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Quality of life and distress among diabetic patients- A Clinic based study

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Research Article

Keywords:

Posted Date: March 9th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9052468/v1

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Additional Declarations: The authors declare no competing interests.

Quality of life and distress among diabetic patients-A Clinic based study

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Diabetes mellitus is a chronic metabolic condition characterised by high blood glucose levels due to insulin secretion, action, or both. It offers substantial health challenges worldwide, affecting many groups and causing multiple complications (Antar et al., 2023). The term "diabetes" originates from the Greek word meaning "to siphon" or "to pass through," referring to the excessive urination characteristic of the condition. In Latin, "mellitus" means "sweet," highlighting the presence of high sugar levels in the urine of individuals with diabetes. It is one of the most common and rapidly developing diseases worldwide.(Hossain et al., 2024). Diabetes is characterized as Type 1, Type 2, specialized forms, and gestational diabetes. The most common type of diabetes is type 2 diabetes (T2D), which is caused by β-cell malfunction and insulin resistance. Chronic hyperglycemia can cause organ damage and raise the risk of vascular problems such as retinopathy, nephropathy, neuropathy, and cardiovascular disease(Lu X et al., 2023). The prevalence of diabetes mellitus has sharply increased over the last few decades, making it a primary global health concern. As per the International Diabetes Federation (IDF), over 537 million persons aged 20-79 had diabetes globally as of 2021, accounting for 10.5% of the adult population. It is predicted that this number would increase to 643 million by 2030 and 783 million by 2045.(Yameny et al., 2024: Sacks et al., 2023). Currently, the countries with the highest numbers of older adults diagnosed with diabetes mellitus are China (34.1 million, ~20% of all older adults), USA (11.5 million, ~21% of all older adults), India (11.0 million, ~17% of all older adults), Germany (4.9 million, ~27% of all older adults) and Brazil (4.3 million, ~22% of all older adults) (Bellary S et al., 2021).

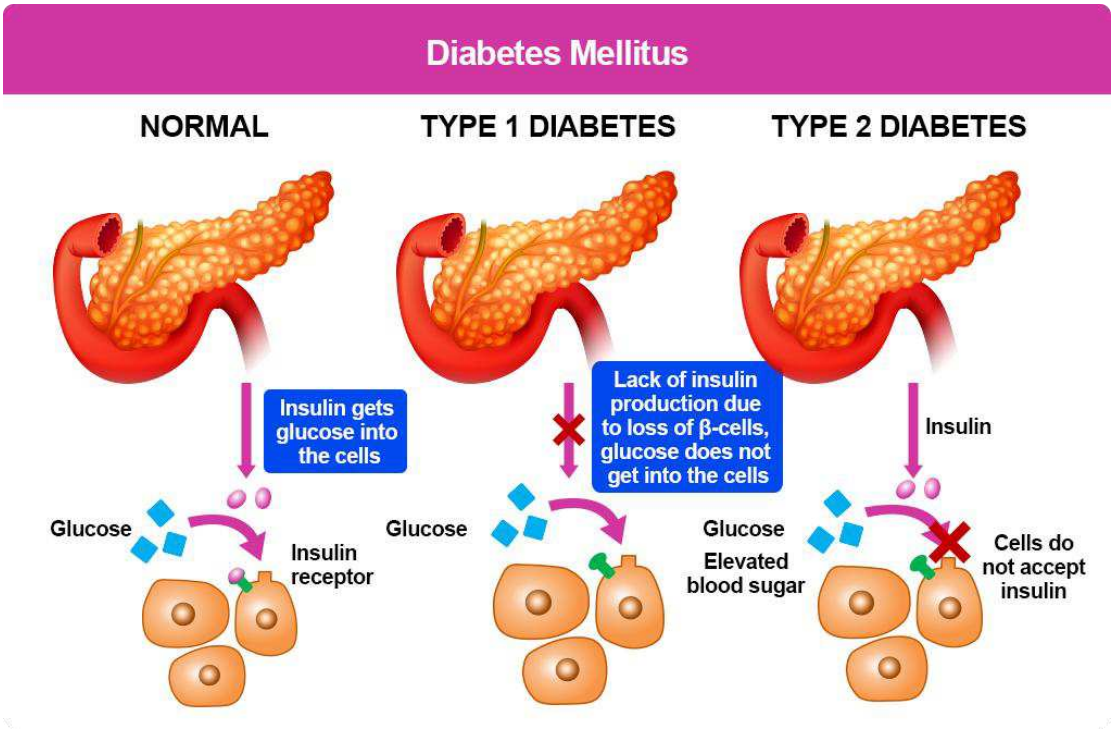


Fig. 1.Types of diabetes
(adopted from Atkinson *et al*., 2023)

