A Study on Medication Adherence in Patients With Type 2 Diabetes Mellitus With Hypertension in A Tertiary Care Hospital

Short title: *Medication Adherence in Patients with Type 2 DM with HTN*

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Abstract : This is a prospective study carried out in the General Medicine Ward for a period of 12 months. The medication adherence of all the adult patients (≥18 years of age) of both gender needed to be assessed is included in the study. Vulnerable subjects were excluded from the study. Out of 100 patients, the distribution of males and females were found to be 66% and 34% respectively. This study shows that 77% were adherent to their medications and 23% were not. 72% has shown to have improved in their overall QOL and 28% of the patients showed no improvement in their overall QOL, out of which most were, geriatric patients due to multiple co morbidities, physiological changes and poly-pharmacy. The study findings revealed that geriatrics were more prone to develop T2DM with HTN. It is found that low socio economic status is one of the main reasons for non-medication adherence. This shows that the medication adherence have direct influence on patient's quality of life. So, increased medication adherence improves the overall QOL.

Key words : Co- morbidities, Hypertension, Medication adherence, Quality of life, Type 2 Diabetes Mellitus.

I.   INTRODUCTION:

1.1 Diabetes:

Chronic type 2 diabetes impairs the ability of cells to efficiently utilize blood sugar for energy and renders blood glucose uncontrollable. When cells lose their sensitivity to insulin, the blood glucose progressively rises to an unhealthy level[1]. There are two reasons for this; first, the cells of the body become resistant to insulin. Insulin works like a key to let glucose move out of the blood and into the cells where it is used as fuel for energy. Secondly, insufficient insulin, if the cells require more and more insulin, the pancreas can't make enough insulin to keep up and begins to fail[1].

1.2 Hypertension:

Consistently elevated blood pressure (BP) in the arterial system is what defines hypertension. The ratio of the systolic and diastolic blood pressures, or the pressure the blood exerts on the artery walls as the heart contracts and relaxes, is a typical way to represent blood pressure.The most frequent risk factor for heart disease, chronic kidney disease (CKD), and cognitive impairment is hypertension, which is also the main cause of mortality and disability globally[2].

Diabetes associated with Hypertension:

More than 50% of people with diabetes mellitus (DM) have hypertension (HTN), which is a major factor in both micro vascular disease and macrovascular disease in DM. In fact, DM and HTN patients have a four-fold greater risk of cardiovascular disease (CVD) than normotensive non-diabetic controls. DM is linked to an almost two-fold higher risk for coronary heart disease, stroke, and fatalities from cardiovascular causes, such as heart failure, cardiac arrhythmia, sudden death, hypertension, and aortic aneurysms, according to a meta-analysis of 102 studies involving 698,782 people[3].Therefore, the primary goal of this study was to evaluate patient quality of life in relation to adherence. Findings related to antihypertensive medication adherence in family practice patients with DM and hypertension served as a secondary goal.

1.3 Medication Adherence:

The degree to which a patient follows the recommended dose and interval of their prescription regimen is referred to as medication adherence. When more than 80% of the tablets recommended by the doctor are taken by the patient in a particular period, that patient is said to be adhering to their medication regimen[4].Self-reported interviews, pill counts, medicine levels, physiological parameters, pharmaceutical claims, electronic medication monitoring, and physician ordering in electronic health records are just a few of the many techniques that have been mentioned to evaluate medication adherence (EHRs)[4].

Medication non-adherence results in substandard results, a rise in the use of healthcare services, and an increase in total healthcare expenses. Increased risks of morbidity and death have been linked to non-adherence to cardiovascular medicines[4].In comparison to provider- or payment-related variables, patient-related variables have a stronger impact on predicting adherence. Although the majority of doctors think that patients' deliberate choices to not adhere are caused by impaired access or memory, this is not always the case. The "next frontier in quality improvement" is increasing drug adherence.[4].

The MMAS-8 is a self-report questionnaire with 8 questions (items), the phrasing of which is designed to prevent respondents from selecting "yes" regardless of the question's substance. Items 1 through 7 offer a

"yes" or "no" response option, while question 8 includes a 5-point Likert option.Except for item 5, where each "yes" response is scored as "1" and each "no" response is rated as "0," each "no" response is rated as "1" and each "yes" response is rated as "0." For item 8, a patient's score is "0" if they select option "0," and "1" if they select option "4". Responses "1, 2, 3' are graded as "0.25, 0.75, 0.75" accordingly. The MMAS-8 has three degrees of adherence, with total values ranging from 0 to 8. 8 is high, 6 to 8 is middle, and 6 is low[5].

