worldwide [1]. The WHO report in the year 2000, put the estimates at 171 million. Which is expected to rise to 366 million in 2030 [2,3].Diabetes mellitus is a chronic disorder of glucose metabolism resulting from dysfunction of pancreatic beta cells and insulin resistance. It is still a serious global health problem. The disease prevails in both genders and all age groups, so there is concern among the general public about its control and treatment. The therapeutic goal of diabetes control is reaching the normal level of blood glucose without hypoglycemia and without causing any disturbance in the daily life activities of patients.

Diabetes mellitus is characterized by symptoms such as hyperglycemia, polyuria, polydipsia, weight loss, delayed healing of the ulcers, blurred vision, increased glucose in the urine and some other symptoms [4]. The importance of this disease is due to the prevalence of its complications. Diabetes can damage the heart, arteries, eyes, kidneys and nerves, leading to death and early disability [5,6]. Diabetes complications include skin lesions, hypertension and weight gain , also vascular complications of diabetes include neuropathy, nephropathy and retinopathy and macro-vascular diseases, which are among the leading causes of death in diabetic patients. Blood glucose as well as high blood pressure and high blood fat contribute to the risk of cardiovascular diseases [7].

According to American Diabetes Association, the total costs associated with diagnosed diabetes have risen to $245 billion in 2012 from $174 billion in 2007, representing a 41% increase over a 5 years period. The World Health Organization (WHO) is urging health decision makers to develop effective management strategies to halt the rising trend of DM through trouble-free and cost effective treatment modalities. Recent studies also prove that poor diabetic victims are more prone to complications as they have lesser access to quality health care [8]. Health promotion, disease prevention and chronic disease management are proactive approaches to health care that stresses prevention at different points along the health care continuum. Health promotion and disease prevention strategies focus on keeping people well and preventing diseases from occurring. These strategies are referred to as primary prevention activities [9].Siddha system of traditional medicines have enormous formulations either alone or in combination's with versatile herbs tend to control the diabetes complication since several centuries. Adjoining therapy of siddha system with conventional allopathic therapy possess significantly higher level of impact in treating T2DM. The main aim of the present investigation is to carry out the systematic observational analysis on the usage of add on therapy for patients with complications of T2DM and belief on siddha therapy among the study population in the outpatient department of Arignar Anna Government Hospital of Indian medicine, Chennai, Tamil Nadu, India.

## 2. Materials and Methods

### 2.1. Study design

Cross sectional observation study comprises of 100 volunteers subjected to survey on Type II diabetes (Madhumegam) was chosen for the individualized in-depth evaluation. The entire study was conducted on Out-patient department of Arignar Anna Government Hospital of Indian medicine, Chennai, Tamil Nadu, India. Institutional ethical committee clearance was obtained for this study [IEC approved no: GSMC-CH-ME-5/031/2018]. Participants were also explained that completion and submission of the questionnaire would be taken as consent to participate in this study. Data were dealt with the high level of anonymity and confidentiality.

### 2.2. Questioner Pattern

The questionnaire was divided into two sections. The first section included demographic information such as gender, age and duration of illness. The second section included with questions on mode of diagnosis, preference on treatment, betterment of therapy etc.

## 3. Results

### 3.1.Gender, Age and Duration of Disease Impact on study population

In the present observational study about 40% of the populations are male and remaining 60 % belongs to female gender. In which majority of the cases of nearly 60% of them belongs to age 51-70 yrs. The minimum age identified as 33 years and maximum

was about 78 years at the time of consent. The sustainable duration of illness on the selected population were majorly relies on 0-5 years in 49 % of the cases and 6-10 years in 24 % of cases, remaining 27% of them between 11 to 25 years.

**Table 1: Gender Distribution**

| Sex | Frequency | Percent |
|---|---|---|
| Male | 40 | 40.0 |
| Female | 60 | 60.0 |
| *Total* | 100 | 100.0 |

**Table 2: Age Categorization of the study population**

| Age | Frequency | Percent |
|---|---|---|
| 31-40 | 11 | 11.0 |
| 41-50 | 22 | 22.0 |
| 51-60 | 30 | 30.0 |
| 61-70 | 30 | 30.0 |
| 71-80 | 7 | 7.0 |
| Total | 100 | 100.0 |

**Table 3: Duration of Illness**

| Duration of Illness | Frequency | Percent |
|---|---|---|
| 0-5 Years | 49 | 49.0 |
| 6-10 Years | 24 | 24.0 |
| 11-15 Years | 15 | 15.0 |
| 16-20 Years | 10 | 10.0 |
| 21-25 Years | 2 | 2.0 |
| Total | 100 | 100.0 |

### 3.2. Mode of Diagnosis

It was observed that about 56 % of the cases were identified with routine clinical investigation and for 15 % of them has familial history and 29 % of them belong to other ailment category.

