# MRCI AND ITS IMPACT ON MEDICATION ADHERENCE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND CARDIOVASCULAR DISEASE: AN OBSERVATIONAL STUDY - RESEARCH ARTICLE

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## Abstract:

**Background:**

Type 2 diabetes mellitus (T2DM) and cardiovascular disease are long – lasting worsening health issues that greatly impact global illness and death rates. Patient with these accompanying health issues frequently need several medications, resulting in a more complicated medication schedule. The Medication Regimen Complexity Index (MRCI) is an established tool designed to evaluate the intricacy of medication plans based on the types of dosage forms, the frequency of administration and any supplementary instructions. Greater complexity in treatment regimens has been linked to reduced adherence to medication, which can lead to insufficient control of blood sugar levels, a higher risk of heart problems and negative health outcomes.

**Methods:**

An observational study was carried out in a hospital involving patients who have been diagnosed with Type 2 Diabetes Mellitus and Cardiovascular Disease. Data were gathered utilizing a systematic data

collection form. The complexity of medication schedule was assessed by utilizing the Medication Regimen Complexity Index (MRCI) scoring system. Medication compliance was evaluated utilizing MARS – 10 (Medication Adherence Report Scale – 10) questionnaire. Sociodemographic information, clinical measurements (such as HBA1C,Fasting blood sugar, Postprandial blood sugar and lipid profile ), duration of illness, existing health conditions and treatment expenses were documented. A Statistical analysis was conducted to identify the relationship between MRCI scores and levels of medication adherence.

**Results:**

The research included 122 individuals with Cardiovascular disease and Type 2 Diabetes Mellitus. According to Spearman's correlation analysis, the Medication Regimen Complexity Index (MRCI) was not strongly correlated with medication adherence (MARS – 10). There was no statistically significant correlation between adherence and sociodemographic variables like education, income and the cost of therapy treatment ($p>0.0001$).When looking at clinical factors, the number of drugs and co-morbidities did not show a significant link to adherence, but the length of CVD and blood glucose levels showed only a little connection. In general, there was no discernible correlation between how complicated a treatment plan was and how well patients followed it.

**Conclusion:**

The influence of the Medication Regimen Complexity Index (MRCI) on medication adherence was evaluated in this observational study involving 122 individuals with T2DM and CVD. The results indicated no correlation between adherence and MRCI ($p = 0.040$, $p = 0.666$). With the exception of minor associations with blood glucose levels and the length of Cardiovascular disease, the majority of sociodemographic and clinical variables were not significantly linked to adherence. In general, the findings indicate that in this population, adherence to medication may be more influenced by variables other than the regimen's complexity.

**Key words:**

Medication Regimen Complexity Index (MRCI), Medication Adherence, Type 2 Diabetes Mellitus, Cardiovascular Disease, MARS-10 Scale, Glycemic Control.

## Introduction:

Chronic metabolic disease known as type 2 diabetes mellitus (T2DM) is characterized by sustained hyperglycemia brought on by insulin resistance, progressive β-cell dysfunction, and aberrant glucagon

production [1]. A class of disorders known as cardiovascular diseases (CVDs) affects the heart and blood vessels, including stroke, coronary artery disease (CAD), and heart failure (HF). Atherosclerosis, a chronic inflammatory illness marked by endothelial malfunction, lipid deposition, plaque development, and thrombotic problems, is the main cause of CVDs[2] .The complexity of a medicine regimen goes beyond the sheer quantity of medications prescribed and includes dosage forms, administration instructions, dosing frequency, and specific handling needs. Patients with many chronic illnesses frequently need complicated treatment regimens, which raise the treatment burden and have a detrimental impact on medication adherence and clinical results [3]. The Medication Regimen Complexity Index (MRCI), created by George et al. in 2004, was a response to the necessity for uniform measurement [4]. The instrument includes 65 weighted items, which are broken down into: Forms of Dosage are covered under Section A. Dosing Frequency; Section B Supplementary instructions are covered in Section C. The overall MRCI score is the sum of weighted scores from each of the 17 categories. Its usefulness in identifying patients who may benefit from medication therapy management interventions has been supported by subsequent validation studies that have shown high reliability and construct validity [5, 6]. The degree to which a patient's medication-taking behavior aligns with agreed therapeutic recommendations is known as medication adherence [7]. With about half of patients in developed nations with chronic diseases not properly adhering to their prescribed treatments [8], non-adherence continues to be a major worldwide issue. The Medication Adherence Report Scale (MARS), which has been proven to be reliable, is a self-report questionnaire used to evaluate both intentional and unintentional non-adherence actions. The MARS-10 combines components of prior adherence questionnaires and has been shown to have adequate psychometric qualities across different patient groups. Later, a reduced MARS-5 version was created, which was still trustworthy, but made it easier to use in clinical settings [9]. The inverse correlation between the complexity of a medication regimen and adherence is consistently supported by evidence. Patients with type 2 diabetes mellitus had significantly lower MRCI scores, which were linked to better glycemic control and greater adherence [10].