1.4 Quality of life:

WHO defines health as "a condition of complete physical, mental, and social well-being, and not only the absence of sickness or disability?" The phrase "well-being" used in this definition of health has greatly increased the conceptual ambiguity around what constitutes health and what constitutes QOL[6].It is true that improving quality of life is the main objective of diabetes and hypertension early diagnosis and treatment (QOL). Although the phrase "quality of life" (QOL) is still vague, it is generally accepted that it consists of four elements: the physical, mental, cognitive, psychological, and social components.These four elements have been the subject of several essays. Diabetes affects patients' life, it's a fact. Simply having diabetes and hypertension lowers a person's quality of life (QOL). The impact is significantly severe when diabetes coexists with other chronic conditions[7].In light of the increased prevalence of diabetes and hypertension, it is crucial to assess the patients' quality of life. One of the most practical measures for measuring people's quality of life, the EQ-5D was developed by Brook in 1991 and rates how well people perform physically, mentally, and socially[8].

Mobility, self-care, usual activities, pain or discomfort, and anxiety or depression are the five dimensions that make up the European Quality of Life 5-Dimensions (EQ5D) questionnaire. Each dimension has five statements, from which the subject can select the one that best describes their current state of health. A scale is then used to reflect the subject's health status.The numbers on this scale range from 0 to 100. The highest level of health imaginable is 100. The poorest possible health score is zero. To indicate how your health is right now, mark an X on the scale. 0-50 equals low; 50 is high[8].

II. MATERIAL & METHODS

Ethics Committee approval was obtained on 31st March 2021 from the Institutional Ethics Committee of The Oxford College Medical College, Attibele, Bengaluru, approved the study prior to the commencement of the study. (Reference no: IEC/TOMCHRC/183/ 2020-21).This is a prospective study carried out in the General medicine department of The Oxford Medical College and Research Centre located in Attibele, Bangalore for 12 months. Coming to the sample size, 100 Cases admitted during the period of 2021-22 was followed after obtaining the informed consent to get outcome analysis (by evaluating medication adherence and non-adherence).

2.1 Collection of Data:

The medical records of patients with Type 2 Diabetes Mellitus with Hypertension who are admitted in the hospital during the period of 2021-22 were collected from the General Medicine Ward.The patient was interviewed and the necessary demographic details such as name, age, social and family history, past medical and medication history were collected.Medical record of the patient was used to obtain details regarding the IP. No., laboratory reports, diagnosis, and the drugs prescribed then recorded in the data entry form.

The patient was then interviewed regarding his/her medication adherence of drugs using Morisky Medication Adherence scale (MMAS) and quality of life by using suitable questionnaire like EQ-5D(Euro QOL-5 Dimensions)

2.2 Study procedure:

Step 1: All the annexure used in the study were translated to the local language (Kannada) and consent was obtained from patients.

Step 2: Demographic details of the patient (Name, Age, Sex, IP number etc) was collected including data regarding diagnosis, prescribed drugs, indication and their route of administration.

Step 3: Assessment of medication adherence and non-adherence in Type 2 Diabetes Mellitus with Hypertension among the patients using Morisky Medication Adherence scale (MMAS)

Step 4: Assessment of quality of life by using suitable questionnaire like EQ-5D (Euro QOL-5 Dimensions)

Step 5: The obtained data was subjected for suitable statistical method using SPSS software.

2.3 Inclusion criteria:

Inpatients & outpatients who are above 18 years of age andhaving the treatment of Type 2 Diabetes Mellitus with Hypertension were included in the study.

2.4 Exclusion criteria:

Patients who are not willing to participate in the study and not having hypertension with diabetes were excluded from the study.

2.5 Source of data:

Patient case records, Case Record Form (CRF), Interview with patients were the sources of data for this study.

2.6 Statistical Analysis:

The statistical tools used are p-value, odds ratio, Chi-square analysis and SPSS (Statistical Package for Social Sciences) software.

III. RESULTS

In this study, total 100 patient's details and medication charts were collected from General Medicine Ward and analyzed.Out of 100 patients, males (66%) were more affected than females (44%). Age wise distribution of patients was given in Table 1. Coming to the educational status the results found that majority of the patients had poor educational status i.e. below 5th standard (43%) which was followed by high school with 26% then Pre University with 11%, Degree with 5% and illiterate were 11%. From the analyzed data wecan understand how much each patient understands about the disease and the level of medication adherence can be analyzed. On analyzing occupation status of the subjects, it is found that the farmers (36%) followed by housewives

(24%) then business persons (10%), teachers (5%), drivers (5%), tailors (4%), carpenters (4%), labour (4%) and others less than 3%.