**Table 4: Mode of Diagnosis**

| **Diagnosed by** | **Frequency** |
|---|---|
| Other ailments | 29 |
| Routine investigation | 56 |
| Family history | 15 |
| Total | 100 |

### 3.3. Preference towards siddha and other method of treatment

Result analysis of the present investigation has clearly reflects that about 14% of the population identified through routine clinical investigation would prefer to undergo siddha method of treatment where as 42% would prefer both.

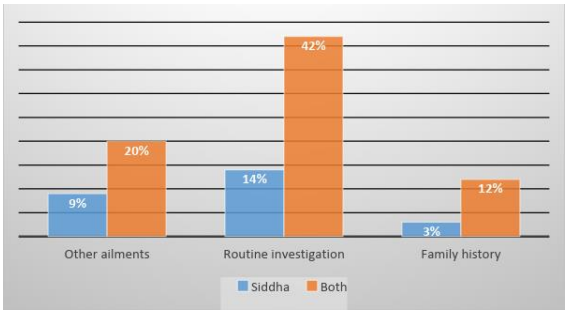


**Figure 1: Preference towards siddha and other method of treatment**

### 3.4. Distribution of Clinical Complications associated with Type II diabetes

Versatile distribution of clinical complication prevails in most of the cases and their distribution analysis was presented in figure 2. Out of all complications weakness, polyuria and parasthesia feet holds higher level of percentage.

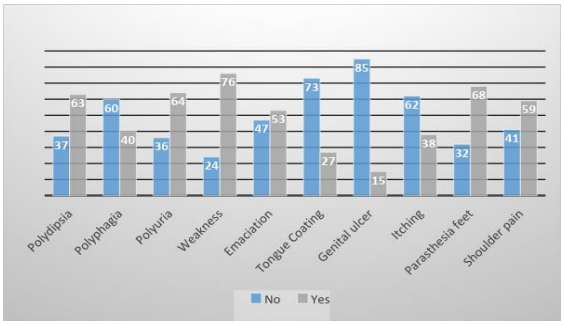


**Figure 2: Distribution of Clinical Complications associated with Type II diabetes**

### 3.5. Control of clinical complications with siddha and other method of treatment

It was observed that 12 % of the cases shown good control and 4 % of them has moderate control after preferred to siddha system of medicines. 33% who undergone both siddha and other treatments has shown good control on type II diabetes and its complication's.

**Table 5: Control of clinical complications with siddha and other method of treatment**

| Treatment | Good | Moderate | Bad | Total |
|---|---|---|---|---|
| Siddha | 12 | 4 | 10 | 26 |
| Both | 33 | 13 | 28 | 74 |
| Total | 45 | 17 | 38 | 100 |

### 3.6. Population preferences towards siddha and allopathy and their control on type II diabetes

Results analysis of the present study have clearly justified that 24 % of the cases reveals high preference to siddha and 37 % of them prefer both. In which 21% of the population on siddha treatment had feel better line of control.

**Table 6: Population preferences towards siddha and allopathy**

| Treatment * which system is best | Siddha | Both | Total |
|---|---|---|---|
| Siddha | 24 | 2 | 26 |
| Both | 37 | 37 | 74 |
| Total | 61 | 39 | 100 |

**Table 7: Treatment line of control between siddha and allopathic system of medicines**

| Treatment* Control level | Siddha | Allopathy | Both | Total |
|---|---|---|---|---|
| Siddha | 21 | 2 | 3 | 26 |
| Both | 33 | 15 | 26 | 74 |
| Total | 54 | 17 | 29 | 100 |

### 3.7. Diet, Exercise and its relevance in treating Type II diabetes

It was been keenly observed that siddha system of medicine have insist more on the importance of diet in treating diabetic complications. On which high preference were been provided towards walking and yoga.

**Table 8: Diet and its relevance in treating Type II diabetes**

| Treatment * which system advices Diet | Siddha | Allopathy | Both | Total |
|---|---|---|---|---|
| Siddha | 19 | 0 | 7 | 26 |
| Both | 32 | 3 | 39 | 74 |
| Total | 51 | 3 | 46 | 100 |

**Table 9: Exercise and its relevance in treating Type II diabetes**

| Treatment * what kind of exercise | Walking | Walking% | Yoga | Yoga% | Gym Workout | Gym Workout % | Total | Total% |
|---|---|---|---|---|---|---|---|---|
| Siddha | 16 | 23% | 2 | 3% | 0 | 0% | 18 | 26% |
| Both | 44 | 63% | 7 | 10% | 1 | 1% | 52 | 74% |
| Total | 60 | 86% | 9 | 13% | 1 | 1% | 70 | 100% |

### 3.8. Distribution of secondary Complications associated with Type II diabetes

It was observed that there was marked decrease in secondary complication associated with type II diabetes in patients undergoing both siddha and allopathic system of medicines.

