# Identification of Therapy Pattern and Compliance of Life Style Modifications in Diabetic Patients from Rural Areas of Puducherry

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#### ABSTRACT

**Background:** Diabetes mellitus is one of the leading causes of mortality and morbidity throughout the world. Despite India being the diabetes capital of the world with a high prevalence even in rural regions, pharmacotherapy of diabetes is not uniform throughout the country. With this background, we aimed to identify patterns in pharmacotherapy and willingness and preferred choices of lifestyle modifications in diabetic patients hailing from rural areas of Puducherry.

**Methods:** A facility-based cross-sectional survey was conducted with a validated questionnaire among 200 diabetic patients in rural areas of the union territory of Puducherry. Eligible patients fulfilling the inclusion criteria were enrolled in the study and were subjected to the validated questionnaire. Data were entered into M.S. Excel 2010. Categorical variables were expressed as frequencies and percentages.

**Results:** The current study shows that 78% (n=156) of the study population was overweight. Only 15% (n=30) of the patients observed symptoms of diabetes mellitus indicating poor glycemic control and more than 25% (n=50) of the patients had retinopathy within two years of diagnosis. Almost 17% (n=34) of the patients felt that they should attend the doctor's clinic only for complications. Approximately 2% (n=4) of the population did not involve in any of the physical activities and 4% (n=8) of the population were not following any dietary changes to control their blood sugars.

**Conclusion:** A proper updated educational program is needed to update the knowledge of both the rural community and the primary healthcare physicians on recent advances in the holistic management of diabetes mellitus.

Keywords: Diabetes Mellitus, Diabetic Complications, Healthcare Education, Lifestyle Modifications, Therapy Pattern

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### **INTRODUCTION**

India has the highest number of diabetic patients in the world, making it the diabetic capital of the world. There is an alarming prevalence of diabetes in developing countries, which has gone beyond the epidemic form to a pandemic form.<sup>1</sup> Annually, over three million deaths worldwide are tied directly to diabetes.<sup>2</sup> The International Diabetes Federation estimates that the number of diabetic patients in India more than doubled from 19 million in 1995 to 40.9 million in 2007 and is projected to increase 69.9 million by 2025.<sup>3</sup>

Diabetic patients should regularly take their prescribed medicines. In addition to drug therapy, certain lifestyle modifications should also be strictly advised. Both components of therapy provide effective and holistic management of diabetes mellitus in addition to preventing associated complications.<sup>4</sup> Patients are prescribed different drugs based on the type and severity of diabetes mellitus. Awareness regarding lifestyle modifications is also achieved through special camps. However, compliance with drugs and life modifications poses a major hurdle in the effective management of diabetes mellitus.<sup>5</sup>

*Cite this article as:* Reka, Rajendran P, Narayan G. Identification of Therapy Pattern and Compliance of Life Style Modifications in Diabetic Patients from Rural Areas of Puducherry. Global Journal of Medical Students. 2022 Nov 10;2(2):15–20.

Submit	ted 07-07-2022	Accepted	26-09-2022	Published 10-11-2022
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Table 1. Comparative Profile of Demographic, Socio-Economic, Health Indicators of Uttarakhand					
S.NO	Type of Chronic Illness	Frequency (n) & Percentages			
1.	Diabetes Mellitus – type 2	200 (100%)			
2.	Hypertension	160 (80%)			
3.	COPD – Chronic Obstructive Pulmonary Disease	12 (6%)			
4.	Skin Illnesses	4 (2%)			
5.	Tuberculosis - TB	3 (1.5%)			

This threat is even higher in rural populations, where knowledge about lifestyle modifications and drug therapy is minimal, and patients living in rural regions find it difficult to achieve good glycemic control.<sup>6</sup> With this background, we aimed to identify the patterns in therapy and lifestyle modifications in diabetic patients in rural areas of Puducherry.

# **MATERIALS AND METHODS**

**Study settings:** A facility-based cross-sectional survey was conducted with a validated questionnaire among diabetes patients in rural areas of the union territory of Puducherry from 1 May, 2014 to 30 June, 2014.

**Study Participants:** A convenience sample of 200 diabetic patients attending NCD clinic in a public primary health centre in rural setting of puducherry

**Inclusion criteria:** The study included patients attending noncommunicable disease (NCD) clinics at rural primary health centers (PHCs) who were ready to give consent for participation, were known case of diabetes mellitus and on treatment for the same irrespective of concomitant comorbidities, and with their primary residence hailing in a rural setting (as defined by the latest census)<sup>7</sup>.