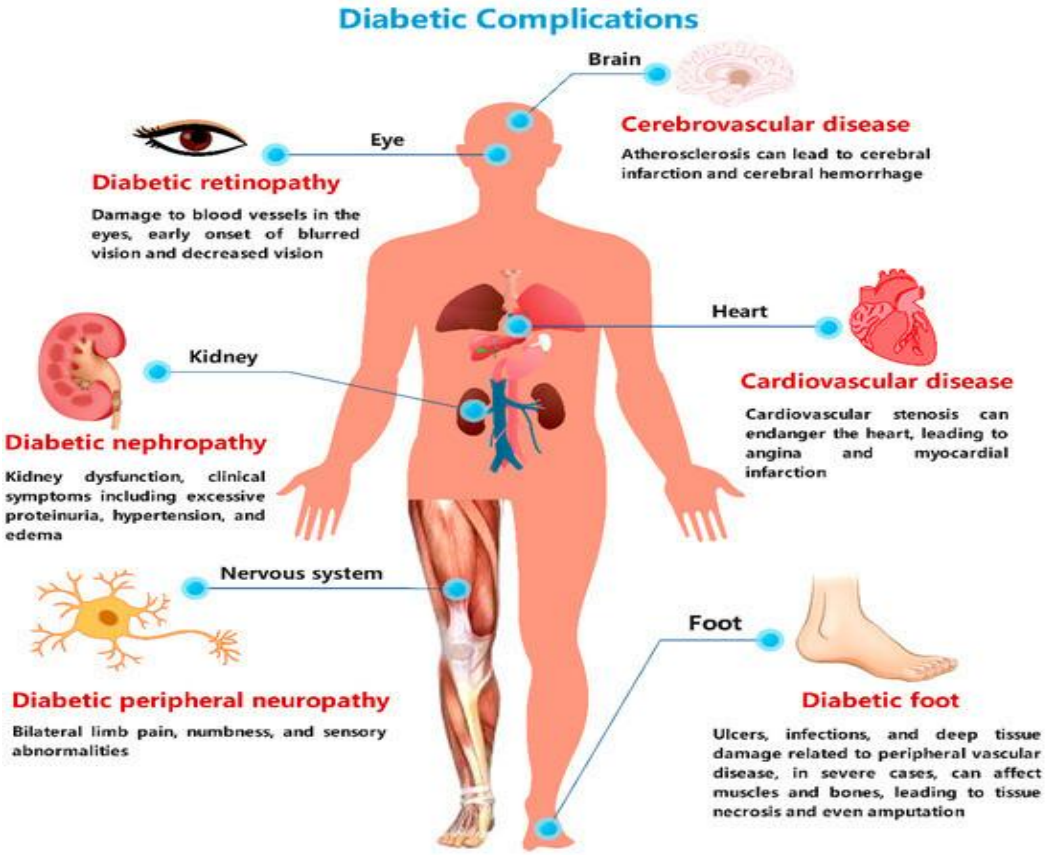


Fig. 2. Complications of diabetes (adopted Zhang *et al.,* 2024)

The World Health Organization defines medication adherence as "the degree to which the person's behavior corresponds with the agreed recommendations from a healthcare provider" (Jimmy B et al., 2011). The eight-item Morisky Medication Adherence Scale (MMAS-8) is a structured self-report measure of medication-taking behavior. It was developed from a previously validated four-item scale and supplemented with additional items addressing the circumstances surrounding adherence behavior. MMAS-4 has four items, whereas MMAS-8 has eight items. Both MMAS-4 and MMAS-8 are tools used to assess medication adherence; the most obvious difference is the number of items in each scale (Huang et al., 2021; Laghousi et al., 2021).

Quality of Life (QOL) is a broad and multidimensional concept that reflects an individual's overall well-being, encompassing not only physical health but also psychological state, level of independence, social relationships, personal beliefs, and their interaction with the environment. It provides a holistic view of a person's life as perceived by themselves within the context of their culture and value systems. The World Health Organization (WHO) defines QoL as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns." This subjective evaluation highlights that QoL is not merely the absence of disease but is influenced by a range of factors, both internal and external, including emotions, cognitive functioning, social support, financial security, and physical surroundings. While often used interchangeably with similar terms like "standard of living," QoL is more comprehensive, extending beyond material wealth to include emotional, spiritual, and social well-being. It is also important to distinguish QoL from health-related quality of life (HRQoL), which is a subset focusing specifically on how an individual's health status affects their ability to live a fulfilling life(Veenhoven et al., 2024; The WHO 2025).

Diabetes distress refers to the emotional and psychological challenges that arise specifically from living with and managing diabetes. Unlike clinical depression or generalized anxiety, DD is uniquely rooted in the day-to-day burden of diabetes care. Individuals may experience persistent worry, frustration, or even emotional burnout while trying to meet the demands of self-management, including regular blood glucose monitoring, dietary restrictions, medication adherence, fear of complications, and long-term lifestyle changes. Rather than being a generalized low mood, diabetic distress centers around diabetes-related concerns, such as fear of hypoglycemia, frustration over fluctuating blood sugar levels, difficulty navigating healthcare systems, and interpersonal stress related to living with a chronic condition (Sinha et al., 2024). It is a dynamic condition that may fluctuate over time and is often influenced by changes in health status, personal support systems, or life circumstances. High levels of DD have been strongly associated with poor glycemic control, reduced self-care behaviors, diminished quality of life, increased risk of complications, and higher healthcare costs (Fisher et al., 2007; Sinha et al., 2024; Perrin et al., 2017). It is crucial to distinguish DD from depression, though they may coexist. While both can impact emotional well-being, DD requires diabetes-specific interventions that address the unique psychological stressors faced by people with diabetes. Prevalence estimates of DD vary globally, with rates ranging from 18% to 35% (Fisher et al., 2007). In India, although comprehensive data remains limited,

a study conducted in Chennai found the prevalence of DD among T2DM patients to be as high as 61.3% (Natesan et al., 2016).Up to 36% of patients with type 2 diabetes mellitus experience diabetes distress (Perrin et al., 2017; Polonsky et al., 1995).

The DDS17 is a widely used, 17-item questionnaire that evaluates distress over the past month across four domains: emotional burden, physician-related distress, regimen-related distress, and interpersonal distress. Scoring: Each item is rated on a 6-point Likert scale (1 = not a problem to 6 = a severe problem).Interpretation: Average item score? 3 indicates moderate to high distress and may warrant clinical attention (Schmitt et al., 2015).

The DDS-17 is a validated instrument developed by Polonsky et al. (2005) to assess emotional distress associated explicitly with living with and managing diabetes. Unlike general psychological tools, the DDS-17 targets the diabetes-specific burdens that patients may experience in their daily lives, making it especially useful in both clinical practice and research involving people with type 2 diabetes mellitus. This 17-item scale is designed to evaluate the emotional impact of diabetes self-management, interactions with healthcare providers, treatment regimens, and social support systems. It provides insights into how patients feel about their disease and its demands.

1.11.2.3 Scoring and Interpretation Sub-scale scores are calculated by averaging the items within each domain. The Total DDS-17 score is the mean of all 17 items. No items are reverse-scored. Table 1.11.2.3.Interpretation of Scores Score Range Interpretation < 2.0 2.0- 2.9? 3.0 Little or no distress Moderate distress High distress Scores? 3.0 on any sub-scale or total score is considered indicative of clinically meaningful diabetes-related distress and suggests the need for psychological support or behavioral interventions. The DDS-17 has been extensively used in both cross-sectional and interventional studies involving patients with type 2 diabetes. It helps identify the specific areas where patients experience the most distress, thereby enabling healthcare professionals to offer personalized emotional and behavioral support. It is beneficial for uncovering hidden emotional struggles that may otherwise go unrecognized in standard clinical assessments (Polonsky et al., 2005; Fisher et al., 2008).