Considering the socio-economic status, it reveals that majority of patients belonged to the moderate class (45%) followed by low class (43%) and then high class (12%).Residential status of most of the patients belongs to urban area (65%) then followed by rural area (35%).

Table 1: Age wise distribution

Age	Frequency	Percent
20-30	4	4.0
31-40	14	14.0
41-50	16	16.0
51-60	28	28.0
61-70	32	32.0
71-80	6	6.0
Total	100	100.0

Scoring of medication adherence using Morisky Medication Adherence Scale (MMAS) represented in Fig 1 showing that majority of the patients were having high adherence (56%). During our visit, majority of the patients involved in the study answered the questions correctly related to medication adherence.Scores of each question VS number of subjects were represented in Fig 2. Distribution of gender according EQ5D was represented in Fig 3. During our visit, the questions related to the quality of life were answered correctly by the patients involved in the study. Out of which 72% has shown improvement in their overall quality of life and 28% has not shown much improvement in their quality of life. Risk factor analyses were done and factors influencing adherence scores were given in Table 2. The employment status and age categorization shows a direct influence on overall adherence score which shows significant p-value and risk, while gender, educational status does not show statistically significant p-value.
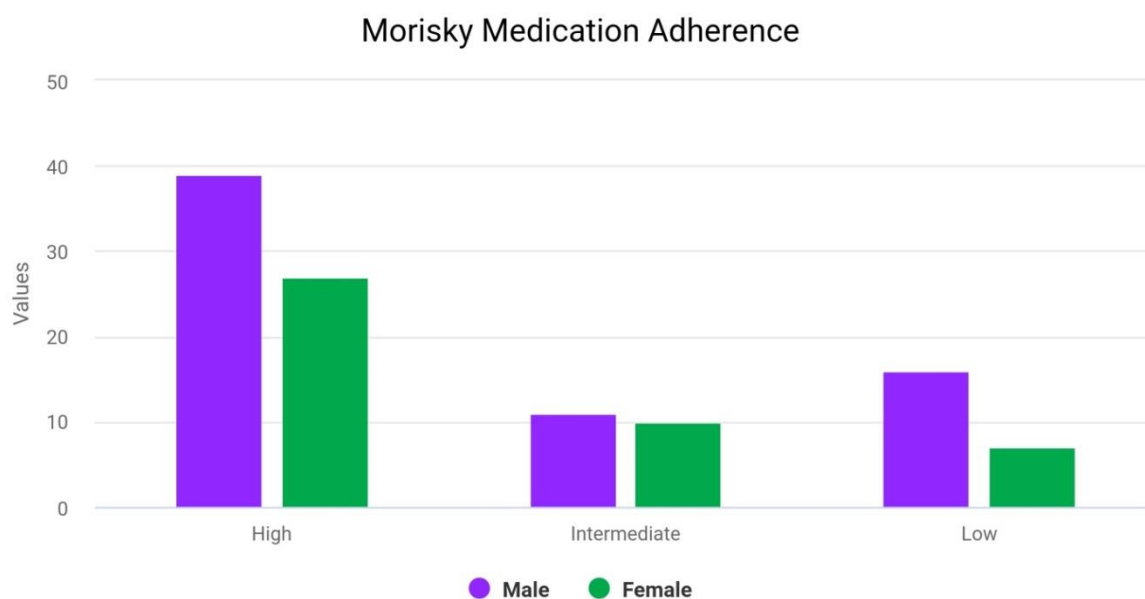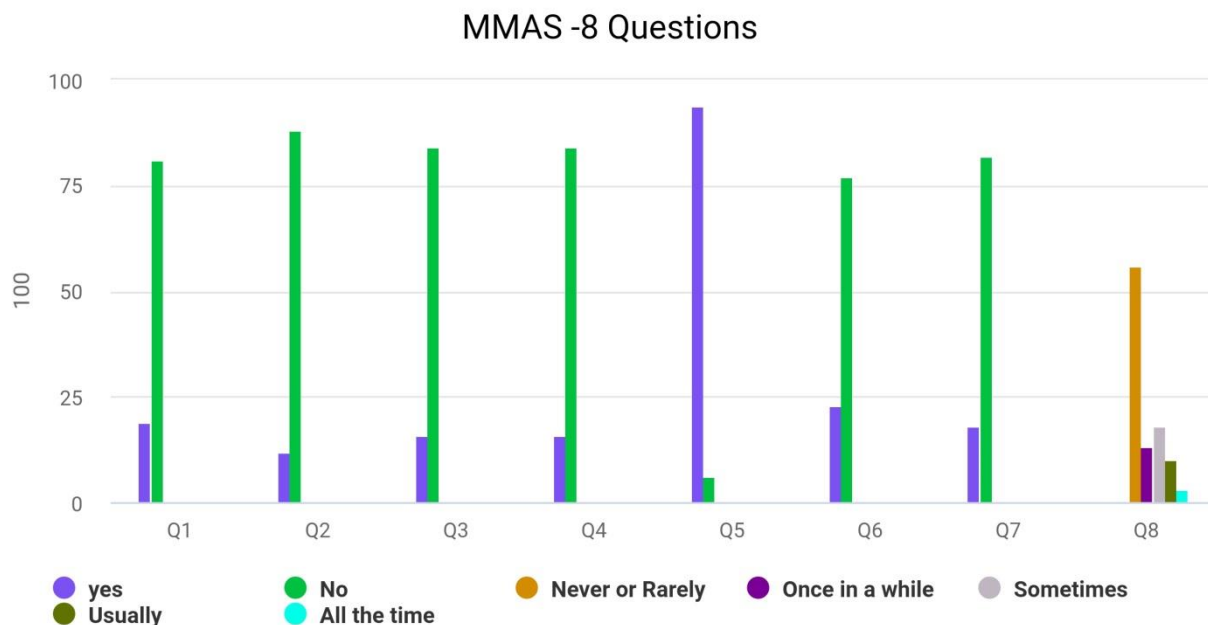