**Literature review:**

**Desai et al. (2022)** To analyse the link between MRCI and medication adherence, we performed a systematic review and meta-analysis of 12 trials including 15,432 patients with Type 2 Diabetes Mellitus. The study discovered a strong inverse relationship, with greater regimen complexity associated with poorer adherence (OR = 0.7, $p < 0.01$). Treatment complexity and adherence were both decreased by changes in polypharmacy and comorbidities. The authors came to the conclusion that regularly monitoring MRCI and simplifying medication regimens could enhance adherence and clinical outcomes in individuals with type 2 Diabetes [11].

**Ahmad et al. (2020)** To explore the link between MRCI and medication adherence, a cross-sectional study was conducted on 250 patients with type 2 diabetes. According to the study, there was a strong inverse correlation between adherence and the complexity of the regimen ($p < 0.001$). A patient's likelihood of noncompliance was 2.5 times greater if their MRCI score was higher than 7 (OR = 2.5; 95% CI: 1.5–4.2). The authors came to the conclusion that greater medication regimen complexity is an independent predictor of non adherence and suggested simplifying treatment plans to enhance glycaemic control [(12)].

**Ayele et al. (2020)** In order to determine the correlation between medication adherence and the Medication Regimen Complexity Index (MRCI), we carried out cross-sectional research in Ethiopia among 200 patients with Type 2 Diabetes Mellitus, utilizing MMAS-8. The study discovered a strong inverse correlation between regimen complexity and compliance ($p < 0.001$). Patients with an MRCI score of >7 were three times more likely to be non-adherent (OR = 3.2; 95% CI: 1.8–5.6). The results highlight that reducing the complexity of medication regimens may increase adherence and glycaemic management in people with T2DM [(13)].

**Das et al. (2020)** To evaluate the effect of simplifying the medication regimen on adherence, a prospective cohort experiment was carried out with 250 patients suffering from T2DM. The MRCI was evaluated at baseline and again six months later. Simplification resulted in a notable 12% increase in adherence, according to the study ($p < 0.05$). According to the results, simplifying the treatment plan and providing patient education improves long term medication compliance [(14)].

**Gao et al. (2020)** to assess pharmacist-led MRCI evaluation, we performed a randomized controlled trial involving 300 people with type 2 diabetes mellitus. Patients who had a planned medication review had an 18% higher adherence rate than those receiving conventional treatment ($p < 0.01$). In addition, the intervention group showed improvements in blood pressure, LDL cholesterol, and HbA1c. According to the research, a pharmacist-led MRCI evaluation dramatically improves medication adherence and cardiometabolic results for patients with T2DM [(15)].

**Huang et al. (2020)** conducted a randomized controlled experiment to evaluate pharmacist-led MRCI-guided interventions in people with T2DM. In comparison to conventional treatment, the intervention group experienced a notable 25% decrease in the complexity of their medication plan ($p < 0.001$). Lower MRCI ratings were accompanied by better compliance. Improved blood pressure management and greater patient contentment were among the secondary outcomes. The integration of pharmacist-led deprescribing into chronic illness care is supported by the research [(16)].

**Kumar et al. (2020)** To investigate the relationship between medication regimen complexity and non-adherence, a cross-sectional survey of 500 patients with Type 2 Diabetes Mellitus was carried out. They discovered that higher regimen complexity was significantly linked to greater non-adherence using the MRCI (OR = 1.4, $p < 0.05$). Patients with complicated regimens were 1.4 times more likely to be noncompliant. Complexity was mostly brought on by the frequency of dosages and the burden of tablets. The research emphasizes the need to make routines easier in order to enhance adherence results [(17)].

**Lee et al. (2020)** In a randomized controlled trial involving 400 individuals with type 2 diabetes, Lee et al. discovered that pharmacist-led interventions considerably decreased the complexity of medication regimens. The MRCI scores for the intervention group decreased by 25% ($p < 0.001$). In contrast to the control group, medication adherence increased by 22% ($p < 0.01$). Moreover, the intervention group's systolic blood pressure fell more, and its overall level of patient satisfaction was much greater. In general, pharmacist-led treatment enhanced clinical results, adherence, and regimen simplicity [(18)].

