



## **Assessing the Medication Adherence of Metabolic Disorders in South India**

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### **Authors' contributions**

*This work was carried out in collaboration among all authors. Author PAS designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. All the remaining authors have managed the analyses of the study and literature searches, read and approved the final manuscript.*

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### **ABSTRACT**

**Aim:** The study's main objective was to assess patients' adherence towards treatment and daily practices among Hypertension (HT), Diabetes Mellitus (DM) Type II and hypothyroid participants in South India before and after providing counseling and education based on WHO standards.

**Study Design:** The present study is a prospective open-labeled observational study.

**Place and Duration of the Study:** The present study was conducted in Vijayawada, South India for six months.

**Methodology:** A total of 490 participants with Hypertension, Diabetes Mellitus (Type II) and Hypothyroidism were assessed for adherence based on the Morisky medication adherence scale containing 8 points at the starting of the study and 6 months after providing counseling and education.

**Results:** At the initial point of study, only 12% of the Hypertensive group, 17% of Diabetes Mellitus (Type II) and 15% Hypothyroid group have high adherence. Towards the completion of the study, around 41% in the Hypertensive group, 50% of Diabetes Mellitus (Type II) and 60% Hypothyroid group had high adherence.

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**Conclusion:** The adherence was low at the initial point of the study among all the three groups. After counseling and education provided through the World Health Organization (WHO) specified criteria, we have seen a good increase in the adherence, measured with the MMAS-8 scale. Greater efforts should be made in educating and counseling the patients suffering from such chronic illnesses to improve their quality of life.

*Keywords: Adherence; morisky medication adherence scale-8; hypertension; type II diabetes mellitus (T2DM); hypothyroidism.*

## 1. INTRODUCTION

Hypertension is a chronic and persistent elevation of arterial blood pressure (BP), [1] which is expressed as the ratio of systolic BP to diastolic BP. [2] Hypertension escalates the probability of developing atherosclerosis, myocardial infarction, heart failure, renal failure, cerebrovascular accident, aneurysm, and retinal hemorrhage and visual impairment. [3] An estimated 1.13 billion people have HT worldwide, ranging from 1 in 4 men and 1 in 5 women. Among which only 1 in 5 people have their condition under control. [4] According to the National Family Health Survey (NFHS-5) prevalence of Hypertension among age 15 years and above (BP > 140/90mmHg) in women and men are 25.3% and 29.0%, respectively, in urban and rural (2019-2020) [5].

Type-2 Diabetes mellitus is a chronic metabolic disorder characterized by persistent elevation of glucose levels in the body, which can be due to either insulin resistance or insufficient secretion. Uncontrolled DM leads to many significant organ dysfunctions and failure to Kidneys, Nervous system, Heart, Blood Vasculature and eyes. [6] The prevalence of T2DM is increasing in many regions of the world and is slowly affects the younger generations. [7] According to NFHS-5 prevalence of Blood Sugar Levels (BSL) among adult age, 15 years and above (BSL > 140mg/dl) in women and men are 19.3% and 21.8%, respectively, in urban and rural (2019- 2020) [5].

Hypothyroidism is the deficiency of thyroid hormone affecting mainly women. Overt hypothyroidism is a condition where we observe decreased levels of free thyroxin (T4) and elevation of thyroid-stimulating hormone (TSH) [8].

The irregularities in the levels of thyroid hormones leads to an increase in BP, increased levels of cholesterol, bone deformities, fertility problems, disturbed sleep and metabolism. [9] An estimated range of 42 million individuals in

India has thyroid disorders (including hyperthyroidism and hypothyroidism), with hypothyroidism in the majority at 1 or 2 men out of 10 and 9 out of 10 women. [10] The occurrence of Hypothyroidism (H) varies among the population, with various factors influencing them. [11] The prevalence of 7.48 was seen self-reporting with, 3.47 going undetected [12,13].

Patient counseling is defined as providing the appropriate information regarding the treatment, their positive and negative effects and upgrading their knowledge on the disease. It also aids in suggesting—fundamental dietary changes that benefits them overall. [14] Explain the role of lifestyle changes such as a healthy diet like a vegan diet, weight reduction, and regular physical activity and adherence to lifestyle changes which can reduce patient disease condition. [15] By regular physical activity like yoga not only for physical strength but also for mental wellbeing. [16] Some studies reveal that the information and counseling provided by pharmacist are aiding in improving the knowledge, attitude and practice of the patients, towards controlling the disease and improving their overall wellbeing [17].