Table 3. Lifestyle modifications undertaken by the study population for effective control of diabetes mellitus						
Lifestyle modifica- tion undertaken	Re- sponse	Preferred Modification	Frequency n (%)			
Dietary	Yes	Dietary fibers	80 (40%)			
Modification		Millets like Ragi and Oats	70 (35%)			
		Green leafy vegetables	30 (15%)			
		Fruits	6 (3%)			
		All of the above	10 (5%)			
	No	None	4 (2%)			
Physical activity	Yes	Walking	120 (60%)			
		Yoga	40 (20%)			
		Exercise	18 (8%)			
		All of the above	10 (5%)			
		Others	10 (5%)			
	No	None	4 (2%)			

Table 2. Pharmacological management of diabetes and hypertension in the study population

Disease managed	Drugs prescribed for the manage- ment	Frequency n (%)
	Oral Hypoglycemic Agents (OHA) only	137 (68%)
Diabetes mellitus	Insulin only	59 (30%)
(DM)	Both OHA and Insulin	4 (2%)
	Total	200 (100%)
	ACE (Angiotensin Converting Enzyme) Inhibitors	61 (38%)
Hypertension in patients with con-	CCB (Calcium Channel Block- ers) + Diuretics	96 (60%)
comitant DM	Other anti-hypertensives	3 (2%)
	Total	160 (100%)

**Exclusion criteria:** Participants who refused to give consent or gave incomplete questionnaires and known cases of psychiatric illness were excluded from the study.

**Study procedure:** Scientific committee and Institute Ethics Committee (IEC) approval were obtained (IEC/C-P/07/2014) prior to the commencement of the study. Written informed consent was obtained from all the participants in their vernacular language (Tamil). Patients attending the NCD clinics at their local rural PHCs were enrolled. Data were collected by direct inquiry of the patients using a self-administered questionnaire. The questionnaire was pilot tested on a sample population of 50 participants. The results from the pilot study were not included in the present study.

The content validity ratio (CVR) as determined by Lawshe's formula by subject matter experts was 0.81. The questionnaire included data on demographic details such as age, sex, height (in cm), weight (in kg), nature of work, disease details, diagnosis and duration of the disease, current medication status of the patient, comorbidities, personal history, family history, details regarding follow-up, lifestyle modification details, information regarding their dietary habits and physical activity, stress management strategies and their knowledge of disease.

**Statistical analysis:** The data were entered and analyzed using Microsoft Excel version 2010. The frequency of people in each criterion was calculated and summarized in percentages.

#### Sample size calculation:

The total sample size was 200. The calculation was based on the formula  $n=4pq/L^2$  where

p - prevalence of diabetes in rural areas of Puducherry according to the study by Ghorpade A et al is 2% (p=0.02)<sup>8</sup>

q = (1-p) = 0.98



Figure 1. Total Duration of Treatment Received by the Populationprevalent

L – Tolerable error in the estimation of prevalence of the disease burden. Considering 20% to be the accuracy in estimation, L=0.02.

Substituting the values in the above formula, n = 196.

## RESULTS

The study was conducted among 200 patients who were diagnosed with diabetes residing in rural areas of Puducherry. The mean age of the study population was 62.8 years, and there was a slight male preponderance of 64% (n=128). The mean height and weight of the study population were 154 cm and 58.2 kg, respectively. The mean body mass index (BMI) of the study population was 24.54 kg/m<sup>2</sup>, with 78% (n=156) of the population falling in the overweight category

as per the body mass index (BMI) cut-offs for the Asian population.9 Seventy-six percent (n=152) of the study population was involved in occupations demanding moderate manual physical work. Table 1 summarizes the distribution of various chronic illnesses in the study population. Figure 1 depicts the total duration of treatment received by the participants in the study population.

A positive family history was elicited in 13% (n=26) of the study population. A total of 25% (n=50) of the

patients had progressed to diabetic retinopathy owing to poor glycemic control. Symptoms of polyuria, polydipsia and polyphagia were noted to be seen in 15% (n=30) of the population. **Figure 2** depicts the method of establishing the diagnosis of diabetes mellitus in the study population as enlisted either in their NCD identification card/local NCD registry. Fifteen per cent (n=30) neither had data on the establishment of diagnosis mentioned in their NCD cards and nor did they remember the test employed and the cut-off values used to establish the diagnosis of diabetes mellitus.