**Nguyen et al. (2020)** carried out a multinational cross-sectional study in the Asia-Pacific area to investigate how the complexity of the medication regimen affects adherence in individuals with T2DM. According to the research, there was a significant correlation between higher MRCI scores and greater non-adherence (OR = 1.3, $p < 0.05$). Complex regimens had a greater impact on patients with several comorbidities. The results highlight the necessity for customized medication simplification approaches to increase adherence in individuals with T2DM who have several comorbidities [(19)].

**O'Connor et al. (2020)** carried out a multinational cross-sectional study in the Asia-Pacific area to investigate how the complexity of the medication regimen affects adherence in individuals with T2DM. According to the research, there was a significant correlation between higher MRCI scores and greater non-adherence (OR = 1.3, $p < 0.05$). Complex regimens had a greater impact on patients with several comorbidities. The results highlight the necessity for customized medication simplification approaches to increase adherence in individuals with T2DM who have several comorbidities [(20)].

# Methodology:

### STUDY DESIGN:

Cross – sectional, Analytical study.

**STUDY SITE:**

The study was conducted at the Cardiology Department of Vivekanandha Medical Care Hospital (VMCH) in Elayampalayam, Tiruchengode, Namakkal District. Tamil Nadu, India.

**ETHICAL COMMITTEE APPROVAL:**

The proposed study was approved by Institutional Ethical Committee of Vivekanandha Medical Care Hospital

**STUDY DURATION:**

The study was conducted over a period of six months.

**STUDY POPULATION:**

Total of 122 patients were screened and included in the study after getting patient's consent and the required data

was collected in the specially designed case analysis form.

**SAMPLE SIZE:**

MULTIVARIABLE LOGISTIC REGRESSION =$\boldsymbol{EPV}\times\boldsymbol{K}/\boldsymbol{P}(\boldsymbol{event})$

N=Sample Size.

k= No. of. Predictors (MRCI + 5 Covariate)

EPV=Events per variable

P=expected proportion with outcome (Non – adherence) using EPV rule for multivariable logistic regression.

N = EPV×K/P (event)

=10 × 6/0.40 N

=150 (Approx.)

Allowing for 10% incomplete data, the final feasible sample size is = 170 participants

**SELECTION CRITERIA**

**INCLUSION CRITERIA**

• Adult patients (≥ 18 years) diagnosed with type 2 diabetes mellitus and cardiovascular disease.

• Patient who has been in treatment for at least 3 months.

• Patients who are willing to participate and provide informed consent for the study.

• Patients with additional comorbidities are included.

**EXCLUSION CRITERIA**

• Patients with type 1 diabetes mellitus, gestational diabetes.

• Patients with incomplete medical records.

• Pregnant or breastfeeding women.

• Patients with medication regimen changes within past 4 weeks.

**Data Collection:**

Patient demographic and clinical data were collected from medical records and patient interviews. The collected variables included:

- Age
- Gender
- Duration of diabetes
- Duration of cardiovascular disease
- HbA1c
- Fasting blood glucose
- Postprandial blood glucose
- Medication regimen details
- Medication adherence score

**Statistical Analysis:**

Datas were analyzed using IBM SPSS version 31. Spearman's rank correlation coefficient (ρ) was used to assess associations between MRCI, medication adherence (MARS-10), and relevant demographic and clinical variables. A p-value < 0.05 was considered statistically significant.

## Results:

**Age wise distribution of the study population:**

According to the data, the majority of respondents are in the 51–70 age range, with the 61–70 age groups having the greatest proportion. A large portion of the research participants are older people and younger age groups are underrepresented. The study seems to be mostly concerned with older and senior individuals.

**Table1: Age wise distribution of the study population**

| S. no | Age (year) | No. Of. Patients (n=122) | PERCENTAGE (%) |
|---|---|---|---|
| 1. | 30 -40 | 1 | 0.83% |
| 2. | 41 – 50 | 12 | 9.92% |
| 3. | 51 – 60 | 40 | 33.06% |
| 4. | 61 – 70 | 41 | 33.88% |
| 5. | 71 – 80 | 22 | 18.18% |
| 6. | 81 -90 | 6 | 4.96% |