Fig 1: Scoring of medication adherence

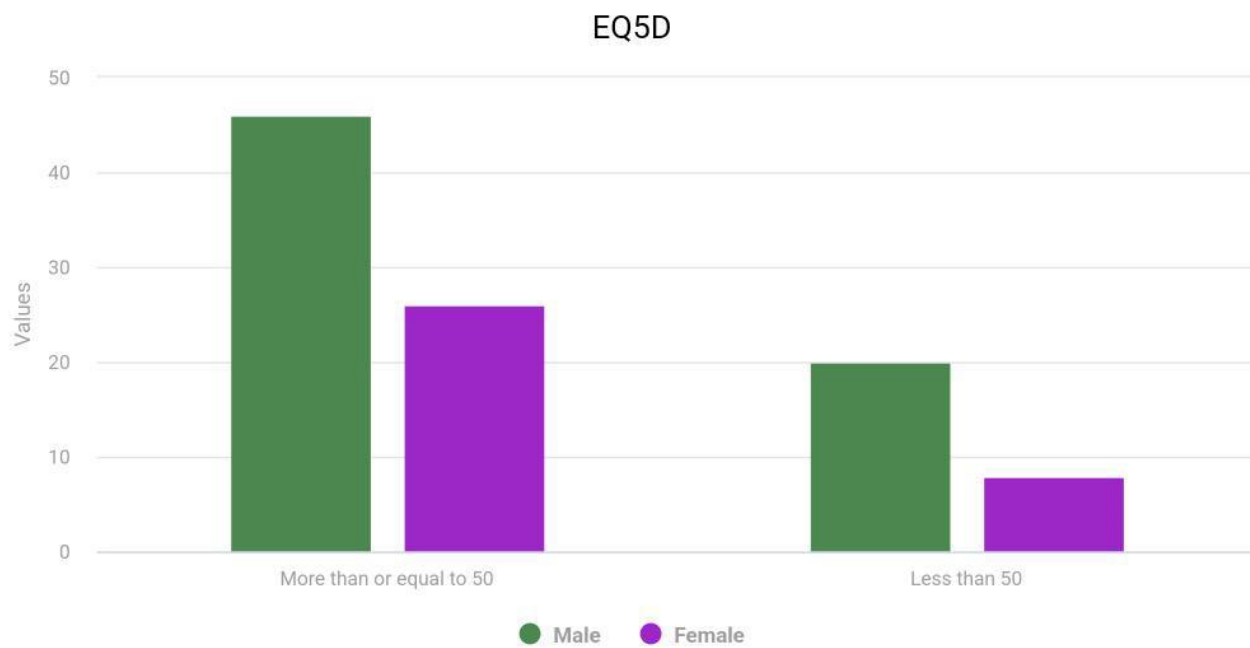Figure 2: Scores of each questions VS number of subjects

Fig 3: *Distribution of gender according to EQ5D.*

Table 2: Factors influencing adherence scores.