A total of 31.5% (n=63) of the population used insulin for the control of blood sugar either as a sole medication or in addition to oral hypoglycemic agents (OHA). The pharmacological management approaches used for the control of diabetes and concomitant hypertension if present



Figure 2. The method of establishing the diagnosis of diabetes mellitus percentage of population (%)



Figure 3. Perceptions on Treatment seeking behaviour for diabetes mellitus in the study population - Reason for seeking treatment

in the study group is summarized in Table 2.

While **Figure 3** depicts the perceptions of the study participants on the reasons for seeking treatment of diabetes mellitus, **Figure 4** shows their opinions on their preferred physician of choice for seeking that treatment. These two parameters sum up the healthcare seeking behavior of the study population. **Table 3** summarizes the preferred dietary modifications and the choice of physical activity employed by the study group to bring out an effective lifestyle modification for the control of diabetes mellitus.

## DISCUSSION

The present study, involved 200 diabetic patients hailing from the rural areas of Puducherry. It was shocking to note that despite 67% (n=134) of the study population had involved themselves in labor demanding moderate manual physical work, 78% (n=156) of the population fell into the overweight category. Though, the prevalence of obesity as determined by Ramya et al (Sep'2014-Oct'2015) in rural Puducherry was 11.39%, the present numbers seem to be alarming. Further, the results of the present study second the notion of increased prevalence of non-communicable diseases like diabetes and hypertension to be linked with obesity and the effect of a positive family history in patients with diabetes mellitus.<sup>10</sup> In the context of co-existing chronic illnesses in the study population, it was interesting to note that almost 3% (n=6) of the study population had been suffering from tuberculosis (TB). It has been effectively studied in literature that tuberculosis potentiating the development of diabetes and diabetes mellitus being a potential risk factor in the development of tuberculosis is a vicious cycle. The present study gives a rough estimate of the burden of diabetes mellitus-tuberculosis coexistence in rural areas of Puducherry and agree with the findings of Raghuraman S et al. Thus, it becomes important to screen TB patients for diabetes mellitus and diabetic patients for TB.<sup>11</sup>.

More than 25% of the patients with type II diabetes had retinopathy within two years of diagnosis. This finding is in concordance with the report by the American Diabetes

> Association.<sup>12</sup> A significant proportion of patients had retinopathy even at the time of diagnosis of diabetes mellitus. It was also observed that patients were not fully aware of the complications of diabetes; hence, health care education failed in this aspect. Further, this part of the survey revealed that 84% (n=168) of the patients were ignorant and were not aware of permanent end organ damages such as vision loss, caused by diabetes. Hence, health education should be instituted to the public regarding eye check-up and end-organ damage screening at the time of diagnosis of diabetes mellitus to prevent development of complications.





Figure 4. Perceptions on Treatment seeking behaviour for diabetes mellitus in the study population – Doctor of choice for seeking treament

The current study shows that only 15% (n=30) of the patients observed symptoms of diabetes mellitus (Polyuria; Polyphagia; Polydipsia). Pawar *et al* also reported that only 15% of Indian populations had typical symptoms.<sup>13</sup> Further, presence of symptoms despite receiving treatment can be linked to poor glycemic control or poor compliance to treatment. These finding warrants developing programs which could effectively track follow-up records in patients.

The establishment of a diagnosis of diabetes mellitus in 60% of the patients was performed by fasting (FBS) and postprandial blood sugar (PPBS) levels. This finding reveals that importance should be given for the estimation of FBS and PPBS in the diagnosis of diabetes mellitus, as symptoms alone accounted for only 15% of diabetes. Despite rural setting, 15% population had marked the use of HbA1C testing for aiding the diagnosis of diabetes mellitus. Glycated hemoglobin (HbA1C) being the mirror that shows the past three months status of the control of diabetes; is of better value in establishing the diagnosis of diabetes mellitus, more so in doubtfulcases.14 Also, HbA1C can be a wonderful tool to evaluating follow-up and prognosis. Studies have proven that maintaining HbA1C within a normal range aids in prevention of dangerous complications of diabetes like diabetic nephropathy, neuropathy, and retinopathy.<sup>12,15</sup> Thus, it has become important for primary care physicians who are treating diabetic patients to understand the relevance of HbA1C in management of diabetic patients. Further, the present study also highlights the importance of random blood sugar (RBS) values in incidental/accidental diagnosis of diabetes. Figure 2 also reflects lack of proper documentation from the treating physicians and/or ignorance in the patient population with regards to the testing of blood for sugar values.