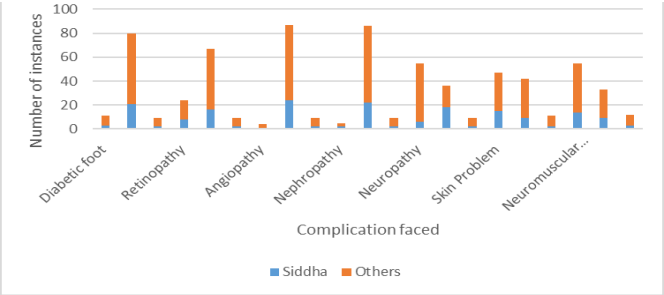


**Figure 3: Distribution of Secondary Complications associated with Type II diabetes**

## 4. Discussion

Diabetes mellitus is a complex metabolic disorder resulting from either insulin insufficiency or insulin dysfunction. Type I diabetes (insulin dependent) is caused due to insulin insufficiency because of lack of functional beta cells. Patients suffering from this are therefore totally dependent on exogenous source of insulin while patients suffering from Type II diabetes (insulin independent) are unable to respond to insulin and can be treated with dietary changes, exercise and medication.

There is increasing evidence that sex and gender differences are important in epidemiology, pathophysiology, treatment, and outcomes in many diseases, but they appear to be particularly relevant for non-communicable diseases. Many organizations now call for the inclusion of the sex and gender dimension in biomedical research, to improve the scientific quality and societal relevance of the produced knowledge, technology, and/or innovation [10]. Genetic background, lifestyle, and environment contribute to the pandemic increase of T2DM and its associated complications presenting a challenge for healthcare systems [11]. In the present observational study about 40% of the populations are male and remaining 60 % belongs to female gender. In which majority of the cases of nearly 60% of them belongs to age 51-70 yrs. The minimum age identified as 33 years and maximum was about 78 years at the time of consent. The sustainable duration of illness on the selected population were majorly relies on 0-5 years in 49 % of the cases and 6-10 years in 24 % of cases, remaining 27% of them between 11 to 25 years.

Dietary intake and physical exercise are the two main determinants of the energy balance[12], and they are considered as a basic base in the treatment of patients with diabetes. Adequate rest is

also very important for maintaining energy levels and well-being, and all patients should be advised to sleep approximately 7 h per night [13]. Evidence supports an association of 6 to 9 h of sleep per night with a reduction in cardiometabolic risk factors [14], whereas sleep deprivation aggravates insulin resistance, hypertension, hyperglycaemia, and dyslipidaemia [15]. On the other hand, a screening of patients with suspected obstructive sleep apnoea should be performed, and refer them to a sleep specialist for evaluation and treatment.

The chronic complications of diabetes are broadly divided into microvascular and macrovascular, with the former having much higher prevalence than the latter. Microvascular complications include neuropathy, nephropathy, and retinopathy, while macrovascular complications consist of cardiovascular disease, stroke, and peripheral artery disease (PAD). Diabetic foot syndrome has been defined as the presence of foot ulcer associated with neuropathy, PAD, and infection, and it is a major cause of lower limb amputation [16]. Finally, there are other complications of diabetes that cannot be included in the two aforementioned categories such as dental disease, reduced resistance to infections, and birth complications among women with gestational diabetes [17]. In the present study versatile distribution of clinical complication prevails in most of the cases and their distribution analysis was presented . Out of all complications weakness, polyuria and parasthesia feet holds higher level of percentage.

Extensive evidence from observational studies indicate that patients with diabetes have higher rates of hospital complications, longer hospital stay, higher health care resource utilization, and greater hospital mortality than non-diabetic subjects [18-20]. The higher morbidity and mortality in diabetic patients relates in part to the heightened incidence of comorbid conditions including coronary heart disease, heart failure, hypertension, and renal insufficiency [21], as well as the adverse effects of hyperglycemia in clinical outcome [22-26].

Type 2 diabetes mellitus is a chronic metabolic disorder in which prevalence has been increasing steadily all over the world. As a result of this trend, it is fast becoming an epidemic in some countries of the world with the number of people affected expected to double in the next decade due to increase in ageing population, thereby adding to the already existing burden for healthcare providers, especially in poorly developed countries [27]. It was been keenly observed from the present analysis that siddha system of medicine have insist more on the importance of diet in treating diabetic complications. On which high preference were been provided towards walking and yoga. It was further observed that there was marked decrease in secondary complication associated with type II diabetes in patients undergoing both siddha and allopathic system of medicines.

## 5. Conclusion

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia. In general, drug therapy includes not only initial hypoglycaemic agents, but other intensification strategies to maintain glycaemic control over time, often requiring several drugs with different mechanisms of action. Physicians should be familiar with the different types of existing drugs for the treatment of diabetes and select the most effective, safe and better tolerated by patients. From the present observational study it was concluded that adjoining siddha with allopathic system of medicine has higher level of impact in alleviating the complication and provided better line of control in treating T2DM. This study provides evidence based data's which would improvise the advanced strategy of combining the uniqueness of siddha system of medicine in clinical management of T2DM.

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