	Factors	Overall adherence score		Chi square	Odds ratio (95% CI)	P-value
		<4	≥4			
Age	≤50 years(n=34)	9	25	62.356		0.013*
	>50 years(n=66)	12	54			
Gender	Male(n=66)	16	50	0.169	1.234 (0.45-3.36)	0.681
	Female(n=34)	7	27			
Education status	≤10th standard(n=58)	11	47	4.524	0.585 (0.22-1.49)	0.340
	>10th standard(n=42)	12	30			
Employment status	Employed(n=31)	3	28	4.503	0.262 (0.0716-0.96)	0.034*
	Unemployed(n=69)	20	49			

Note: Significance level; 0.05 and (*) indicates that results are significant

Relation between medication adherence and QOL is clearly depicted in Table 3. The medication adherence shows a direct influence on the quality of life of the patients involved in the study which shows significant p-value.

Table 3: Relation between Medication Adherence and Quality of Life:

Medication Adherence Scale							
		<4	≥4	Total	Chi Square	Odds Ratio (95%CI)	P-Value
EQ5D	<50	21	7	28	59.37	105(20.257-544.235)	<0.001
	≥50	2	70	72			
	Total	23	77	100			

IV. DISCUSSION

The demographics and clinical characteristics of our study population were similar to the reports of other studies on type 2 diabetes with hypertension. Total numbers of 100 subjects were enrolled in this study.

The maximum number of patients enrolled, both male and female belongs to the age group of 51-60 years i.e. 28 (28%) and 61-70 years i.e 32(32%) which is similar to the study conducted by S. Das et al[9] that showed that the majority number of patients was in 61-70 years i.e. 34(30.36%). Considering the gender wise distribution, male predominance was found. In our study, we found that males 66 (66%) were mostly affected compared to females (34%) which is similar to the study conducted by Manjeet Kumar et al[10]. Since our study

includes 43 patients with low socio economic status, this is considered to be one of the main reasons for non-medication adherence which is similar to the conclusion of the study conducted by MosiurRahmanet al[11].

Study conducted by Anders Thelinet al[12]shows similar result that farmers showed that low risk of type 2 diabetes in farmer was explained in terms of high physical activity and better meal quality, indicating that farmers lifestyles and their work environment are health-promoting. Majority of the patients studied up to primary school level and high school, have the capacity of understanding the disease and medication to some extent which is similar to the study conducted by Emilie E Agardh et al[13], a report that 17.2% of the diabetes burden in men and 20.1% of the burden in women were attributed to lower educational levels in Sweden.

To assess the medication adherence, we used Morisky Medication adherence Scale(MMAS) questionnaire which was similar to the study conducted by Samson okelloet al[14]to assess medication adherence in patients with hypertension and type 2 Diabetes.To assess the health related Quality Of Life (QOL) of Patients we used European Quality of life Five Dimensions (EQ5D), and found that 72% of the patients have good quality of life and 28% of the patients showed no improvement in their overall quality of lifewhich was similar to the study conducted by Abedini MR et al[8].

Finally our study concluding that 77% out of 100%   were adherent to their medications and 72% has shown to have improved in their overall quality of life. So, with increased medication adherence there is an improved overall quality of life. Out of 100 subjects, 23% of the patients involved in the study were found to be non-adherent to their prescribed medications and 28% of the patients showed no improvement in their overall quality of life. Reasons for non- adherence was due to low socio-economic status, educational status and concerns about becoming dependent on the medication. Low improvement in the overall quality of life was mostly seen among the geriatric patients due to multiple comorbidities, physiological changes and Poly-pharmacy.Thus we conclude that, the medication adherence shows a direct influence on the quality of life of the patients involved in the study. So, with increased medication adherence there is an improved overall quality of life.

Limitations:

Study conducted was for short duration & limited number of subjects was enrolled in this study that may not have been powered adequately for several sub group analysis and therefore, the results need to be confirmed in a larger study.

The choice of anti-hypertensive and diabetic drugs should be considered in view of effect of drug on renal function of the patient, which was not considered for this study and Non pharmacological measures for reduction in blood pressure were not taken into account.

V.   ACKNOWLEDGEMENT:

5.1 Financial support & Sponsorship:

None

5.2 Conflict of Interest:

None

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