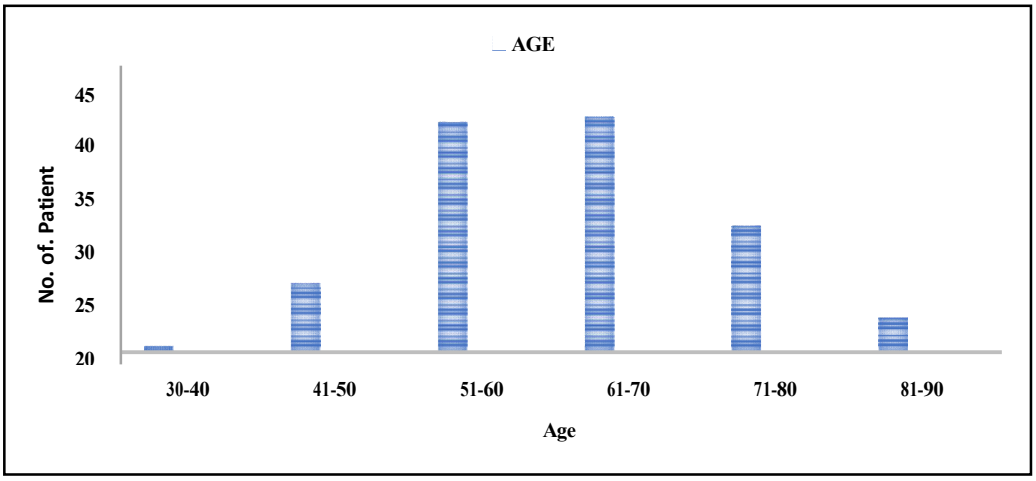



**Fig 1: Age wise distribution of the study population**

**Gender Wise Distribution of the study population:**

With 55.4% of the total sample consisting of men, 44.6% of women, the pie chart displays the gender-wise breakdown of the participants.

**Table 2: Gender wise Distribution of the Study Population**

| S. no | Gender | No. of. Patients (n=122) | Percentage (%) |
|---|---|---|---|
| 1. | Male | 68 | 55.4% |
| 2. | Female | 54 | 44.6% |

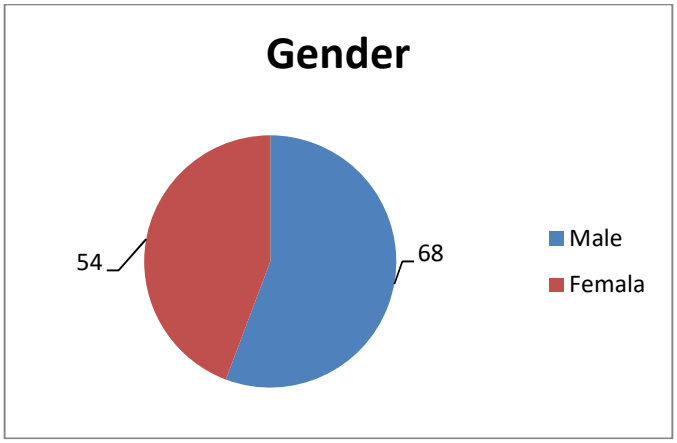



**Fig 2: Gender Wise Distribution of the Study Population**

## SOCIODEMOGRAPHIC DETAILS:

### Education-Based distribution of the study population:

The participants' educational background is shown in the diagram; with the majority of patients were postgraduates (54.5%), a smaller proportion 6-12$^{th}$ STD (0.8%).

**Table 3: Education –Based distribution of the Study Population**

| S. NO | Education | No. of. Patients (n= 122) | Percentage (%) |
|---|---|---|---|
| 1. | Uneducated | 43 | 35.5% |
| 2. | 6-12$^{th}$std | 1 | 0.8% |
| 3. | Diploma | 9 | 7.4% |
| 4. | UG | 2 | 1.7% |
| 5. | PG | 66 | 54.5% |