Diabetes is a highly prevalent metabolic disorder in developed and developing countries. Because of the high prevalence of diabetes and associated complications, assessing patients' medication adherence and quality of life is crucial. Medication adherence was found to be sub-optimal among people with diabetes because of their complex treatment regimens, high medication costs, and lack of awareness about the disease and its management. Poor communication with healthcare providers and limited access to care can contribute to non-adherence. Low adherence to prescribed diabetic medications causes therapeutic failure, causing lower QoL. Thus, evaluating medication adherence and diabetes-specific QoL is crucial among chronic diabetic patients. Psychological factors like distress and depression further reduce motivation to adhere. Diabetic distress negatively impacts patients by increasing emotional burden, which reduces motivation for self-care and medication adherence. High distress levels may lead to poorer glycemic control, diabetes-related complications, and lower quality of life. Addressing the diabetes distress may improve patients' overall health. The present study addresses the emotional and psychological challenges faced by patients with long-term diabetes.

Study design Methodology: A cross-sectional study was conducted to assess medication adherence, quality of life, distress, and prescribing patterns among diabetes patients. Study site: The study was conducted in the department of diabetology, Care Diabetes Centre, Hanamkonda, Telangana state. Study period: The study was conducted from September 2024 to March 2025 for a duration of about six months. Ethical consideration. This study was conducted after ethical clearance and approval were obtained from the Institutional Ethics Committee of the Department of Pharmacy Practice, Care College of Pharmacy, Hanamkonda, India. The objective of this study was explained to the participants in brief. Patients who have given verbal consent are included in the study. Information confidentiality was preserved by eliminating personally identifiable information. Study criteria: Inclusion Criteria: Patients agreed to participate in the study and were willing to respond to the questionnaire. Patients of either sex of any age group with diabetes. Diabetic patients with retinopathy, nephropathy, and neuropathy complications. Currently using insulin or at least one oral antidiabetic agent. Ability to communicate with the prepared questionnaire. Exclusion Criteria: Patients who do not agree to participate, Patients lacking sufficient information about their medication history. Patients with psychological impairments and cognitive defects.

Source of data Methodology Prescriptions of study participants were reviewed, patients and their caregivers were directly contacted, and laboratory and diagnostic data were collected. Methodology: Patients with type 2 DM who visited the endocrinology department after carefully examining the eligibility criteria were included in the study. The following data was collected. 1. Assessment of Socio-Demographic Data Socio-demographic information was collected using a structured questionnaire administered during patients' routine visits. Variables included age, gender, marital status, education level, occupation, monthly income, duration of diabetes, family history of type 2 diabetes, presence of comorbidities (e.g., hypertension, dyslipidemia), and body mass index (BMI). 2. Assessment of Prescribing Patterns. Prescribing patterns were evaluated by reviewing each participant's case sheet. Prescribed drug class and number of oral antidiabetic drugs (such as metformin, sulfonylureas, DPP 4 inhibitors, SGLT2 inhibitors), insulin regimens (type, dose, and frequency), and any adjunctive therapies (e.g., antihypertensives, statins) were recorded. The prevalence of combination therapy and polypharmacy was noted. 3. Assessment of Medication Adherence Medication adherence was measured using the eight-item Morisky Medication Adherence Scale (MMAS 8). The first seven items were answered "yes" or "no" (scored 0 for "yes," 1 for "no"), and the eighth was a five-point Likert question (scored 1 for the most adherent response, zero otherwise). Total scores ranged from 0 to 8, with < 6 indicating low adherence, 6-7 moderate adherence, and eight high adherence. This tool evaluates patients' self-reported adherence behaviors and highlights barriers to medication usage. 4. Assessment of Quality of Life Quality of life was assessed using the WHOQOL BREF instrument, which covers four domains: physical health, psychological well-being, social relationships, and environmental factors. Each domain comprises multiple items rated on a five-point Likert scale; raw scores were transformed to a 4-20 scale (higher scores = better QoL). The analysis focuses on identifying the domains that were mainly affected by diabetes.

Assessment of Diabetic Distress: Diabetes specific emotional distress was evaluated with the 17-item Diabetes Distress The DDS-17 is a validated instrument developed by Polonsky et al. (2005). Patient can rate each item from 1 ("no problem") to 6 ("a severe problem"). Mean scores were calculated for four sub-scales (emotional burden, physician-related distress, regimen-related distress, and interpersonal distress) and overall distress. Scores? 3.0 indicates clinically significant distress.

6.1. Socio-Demographic characteristics of study participants

The study involved 208 participants diagnosed with T2DM, each having different socio-demographic characteristics. In terms of age, the largest group of participants, 60.1% (125), were between 40 and 60 years old, 25.4% (53) participants were over 60 years old, and only 14.5% (30) were under 40. Looking at gender, most participants were male, 60.1% (125), while female participants were 39.9% (83). Regarding residence, 64.5% (134) of participants lived in rural areas, while 35.5% (74) lived in urban areas. The majority of participants, 69.8% (145), had no formal education. Only 30.2% (63) were educated. Most participants were married, 99.6% (07).

Among 208 participants, 98.1% (204) followed a mixed diet. Only 1.9% (4) followed a vegetarian diet. Occupationally, 31.7% were agriculture workers and homemakers each. Others included business 14.5% (30), employed 16.4% (34), and retired 5.7% (12). Social habits showed 35.2% (73) drank alcohol, 1.9% (4) smoked, and another 1.9% (4) did both, while 61% (127) had no such habits. (Table 6.1.)

6.2. Clinical Characteristics of Study Participants

Regarding BMI 40% (83) fell between 18.5 and 24.9 kg/m^{2}, while 38.4% (80) were overweight, with a BMI between 25 and 29.9 kg/m^{2},16.3% (34) were obese (BMI> 30), and 5.3% (11) had a BMI below 18.5 and were underweight.

As for HbA1c levels, 21.1% (44) of participants had HbA1c ?6.5% and 44.8% (93) had HbA1c levels between 6.6% and 8.0%. 22.1% (46) had levels between 8.1%

and 10%, and 12% (25) had HbA1c levels above 10%,

The duration of diabetes among participants was 42.3% (88), who had diabetes for less than 5 years, while 26.9% (56) had diabetes for 6 to 10 years. 14.9% (31) for 11-15 years,

7.7% (16) for 16-20 years, and 8.2% (17) for more than 20 years.

Fasting blood sugar, 60.1% (125) of participants had elevated levels >126 mg/dL, 32.3% (67) had 101-125 mg/dL, while 7.6% 16) had <100 mg/dL. (Table 6.2.).

6.3. Presence of Comorbidities in Study Participants

Among 208 participants, single comorbidities are hypertension 19.2% (40), Hyperlipidemia 5.3% (11), obesity 6.25% (13), hypothyroidism 1.44% (3), bronchial

asthma 1.92% (4), bilateral renal calculi 1.44% (3), acid peptic disease 0.96% (2), cervical spondylitis 0.48% (1), pancreatitis 0.96% (2), hepatitis 0.48% (1), stroke 0.48% (1) and osteoarthritis 0.48% (1).