As defined by WHO, medication adherence is the degree to which the patients' behavior correlates with the suggestions and recommendations provided by the health care team towards his/her condition regarding their therapy, dosage, frequency and time of administration. [18] Non-adherence to medication is a common problem associated with increased hospitalization, progression of disease and mortality. [19] Morisky medication adherence scale is an upgrade version of the previous scale, which is a widely accepted and practical resource to be used in assessing adherence. It consists of 8 questions, of which seven are answered either YES/NO, and the last question is answered using the Likert scale. The obtained final scores divide the patients into high adherent, average adherent and poor adherent. [20] During the past several decades, these are the common disorders that

increased markedly and lead to an increase of complications and disturb the quality of life. Hereby, we plan to assess the adherence of these three chronic conditions in South India.

## 2. METHODOLOGY

### 2.1 Study Site and Design

Our present study was planned and conducted in Vijayawada city located in Andhra Pradesh state in India from September 2019 to February 2020. It is a prospective open labeled study.

### 2.2 Study Objective

To assess the medication adherence among metabolic disorders in the south Indian population before and after providing counseling and education based on WHO standards.

### 2.3 Study Population and Sampling

We have systemically reviewed the individuals in their households and selected the participants who are a known case of Hypertension, Diabetes Mellitus (Type-II) and Hypothyroidism alone with no co-morbidities, between the age groups 18 to 80. Individuals having combination and other co-morbidities, physical and mentally disabled people are excluded. We have ascertained the importance of the survey, by providing a detailed explanation of the Questionnaires and procedure.

### 2.4 Study Procedure

Participants were prior informed that participation was entirely voluntary, no name was recorded on the questionnaires or any forms used, and all of the personal information of participants was kept confidential. Each participant was now given a data collection forms comprising the general characteristics and MMAS-8 questionnaires. This was done once at the initial time and once towards the ending, which is six months. The disease counseling and education were provided to all the participants based on their condition with WHO specified criteria. Filled forms & questionnaires were reviewed for completeness and accuracy before data entry; we also randomly asked a few questions from the forms they filled and checked whether the filled information was genuine and authentic.

### 2.5 Statistical Testing

Then, the data were coded and analyzed by SPSS version 20 using the Chi-square test.

## 3. RESULTS AND DISCUSSION

A total of 490 participants, including Hypertension, Diabetes Mellitus (Type-II) and Hypothyroidism were included and analyzed for checking the adherence and practices they follow towards the disease control. The mean age of the Hypertensive, Diabetic and Hypothyroid groups are 53.4, 56.7 and 35.4 years, respectively. Most of the participants are male in the first two groups compared to more females in Hypothyroid group. In looking at the duration of having the disease majority of the population had the disease for a long time from now among all the groups. The proportions of participants in the high level of education were less among all the groups, with 31, 16 and 5 in Hypertensive, Diabetic and Hypothyroid groups respectively. (Table 1).

Upon using the MMAS-8 at the first visit, in Hypertensive patients, maximum numbers (101) were in average adherent followed by poor adherent (71) state. The same trend has been observed in Diabetic participants with 133 and 47 numbers. However, the trend has differed in Hypothyroid patients where poor adherent was predominant with 44 participants followed by 23 in the average adherent state. At the second and final visit at the end of the study majority of the participants of Hypertensive patients were in the High adherent (81) zone, followed by average adherence (73). The same trend has been observed in Diabetic and Hypothyroid participants with 108 and 89 numbers, 47 and 20 respectively. (Table 2).

Upon assessing the participants with the MMAS-8 scale, we inferred that 12% of HT patients show higher adherence, 52% have average adherence, and 36% have low adherence. In the Diabetic group, 17% showed higher adherence, 62% with average adherence, and 21% show low adherence. These results are in relation to a study conducted by Carlo Capelli et al. [21], where 15%, 24% and 61% are in high, moderate and low adherence regions. A study in Tanzania assessed the level of anti-diabetic medication adherence in a hospital and found that the medication adherence was found to be 60.2% in the first week and 71.2% in the third month of their study, respectively. Prathyusha et al. [22] this was in accordance with our study where we observe 17% in the first visit and 62% in the final visit in the high adherence region.