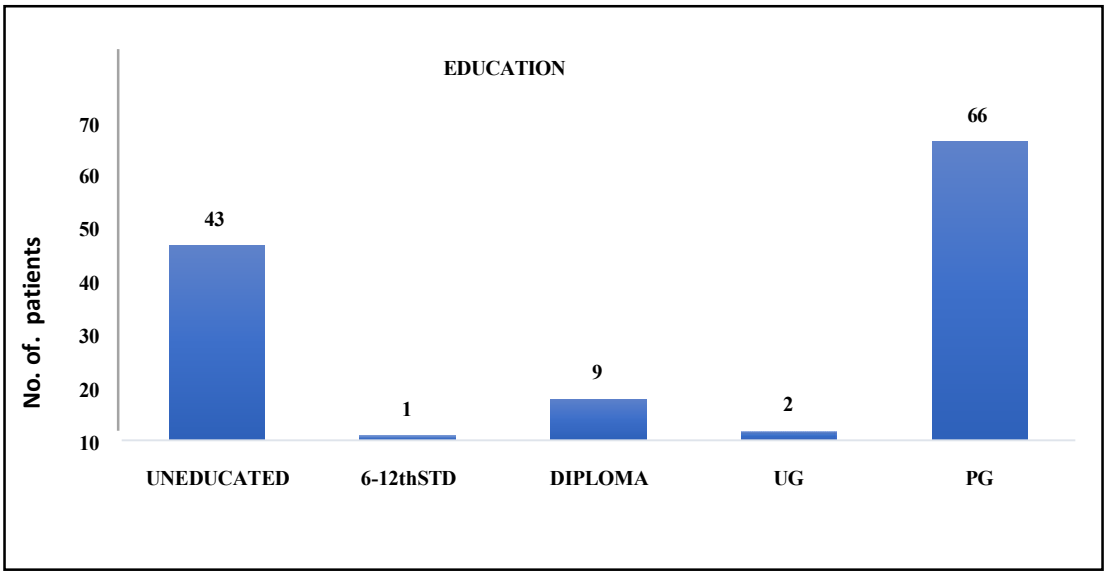



**Fig. 3: Education –Based distribution of the Study Population**

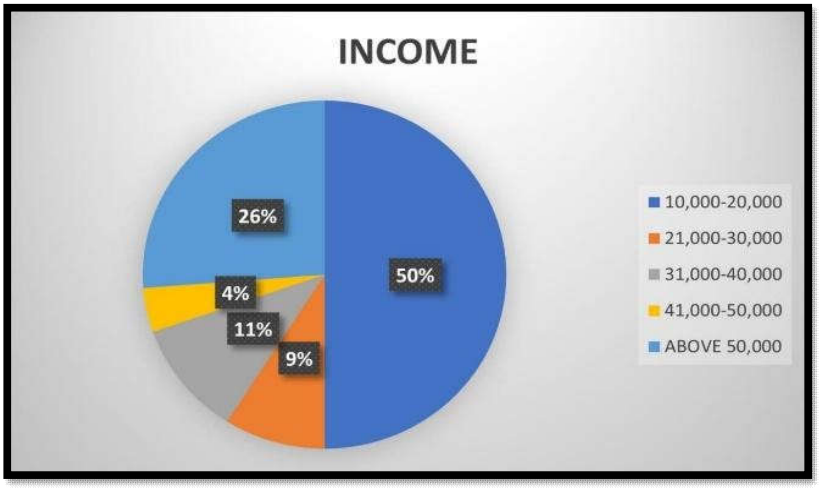
**Monthly income-Based distribution of the Study Population:**

A smaller percentage of the participants belong to higher income categories, whereas half of them are in the ₹10,000–₹20,000 income range.

**Table 4: Monthly income –Based distribution of the Study Population**

| S. no | Monthly income | No. of. Patients (n=122) | Percentage (%) |
|---|---|---|---|
| 1. | 10000 -20000 | 61 | 50% |
| 2. | 21000 -30000 | 11 | 9% |
| 3. | 31000 -40000 | 13 | 11% |
| 4. | 41000 -50000 | 5 | 4% |
| 5. | Above 50000 | 32 | 26% |

**Fig 4: Monthly income-Based distribution of the Study Population**




## CLINICAL DETAILS:

**Duration of Type 2 DM– Based distribution duration of the study population:**

The distribution reveals that 72% of individuals have Type 2 diabetes for more than five years, suggesting a high rate of long-term illness.

**Table 5: Duration of Type 2 DM– Based distribution duration of the study population:**

| S. no | Duration | No. of. Patients (n=122) | Percentage (% ) |
|---|---|---|---|
| 1. | 1 Year | 9 | 7.38% |
| 2. | 2 Years | 27 | 22.13% |
| 3. | 3 Years | 18 | 14.75% |
| 4. | 4 Years | 16 | 13.11% |
| 5. | 5 Years | 8 | 6.56% |
| 6. | Above5 years | 44 | 36.07% |

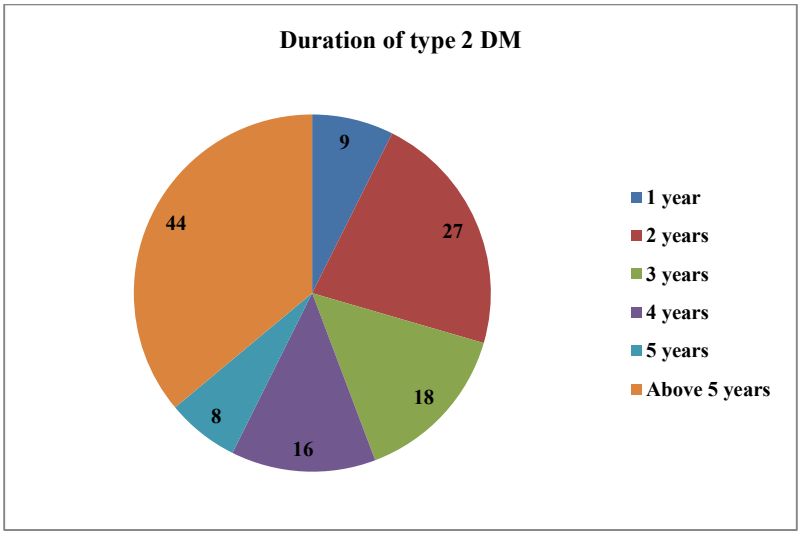



**Fig 5: Duration of Type2 DM–Based distribution duration of the study Population**

**Duration of Cardio Vascular Disease – Based distribution of the study population:**

In the present study, most patients had CVD for more than 5 years, indicating a predominance of long-term disease in the study population.