The most common dual comorbidity is HTN + hyperlipidemia 8.65% (18) and followed by HTN + obesity 4.8% (10), HTN + CAD 3.82% (8), HTN + hypothyroidism 2.4% (5), hyperlipidemia + obesity 1.44% (3), and less common dual comorbidities are HTN + renal calculi 0.48% (1), HTN + anemia 0.48% (1), HTN + asthma 0.48% (1), HTN + fatty liver 0.48% (1), hyperlipidemia + cerebral atrophy 0.48% (1) and hyperlipidemia + myasthenia gravis 0.48% (1).

In the present study triple comorbidities are HTN + hyperlipidemia + obesity 2.9% (6), HTN + hyperlipidemia + hypothyroidism 1.44% (3) and HTN + obesity + APD 1.9% (4) are mostly common and followed by HTN + hyperlipidemia + CAD 0.48% (1), HTN + obesity + OA 0.48% (1), HTN + hyperlipidemia + OA 0.48% (1) and hyperlipidemia + hypothyroidism + obesity 0.48% (1) are less reported. A small number of participants had quadruple comorbidities, HTN + hyperlipidemia + hypothyroidism + obesity, 0.48% (1).

Other rare combinations of quadruple comorbidities included HTN + hyperlipidemia+ hypothyroidism + fatty liver 0.48%(1), and HTN + hyperlipidemia + obesity + fatty liver 0.48% (1), HTN + obesity + APD + CAD 0.48% (1), HTN + obesity + APD + bronchial asthma 0.48% (1), HTN + hyperlipidemia + obesity + APD 0.48% (1). Despite the presence of these complex comorbidities, 17.9% (37) of the participants had no comorbidities other than T2DM (Table 6.3).

6.4. Presence of Complications in Study Participants

Among the 208 participants in this study, a total of 108 individuals (51.9%) were found to have one or more complications related to T2DM. At the same time, 100 participants (48.1%) had no complications. Out of those with complications, 93 participants (44.7%) had single complications. The most commonly reported single complication was DKD, affecting 44 participants (21.1%), followed by neuropathy in 30 participants (14.4%), retinopathy in 8 (3.8%), diabetic foot in 7 (3.3%), and one case each of PVD and stroke (0.48% each).

Additionally, 15 participants (7.2%) experienced dual complications, Neuropathy with DKD in 9 participants (4.5%). Other dual combinations included neuropathy with retinopathy and neuropathy with stroke in 2 participants each (0.96%), and one case each (0.48%) of neuropathy with PVD, DKD with stroke, and DKD with retinopathy (Table 6.4).

6.5. Prescribing Patterns in Study Participants

Among the 208 participants, the majority were prescribed multiple medications as part of their diabetes management. Most participants, 78.84% (164), received more than four

drugs per prescription, while 20.2% (42) were prescribed three to four drugs, and only 0.96% (2) received just one to two drugs. 54.3% (113) of participants were on two OHAs, while 31.7% (66) were receiving one OHA, and 9.6% (20) were prescribed three OHAs. Only 9 participants(4.4%) did not receive any OHA. Regarding insulin therapy, 23.5% (49) were on one insulin, and 10.1% (21) received

two insulins, whereas 66.4% (138) were not prescribed insulin. 9.61% (20) of participants were treated with one insulin and one OHA, 10.6% (22) with one insulin and two OHAs, and 0.96% (2) with one insulin and three OHAs. Additionally, 3.36%

(7) were prescribed two insulins and one OHA, and another 3.36% (7) received two insulins along with two OHAs.

The remaining 150 participants (72.2%) were managed with either OHAs alone or insulin alone, without any combination therapy (Table 6.5).

6.5.1. Pharmacological Classes of OHAs Prescribed in Study Participants

In this study, a total of 351 oral hypoglycemic agents were prescribed to the 208 participants. DPP-4 inhibitors were the most commonly prescribed, accounting for 23.4% (82) of all OHAs, followed by sulfonylureas at 15.7% (55), and biguanides at 14.2%

(50), SGLT2 inhibitors 6.0% (21), and thiazolidinediones 2.9% (10).

When it comes to combinations, the most common prescribed were SGLT2 and DPP-4 inhibitors, 19.0% (67) of all OHA prescriptions. This was followed by biguanides with sulfonylureas, 15.4% (54). Less common combinations included biguanides with DPP-4 inhibitors 0.85% (3), SGLT2 with biguanides 0.85% (3), and a triple combination of SGLT2 inhibitors, DPP-4 inhibitors, and biguanides 1.7% (6) (Table 6.5.1).

6.5.2. Types of Insulin Prescribed in Study Participants

Among the 208 study participants, a total of 71 insulin prescriptions were listed. The most commonly prescribed type was pre-mixed insulin, accounting for 60.6% (43) of all insulin prescriptions. This was followed by short-acting insulin, which was used in 21.1% (15), Long-acting insulin 9.85% (7), while intermediate-acting insulin was prescribed to 5.65% (4) of participants, and rapid-acting insulin was the least used, with only 2.8% (2) of participants receiving it.

6.5.3. Oral Hypoglycemic Agents Prescribed in Study Participants

In this study, a total of 351 oral hypoglycemic agents were prescribed among the 208 participants. Among individual drugs, linagliptin was the most commonly prescribed, 14.9% (52), followed by metformin, 14.3% (50), and glimepiride, 11.7% (41). Other commonly used agents are sitagliptinn8.5% (30), gliclazide 4.0% (14), dapagliflozin 6.0% (21), and pioglitazone 2.9% (10).

Fixed-dose combinations were also used. The most common was dapagliflozin with sitagliptin, accounting for 19.1% (67) of all OHA prescriptions. This was followed by metformin with glimepiride 8.8% (31) and metformin with gliclazide 6.6% (23). Other

combinations are metformin with sitagliptin 0.9% (3), dapagliflozin with metformin 0.9% (3), and triple-drug combinations such as dapagliflozin, metformin, and sitagliptin 1.1% (4), and dapagliflozin, metformin, and vildagliptin 0.6% (2)

(Table 6.5.3).