**Table 1. Socio-demographic data of the conditions**

<b>Characteristics</b>	<b>HT (195)</b>	<b>DM-II (216)</b>	<b>H (79)</b>	<b>P value</b>
Age, years; mean (SD)	53.4(4.2)	56.7(3.1)	35.4(4.5)	< 0.05
Gender; N (%)				
Male	139(71.2)	138(63.8)	64(81)	
Female	56(38.8)	78(36.2)	15(19)	
Level of Education; N (%)				
Higher	31(15.7)	16(7.5)	5(6.1)	
Middle	61(31.6)	72(33.2)	18(22.4)	
Lower/uneducated	103(52.7)	128(59.3)	56(71.5)	
Duration of having the condition, years; N (%)				
<1	21(10.8)	29(13.5)	11(13.9)	
1-5	42(21.5)	65(30)	27(34.1)	
6-10	84(43.1)	97(45)	19(24.1)	
>10	48(24.6)	25(11.5)	22(27.9)	

**Table 2. MMAS-8 scores of the participants before and after counseling and education**

<b>Diagnosis</b>	<b>Highly adherent (8 points) N (%)</b>		<b>Moderate adherence (6 to 8 points) N (%)</b>		<b>Poor adherence (&lt; 6 points) N (%)</b>	
	Before	After	Before	After	Before	After
Timing						
Hypertension scores	23 (12)	81 (41)	101 (52)	73 (38)	71 (36)	41 (21)
T2DM scores	36 (17)	108 (50)	133 (62)	89 (41)	47 (21)	19 (9)
Hypothyroid scores	12 (15)	47 (60)	23 (30)	20 (25)	44 (55)	12 (15)
<i>P</i>	<i>value</i>				< 0.05	

In comparison to a study conducted in Puducherry, low adherence was observed in 39% of participants Rwegerera et al. [23], which was 21% in our study. Another study conducted in Kerala had shown that 74% of the population are less adherent Arulmozhi et al. [24] which was in contradiction with our study with the maximum number found in average adherence, which is 62%. Our results were also in contradiction with a research conducted in Tamil Nadu, where 75.9% of HT is less adherent. Sarkar et al. [25] a similarity was observed when the results of our study were compared with a study conducted in China which was 36% and 32.6% Venkatachalam et al. [26] Most of the patients (84.5%) had poor compliance of drugs in a study. Lee et al. [27], which is in contradiction to our study, shows average adherence majorly. The poor adherence observed was related to a poor literacy rate among the general public Pirasath et al. [28].

When the medication adherence was evaluated using MMAS-8, it was found that patients with a high, medium and low adherence were around 30.0%, 34.8% and 35.2%, respectively; which were 15%, 30% and 55%, respectively in our study. An adherence of 36.8% was found in Hermansen et al. [29], 78% in Briesacher et al. [30] and 76.1% with hypothyroidism Crilly et al. [31]. The results were in accordance with our study where we also observe medium to high adherence among the H participants. A programmed pattern of education and counselling following a well structured pharmaceutical care plan by pharmacists has proven to be significant in improving medication adherence Vezzani et al. [32] It is of prime importance that patients should receive continuing education, counselling about the disease and usage of drugs along with supplying of patient information leaflets (PIL's) encourages the patients to visit the health facility regularly Adepu et al. [33]

#### 4. STUDY LIMITATION

Lack of resources and funding has limited our range of work and exploration. The educational relation with the individuals' practice was not measured.

#### 5. CONCLUSION

Our findings inferred that the adherence was poor during the initial stage and was improved upon counseling and education among all three groups. The major reasons for non-adherence in

the participants, while interviewing was found to be forgetfulness, having no proper education and being unaware of the complications associated. This was mainly due to poor knowledge, attitude and practices of the participants in managing the diseases. Therefore there is a certain requirement for proper counseling, education and practices by the government in addressing such chronic illnesses.

#### CONSENT

As per international standard or university standard, Participants' written consent has been collected and preserved by the author(s).

#### ETHICAL APPROVAL

The study procedure was approved by the Institutional Ethical Committee of the Southern Institute of Medical Sciences with reference number IHEC/SIMS/2019/023

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#### COMPETING INTERESTS

Authors have declared that no competing interests exist.

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