With regard to drugs prescribed for the patients, 68% of the patients were under oral hypoglycemic agents (OHAs) only. Insulin was prescribed for 31.5% of the patients, and approximately 2% of the patients were getting OHA+ insulin. Though studies have reported prevalence of fear amidst diabetic patients in India with respect to taking insulin injection, it was interesting to note that 31.5% of population in the present study were on regular insulin.<sup>16</sup>

With regards to the nature of the OHA prescribed, the majority of the patients were given glibenclamide and metformin. It appears that the physicians were not prescribing OHAs such as glimipride and  $\alpha$ -glucoside inhibitors such as acarbose. It has been shown that acarbose significantly improves glycemic control and lowers triglyceride levels, body weight, body mass index (BMI) and systolic blood pressure. It also produces a risk reduction of 64% for MI.<sup>17</sup> Similarly, in the present study, only 38% (n=76) of the patients were prescribed angiotensin-converting enzyme (ACE) inhibitors for associated hypertension, whereas

calcium channel blockers (CCBs) were used in 60% (n=120) of the cases. ACE inhibitors are known to prevent microalbuminuria and delay the progression of diabetic nephropathy making ACE inhibitors a preferred choice for most patients than CCBs.<sup>15,17-19</sup> It is evident from the present study that newer drugs were underused and treating physicians were not abreast of the scientific developments in the management of non-communicable diseases. This further recommends planning training programs in the form of periodical Continuing Medical Education (CME) for treating physicians to update their knowledge on the pharmacotherapy of diabetes.

With regards to health care seeking behaviour of the study population, only 16% (n=32) agreed on regular follow-ups. While 65% (n=130) of the population stated that they would seek treatment on developing minor symptoms, it was disheartening to note that 17% (n=34) of the population remained ignorant to be reaching out to the doctor only on development of complications. This highlights the lack of knowledge within the rural community about the magnitude, burden, potential complications of diabetes on their health. This ideology also forfeits the concept of preventive health care at the community level.

Majority of the patients (70%, n=140) preferred to be attended only by a specialist doctor. Approximately 29% (n=58) of the patients explained that they would seek help from their local/general physician. This clearly acknowledges the dire need for effective healthcare delivery in India in terms of doctor-patient ratio and leaves a potential question mark on the availability of specialist doctors in the rural areas.<sup>20</sup> It is a pointer to appropriate authorities to address these lacunae.

It was observed from the study that majority of the patients knew the value of dietary fibers and cereals in the management of diabetes. However, 2% (n=4) of patients refrained from incorporating dietary modifications and 2% (n=4) did not involve themselves in any form of physical activity. As approximately  $1/3^{rd}$  of diabetic patients can be managed by diet alone, health education for patients should be focused on lifestyle modification.<sup>21</sup>

## LIMITATIONS

The study fails to look for compliance of the study population and their adherence towards pharmacotherapy and lifestyle modifications. Also, the study fails to appreciate the frequency in which the participants follow the above discussed lifestyle modifications. A longer study duration would aid in evaluating the same. Also, though the study points at many raw areas which need to be revisited for providing effective and holistic treatment for NCDs in the rural community, a qualitative study on the same would help bring out the attitude and approach of the participants towards their healthcare seeking behavior.

#### **Future directions**

We would like to conduct an effective qualitative study to understand the perceptions of people of the rural community towards seeking treatment for NCDs and effectively understand the socio-cultural constructs to acceptance of lifestyle modifications. A similar study on a larger sample of population would further aid in determining the magnitude of disease burden and reflect on the quality of healthcare delivery in rural India.

## CONCLUSION

Our study found few significant findings where the therapy pattern and management of diabetes mellitus in rural areas were lacking. This has to be considered the tip of the iceberg, which holds so many hidden issues underneath. Moreover, proper updated educational programs are needed to update the knowledge of primary healthcare physicians on recent advances in the pharmacotherapy of diabetes mellitus. Equally, emphasis should be given to designing community education models for patients on treatment of diabetes mellitus.

## **END NOTE**

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#### Conflict of Interest: None declared

#### Source(s) of Support: ICMR

Acknowledgement: ICMR STS fund

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