**Table 6: Duration of CVD–Based distribution of the study population:**

| S. no | Duration of CVD | No. of. Population (n=122) | Percentage (%) |
|---|---|---|---|
| 1. | 1 Year | 2 | 1.64% |
| 2. | 2 Years | 4 | 3.28% |
| 3. | 3 Years | 8 | 6.56% |
| 4. | 4 Years | 4 | 3.28% |
| 5. | 5 Years | 16 | 13.11% |
| 6. | Above5 years | 88 | 72.13% |

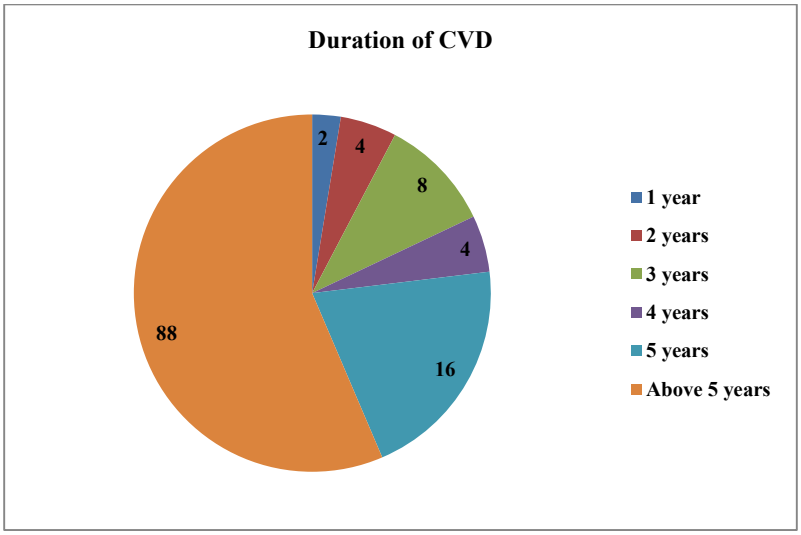



**Fig 6: Duration of CVD–Based distribution of the study Population**

## LABORATORY INVESTICATION:

### HbA1C:

A significant portion is classified in the high HbA1c range, whereas only minimal fraction exhibits slow HbA1c levels. In general, the majority of individuals in the study exhibit normal blood sugar levels, although there is a significant occurrence of high HbA1c among this population.

**Table 7: HbA1C– Based distribution of the study population**

| S. no | Range | No. of. Patients (n=122) | Percentage (%) |
|---|---|---|---|
| 1. | Low | 23 | 18.85% |
| 2. | Normal | 54 | 44.26% |
| 3. | High | 45 | 36.89% |

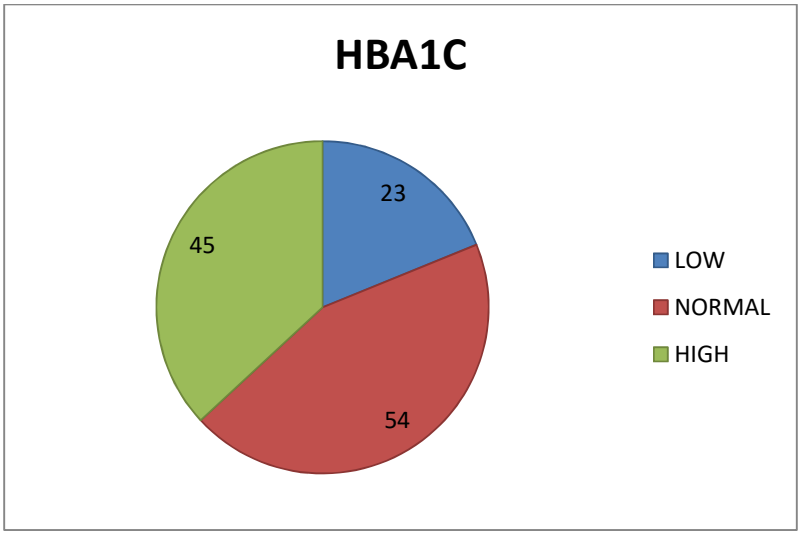



**Fig 7:HbA1C-Based distribution of the study population**

**FBS AND PPBS:**

Postprandial blood sugar (PPBS) values are mostly within the normal range, while fasting blood sugar (FBS) levels are most often found in the higher range. In either case, the lowest group represents the least fraction. Generally speaking, high fasting blood glucose readings are seen more often than high postprandial blood glucose levels.