6.5.4. Concomitant Drugs Prescribed in Study Participants

In this study, a total of 791 drugs other than antidiabetics were prescribed among the

208 participants. Among individual drugs, atorvastatin was the most frequently prescribed, 13.5% (106), followed by multivitamins, 8.4%(66), olmesartan, 7.5%(59),

calcium supplements, 7.2% (57), and cholecalciferol, 5.5% (43). Other frequently

prescribed drugs are telmisartan 5.2% (42), pantoprazole 5.2% (41), paracetamol

4.5% (36), rabeprazole 4.3% (34), domperidone 4.3% (34), and pregabalin with

methylcobalamin 4.2% (34). Less commonly used medications are tramadol 2.4% (19),

torsemide 2.5% (20), spironolactone 1.7% (13), rosuvastatin1.7% (13), nitrofurantoin

1.63% (13), rosuvastatin with clopidogrel 2.2% (17), and various antihypertensives

like clinidipine 1.0% (8), losartan 1.1% (9), metoprolol 1.1% (9), propranolol 1.1%

(9), and ramipril 0.25% (2). Other supportive medications included folic acid 0.75%

(6), cefpodoxime 0.63% (5), azithromycin 0.38% (3), clavulanic acid 0.38% (3),

aspirin 0.38% (3), aspirin with atorvastatin 0.38% (3), aspirin with clopidogrel 0.25%

(2) and miscellaneous drugs 10.0% (79) (Table 6.5.4).

6.5.5. Types of Insulin Formulations Prescribed in Study Participants

In this study, a total of 90 insulin formulations were prescribed among the 208 participants. Among the various types, biphasic human insulin was the most frequently used, accounting for 58% (52) of all insulin prescriptions. This was followed by soluble insulin, prescribed in 21% (19) of participants. Other formulations included insulin glargine at 8.9% (8), insulin glulisine at 5.5% (5), and insulin isophane at 4.4% (4). Biphasic aspart was the least prescribed insulin, recorded in only 2.2% (2) of the total insulin formulations (Table 6.5.5).

6.6. Assessment of Medication Adherence, Quality of Life, and Diabetic Distress

6.6.1. Medication Adherence in Study Participants

Medication adherence was assessed using the Morisky Medication Adherence Scale (MMAS-8) among the 208 participants. The results indicated that a majority of the participants had moderate adherence to their prescribed medications.

Specifically, over half of the participants, 53.4% (111), scored between 6 and 7, indicating moderate adherence. High adherence, with a perfect score of 8, was observed in 27.4% (57) of the participants. On the other hand, low adherence (scores less than 6) was seen in 19.2% (40) of the individuals (Table 6.6).

6.6.2. Quality of Life in Study Participants

In this study involving 208 participants, quality of life was assessed using the WHOQOL-BREF 26 scale, covering overall QOL as well as four specific domains: physical, psychological, social, and environmental. When looking at the overall quality of life, about 33.2% (69) of participants reported a good quality of life, while 50.5% (105) fell into the moderate range, and 16.3% (34) had poor overall QOL. In the physical domain, most participants, 59.1% (123), reported moderate quality of life, followed by 23.1% (48) experiencing good physical well-being and 17.8% (37) reporting poor physical health. Nearly 23.6% (49) of the participants scored in the poor range, while 24.0% (50) of the participants had good psychological health, and 52.4%

(109) had moderate QOL. In the Social domain, 27.4% (57) have poor QOL, and only 18.3% (38) experienced good social QOL, and the remaining 54.3% (113) had moderate levels. When it comes to the environmental domain, 9.1% (19) of participants had

Poor QOL, while 73.6% (153) had moderate satisfaction with their environment, and 17.3% (36) had good environmental QOL (Table 6.7).

6.7.3. Diabetic Related Distress in Study Participants

In the present study, diabetic-related distress was assessed using the DDS-17 scale, covering emotional distress, physician-related distress, regimen-related distress, and interpersonal distress.

In terms of emotional distress, the majority of participants, 61.5% (128), reported high distress, followed by 24.0% (50) experiencing moderate distress. Only 14.4% (30) had no emotional distress.

When it comes to physician-related distress, 68.3% (142) of participants reported no distress, while 29.3% (61) had moderate distress. Only a small number of participants, 2.4% (5), experienced high distress.

In terms of Regimen-related distress, 63.5% (132) of participants experienced high distress, followed by 20.7%(43) who had moderate distress, and only 15.9% (33) had no regimen-related distress.

Regarding Interpersonal distress, 62.9% (131) of participants have high distress in their interpersonal relationships. 24.0% (50) of participants have experienced moderate distress, and 13.0% (27) of participants had no interpersonal distress.

When it comes to the overall distress of 208 participants, 102 (49%) had high levels of distress, followed by 59 (28.4%) of participants who experienced moderate distress, and 47 (22.6%) participants had no diabetes related distress (Table 6.8).

Table 6.1.Socio-Demographic Characteristics of Study Participants (N=208)

VARIABLE	NUMBER	PERCENT
AGE		
Less than 40 years	30	14.5
40 to 60 years	**125**	**60.1**
Above 60 years	53	25.4
GENDER		
Male	**125**	**60.1**
Female	83	39.9
RESIDENCE		
Rural	**134**	**64.5**
Urban	74	35.5
EDUCATION		
Uneducated	145	**69.8**
Educated	63	30.2
MARITAL STATUS		
Married	207	99.6
Unmarried	1	0.4
DIET		
Veg	4	1.9
Mixed	204	98.1
OCCUPATION		
Agriculture worker	66	**31.7**
Business	30	14.5
Employed	34	16.4
Home makers	66	**31.7**
Retired	12	5.7
SOCIAL HABIT		
Alcoholic	73	**35.2**
Smoker	4	1.9
Both	4	1.9
No social habit	127	**61**

Table 6.2. Clinical Characteristics of Study Participants (N=208)

VARIABLE	NUMBER	PERCENT
BMI kg/m^2		
Below 18.5	11	5.3
18.5 to 24.9	83	40
25 to 29.9	80	**38.4**
30 or Greater	34	**16.3**
HbA1c%		
Less than or equal to 6.5	44	21.1
6.6 to 8.0	93	**44.8**
8.1 to 10.0	46	**22.1**
More than 10.0	25	12
Duration (years)		
Less than 5	88	**42.3**
6 to 10	56	**26.9**
11 to 15	31	14.9
16 to 20	16	7.69
More than 20	17	8.17
Blood sugar (fasting)		
Less than 100mg/dl	16	7.6
101 to 125 mg/dl	67	32.3
More than 126 upto 305 mg/dl	125	**60.1**

Table 6.3. Presence of Comorbities in Study Participants (N=208)

VARIABLE	Number	%
Single comorbidity		
HTN	**40**	**19.2**
Hyperlipidemia	11	5.3
Obesity	13	**6.25**
Hypothyroidism	3	1.44
Bronchial Asthma	4	1.92
Bilateral Renal Calculi	3	1.44
Acid Peptic Disease	2	0.96
Cervical Spondylitis	1	0.48
Pancreatitis	2	0.96
Hepatitis	1	0.48
Stroke	1	0.48
OA	1	0.48
Dual comorbidity		
HTN+Hyperlipidemia	18	**8.65**
HTN+CAD	8	3.82
HTN+Anemia	1	0.48
HTN+Asthma	1	0.48
HTN+Fatty Liver	1	0.48
HTN+APD	3	1.44
HTN+Obesity	10	4.8
HTN+Hypothyroidism	5	2.4
Hyperlipidemia+Cerebral Atrophy	1	0.48
Hyperlipidemia+Obesity	3	1.44
Hyperlipidemia+Myasthenia Gravis	1	0.48

Hypothyroidism+Obesity	1	0.48
CAD+Fatty Liver	1	0.48
CAD+Obesity	1	0.48
HTN+Renal Calculi	1	0.48
Hyperlipidemia+Hypothyroidism	3	1.44
Obesity+APD	1	0.48
Triple comorbidity		
HTN+Hyperlipidemia+Hypothyroidism	3	1.44
HTN+Hyperlipidemia+Obesity	6	2.9
HTN+Hyperlipidemia+CAD	1	0.48
HTN+Obesity+Hypothyroidism	1	0.48
HTN+Obesity+APD	4	1.9
HTN+Obesity+OA	1	0.48
HTN+Obesity+CAD	2	0.96
Hyperlipidemia+Hypothyroidism+Br.Asthma	1	0.48
HTN+Obesity+Br.Asthma	1	0.48
HTN+Hyperlipidemia+OA	1	0.48
Hyperlipidemia+Obesity+Anemia	1	0.48
Hyperlipidemia+Hypothyroidism+Obesity	1	0.48
Quadruple comorbidity		
HTN+Hyperlipidemia+Hypothyroidism+Obesity	1	0.48
HTN+Hyperlipidemia+Hypothyroidism+Fatty Liver	1	0.48
HTN+Hyperlipidemia+Obesity+Fatty Liver	1	0.48
HTN+Obesity+Apd+Cad	1	0.48
HTN+Obesity+Apd+Br.Asthma	1	0.48
HTN+Hyperlipidemia+Obesity+Apd	1	0.48
No comorbidity	37	17.9
Total	208	**100**

Table 6.4. Presence of Complications In Study Participants (N=208)

VARIABLE	NUMBER	PERCENT
Single complicaton		
DKD	44	**21.1**
Neuropathy	30	**14.4**
Retinopathy	8	3.8
Diabetic foot	7	3.3
PVD	1	0.48
Stroke	1	0.48
Dual Complications		
Neuropathy+DKD	9	4.5
Neuropathy+Retinopathy	2	0.96
Neuropathy+Pvd	1	0.48
Neuropathy+Stroke	2	0.96
DKD+Stroke	1	0.48
DKD+Retinopathy	2	0.96
No Complications	100	**48.1**
Total	208	100

Table 6.5. Prescribing Patterns in Study Participants (N=208)

VARIABLE	NUMBER	PERCENT
No of drugs per prescription		
1 to 2	2	0.96
3 to 4	42	20.2
More than 4	164	**78.84**
No of OHAs per prescription		
One OHA	66	31.7
Two OHA	113	**54.3**
Three OHA	20	9.6
No OHA	9	4.4
No of insulin per prescription		
One insulin	49	23.5
Two insulins	21	10.1
No insulin	138	66.4
Insulin+OHAs		
1 insulin+1 OHA	20	9.61
1 insulin+2 OHA	22	10.6
1 insulin+3 OHA	2	0.96
2 insulin+1 OHA	7	3.36
2 insulin+2 OHA	7	3.36
No insulin+ No OHA	150	72.2

Table 6.5.1. Pharmacological Class Of OHAs Prescribed in Study Participants (N=351)

VARIABLE	NUMBER	PERCENT
Biguanides	50	14.2
Sulfonyl ureas	55	15.7
DPP4 inhibitors	**82**	**23.4**
SGLT2 inhibitors	21	6.0
Thiazolidinediones	10	2.9
Biguanides/Sulfonyl ureas	54	15.4
Biguanides/DPP4 inhibitors	3	0.85
SGLT2/DPP4 inhibitors	**67**	**19.0**
SGLT2/Biguanides	3	0.85
SGLT2/DPP4 inhibitor/Biguanides	6	1.7
Total	351	100

Table 6.5.2. Types of Insulin Prescribed in Study Participants (N=71)

VARIABLE	NUMBER	PERCENT
Pre-mixed	43	60.6
Short acting	15	21.1
Long acting	7	9.85
Intermediate acting	4	5.65
Rapid acting	2	2.8
Total	71	100

Table 6.5.3. Oral Hypoglycemic Agents Prescribed in Study Participants (N=351)

OHAs	Number	Percent
Metformin	50	**14.3**
Glimepiride	41	11.7
Gliclazide	14	4.0
Linagliptin	52	**14.9**
Sitagliptin	30	8.5
Dapagliflozin	21	6.0
Pioglitazone	10	2.9
Metformin/Gliclazide	23	6.6
Metformin/Glimepirede	31	8.8
Dapagliflozin/Sitagliptin	67	**19.1**
Metformin/Sitagliptin	3	0.9
Dapagliflozin/metformin	3	0.9
Dapagliflozin/metformin/sitagliptin	4	1.1
Dapagliflozin/metformin/vildagliptin	2	0.6
Total	351	100

Table 6.5.4. Drugs Prescribed in Study Participants (N=791)

Drug	Number	Percent
Amlodipine	1	0.12
Clinidipine	8	1.0
Losartan	9	1.1
Metoprolol	9	1.1
Olmesartan	59	**7.5**
Propranolol	9	1.1
Telmisartan	42	5.2
Ramipril	2	0.25
Atorvastatin	106	**13.5**
Rosuvastatin	13	1.7
Pantoprazole	41	5.2
Rabeprazole	34	4.3
Domperidone	34	4.3
Paracetamol	36	4.5
Tramadol	19	2.4
Calcium	57	**7.2**
Cholecalciferol	43	5.5
Multi vitamin	66	8.4
Folic acid	6	0.75
Torsemide	20	2.5
Spironolactone	13	1.7
Azithromycin	3	0.38
Cefpodoxime	5	0.63
Nitrofurantoin	13	1.63
Clavulanic acid	3	0.38