**Table 8: FBS AND PBBS-Based distribution of the study population**

| S. no | Range | FBS | Percentage (%) | PPBS | Percentage (%) |
|---|---|---|---|---|---|
| 1. | Low | 12 | 9.84% | 26 | 21.31% |
| 2.. | Normal | 48 | 39.34% | 61 | 50.00% |
| 3. | High | 62 | 50.82% | 35 | 28.69% |

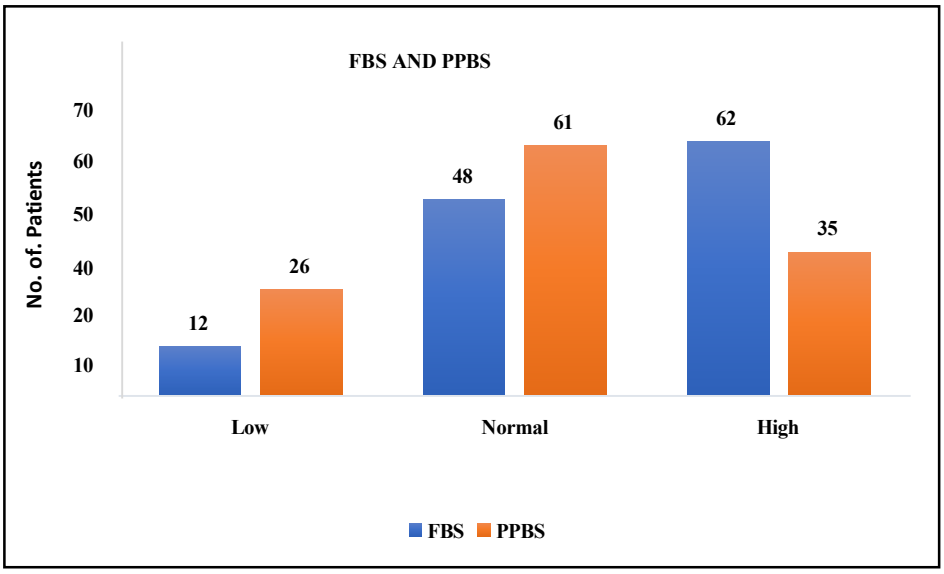



**Fig 8: FBS AND PPBS-Based on distribution of the study population**

**MRCI Scoring:**

The pie chart indicates that most participants have a moderate level of complexity in their medication regimens, which accounts for the largest share. A lower percentage exhibits low complexity, whereas high complexity represents the smallest share. In general, the majority of patients are following medication plans that are of moderate complexity.

**Table 9: MRCI-Based distribution of the study population**

| S. no | MRCI Category | No. of. Patients (n=122) | Percentage |
|---|---|---|---|
| 1. | Low complexity | 22 | 15.7% |
| 2.. | Moderate complexity | 80 | 66.1% |
| 3. | High complexity | 19 | 15.7% |

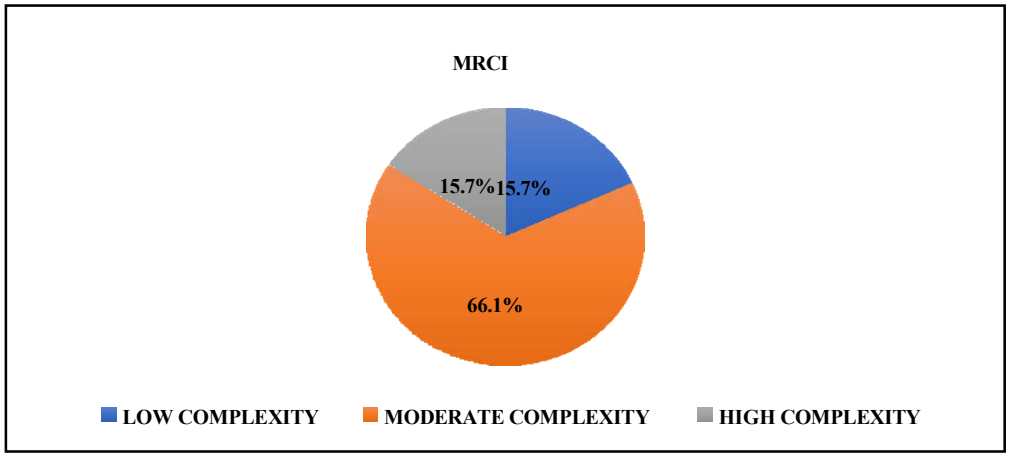



**Fig 9: MRCI -Based distribution of the study population**

**Medication adherence**

The chart indicates that most participants exhibit strong adherence, accounting for the largest share. In general, the majority of participants demonstrate strong adherence to their medication regimen.