Aspirin	3	0.38
Clopidogrel	2	0.25
Aspirin/Atorvastatin	3	0.38
Aspirin/clopidogrel	2	0.25
Rosuvastatin/clopidogrel	17	2.20
Pregabalin/methylcobalamin	34	**4.2**
Miscellaneous	79	**10.0**
Total	**791**	**100**

Table 6.5.5. Types of Insulin Formulations Prescribed in Study Participants (N=90)

Insulin	Number	Percent
Biphasic human insulin	52	**58**
Biphasic aspart	2	2.2
Soluble insulin	19	**21**
Insulin glargine	8	8.9
Insulin isophane	4	4.4
Insulin glulisine	5	5.5
Total	**90**	**100**

Table 6.6. Assessment of Medication Adherence in Study Participants (N=208)

MMA8-SCORE	NUMBER	PERCENT
<6(Poor)	40	9.2
6-7(Moderate)	111	53.4
8(High)	57	27.4

Table 6.7. Assessment of QOL Using WHOQOL-BREF 26 in Study Participants (N=208)

Score range	Overall Qol(%)	Physical Domain(%)	Psychological Domain (%)	Social Domain(%)	Environmental Domain(%)
0-40	34(16.3)	37(17.8)	49(23.6)	57(27.4)	19(9.1)
>40-70	105(50.5)	123(59.1)	109(52.4)	113(54.3)	153(73.6)
>70-100	69(33.2)	48(23.1)	50(24.0)	38(18.3)	36(17.3)

Table 6.8. Assessment of Diabetic Related Distress in Study Participants using DDS17 (N=208)

Distress Level	Emotional Distress	Physician related distress	Regimen related distress	Interpersonal distress	Overall distress
<2.0 (no distress)	30(14.5)	142(68.3)	33(15.9)	27(13.0)	47(22.6)
2.0-2.9 (moderate)	50(24.0)	61(29.3)	43(20.6)	50(24.0)	59(28.4)
>=3.0(High)	**128(61.5)**	**5(2.4)**	**132(63.5)**	**131(63.0)**	**102(49)**

Table 6.9. Quality Of Life, Diabetic Distress, And Medication Adherence in Study Participants (N=208)

Assessment Tool	Category / Score Range	Participants n (%)	Breakdown by Domain
WHOQOL-BREF 26	0–40 (Poor QOL)	-	Overall: 34 Physical: 37 Psychological: **49** Social: **57** Environmental: 19
	41–70 (Moderate QOL)	-	Overall: **105** Physical: **123** Psychological: **109** Social: 113 Environmental:**153**
	71–100 (Good QOL)	-	Overall: 69 Physical: 48 Psychological: 50 Social: 38 Environmental: 36
DDS-17 (Diabetes Distress)	<2.0 (No Distress)	-	Emotional: 30 Physician: 142 Regimen: 33 Interpersonal: 27 Overall :47
	2.0–2.9 (Moderate Distress)	-	Emotional: 50 Physician: 61 Regimen: 43 Interpersonal: 50 Overall :59
	≥3.0 (High Distress)	-	**Emotional: 128** Physician: 5 **Regimen: 132** Interpersonal:**131** Overall :**102**
MMAS-8 (Medication Adherence)	<6 (Low Adherence)	40 (19.2%)	-
	6–7 (Medium Adherence)	111 (53.4%)	-
	8 (High Adherence)	57 (27.4%)	-