**Table.10 Medication adherence –Based distribution of the study population**

| S. no | Adherence | No. of. Patients (n=122) | Percentage (%) |
|---|---|---|---|
| 1. | Low adherence | 2 | 0.8% |
| 2. | Medium adherence | 9 | 7.4% |
| 3. | High adherence | 111 | 91.7% |

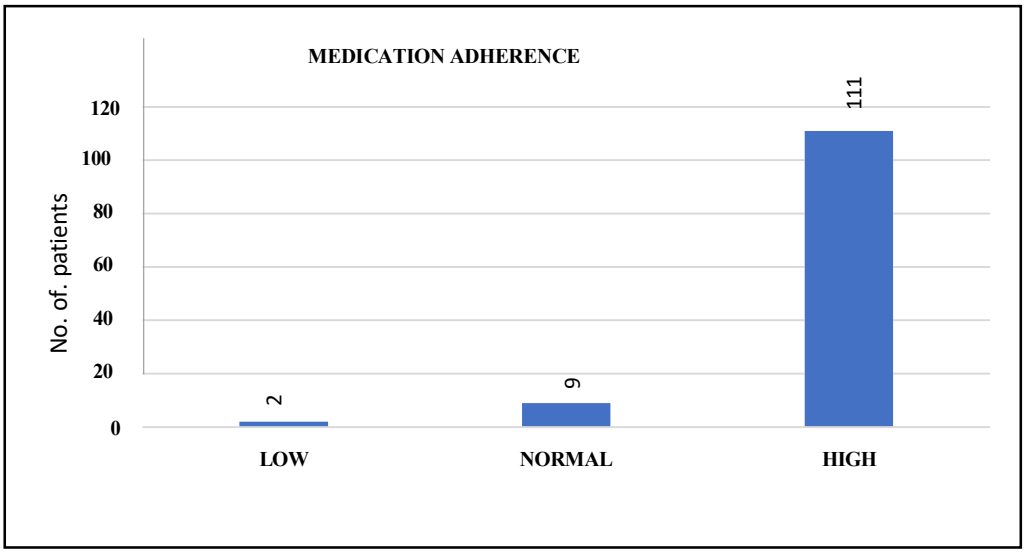



**Fig 10 Medication adherence – Based distribution of the study population**

**Discussion:**

Both Type 2 Diabetes Mellitus (T2DM) and cardiovascular disease (CVD) require lifestyle adjustments and long-term pharmacotherapy, medication adherence is a key factor in their treatment. Due to the increased number of pills, dosage frequency, and administration instructions, it is widely assumed that a more complicated medication schedule has a detrimental impact on adherence. But in this work, there was no statistically significant link between medication adherence and MRCI scores. There are a number of reasons for the lack of a strong connection. Patients with chronic illnesses, like T2DM and CVD, may have adjusted to complicated regimens over time, particularly if they have been receiving ongoing medical counselling. Second, adherence behaviour is complex and impacted by psychological variables, patient beliefs, health literacy, family support, and physician-patient interaction—all of which were not directly evaluated in this study. Even if sociodemographic characteristics like education and income are frequently found to have an impact on adherence, this study found no statistically significant correlation between them. Surprisingly, there were just moderate correlations between adherence and some clinical characteristics, like the duration of CVD and blood sugar levels. Patients with extended disease duration may experience treatment fatigue, which lowers compliance. In a similar vein, inadequate glycemic management may indicate suboptimal adherence, even if the connection seems minor in this research. According to the research, medication adherence in individuals with CVD and T2DM is complicated and cannot be attributed only to the complexity of the treatment regimen. As a result, interventions intended to

increase adherence should take a holistic approach, addressing behavioural, educational rather than just concentrating on making medicine regimens simpler.

### Conclusion:

The effect of the Medication Regimen Complexity Index (MRCI) on medication adherence in patients with Type 2 Diabetes Mellitus (T2DM) and cardiovascular disease (CVD) was assessed in this observational research. The results of the analysis of 122 subjects indicated that, MRCI was not significantly related to medication adherence as determined by the MARS-10 scale. The majority of sociodemographic variables, such as income, education level, and therapy expense, did not correlate significantly with adherence. The only clinical variables that showed weak correlations with adherence were blood glucose levels and CVD duration; the number of drugs and other comorbidities, however, did not have statistically significant correlations. In conclusion, the study suggests that elements other than regimen complexity may have a greater impact on medication adherence in patients with T2DM and CVD.

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