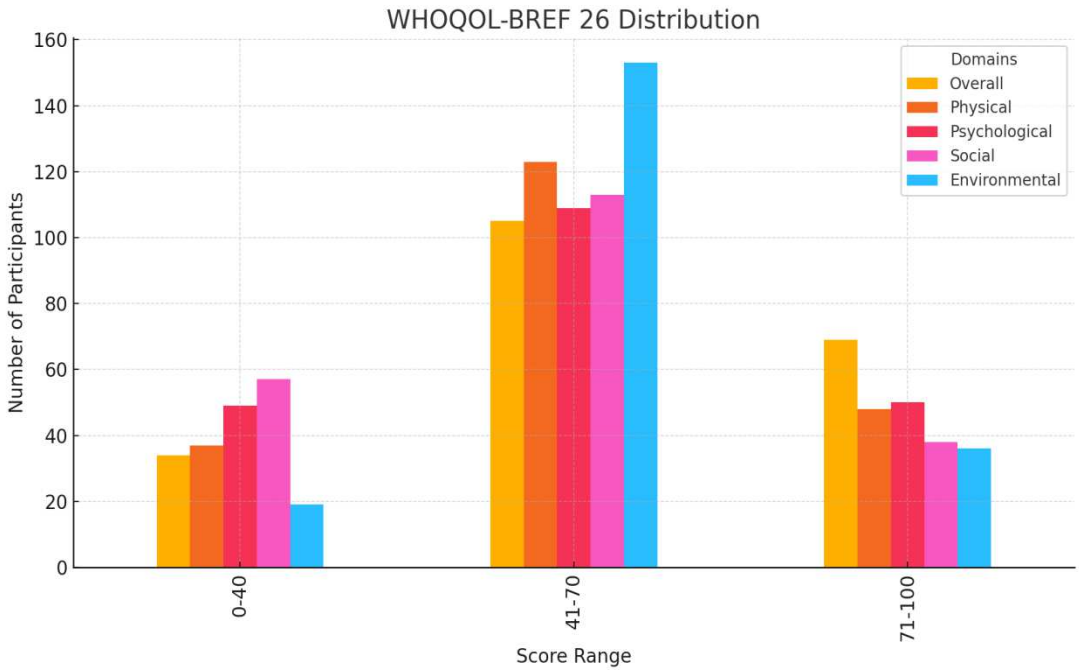


Fig 1.6. Quality of Life in study participants

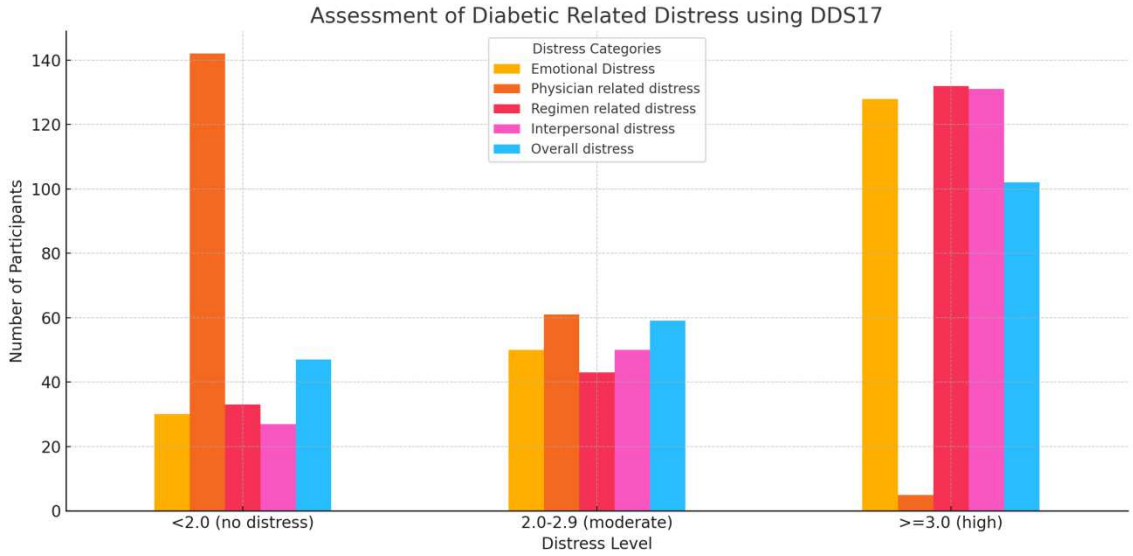


Fig 1.7. Diabetic Related Distress in study participants

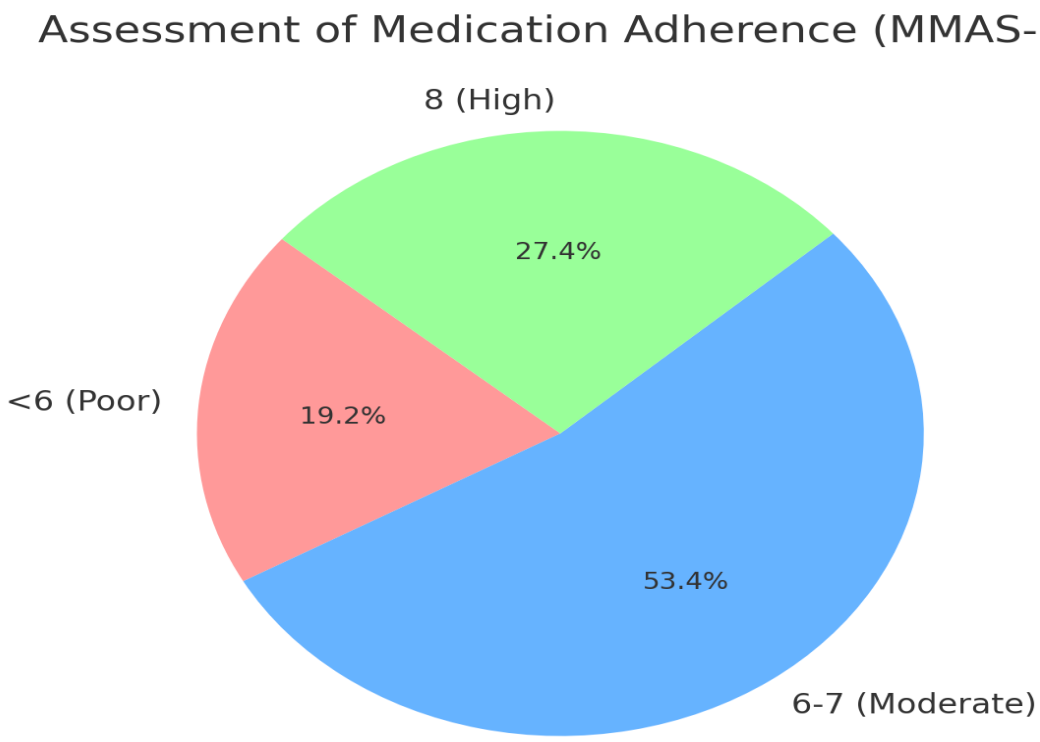


Fig 1.8. Medication Adherence in study participants

Discussion

In the present study, most of the diabetic patients were found in the age group of 40-60 years (60.1%), whereas a study conducted by Butt et al. (2023) found that most of the patients were in the age group of 41-50 years (39%) due to poor glycemic control among the elderly population. The prevalence of diabetes increases with age; this may occur due to a deficiency in insulin secretion following beta pancreatic function (Talukder et al., 2020). In the current study, males were predominant with diabetes, consisting of 60.1% when compared to females, whereas in a study conducted by Nithesh et al. (2018 both males and females were equally prevalent with T2DM. Most of the study patients were from a rural background, comprising 64.5%. In a study conducted by Tripathy et al. (2020, 61% of the patients were rural residents, as most of the patients were undiagnosed in their initial stages. The study suggests that diabetes is no longer confined to urban areas and is a matter of concern in rural areas as well. In the present study, 69.8% of diabetic patients were found to be uneducated, whereas a study conducted by Nithesh et al. (2018) 75% of the study population were educated.

In the present study, 63.4% of the population were found to be homemakers and agricultural workers, whereas in a study conducted by Nithesh et al. (2018, 64.9 % of the patients were self-employed. Among the study population, 39% were found to be alcoholics and smokers, and 98% were found to have a mixed diet in their daily routine. In a study conducted by Nithesh et al. (2018, the results are similar, where 67.6% of people with diabetes had social habits. This indicated the importance of social habits in the progression of diabetes. Increased BMI is often associated with diabetes. Most of the overweight and obese patients were found to have high insulin resistance and low insulin sensitivity. In the present study, 54.7% patients were found to have a BMI >25kg/m^{2}, whereas in a study conducted by Butt et al. (2023, 90.2 % of patients were found to be overweight (BMI>25kg/m^{2}).

Glycated haemoglobin reflects average plasma glucose over the previous 8-12 weeks. Quantifying HbA1C has the advantage of early identification and treatment of diabetes and reducing diabetic complications. In the present study, 44.8% of diabetic patients were found to have HbA1C values between 6.6-8% and 22% of patients were found to have 8.1%-10% of HbA1C. This clearly indicates poor control of diabetes among study patients.

The duration of diabetes plays a crucial role in diabetes management. In the present study, 42.3% of the population had a diabetic history of less than 5 years of duration. In a study conducted by Upadhyay et al. (2024, 70.33% had a history of diabetes for less than 5 years. Patients with long duration may have a high risk of developing complications.

Measurement of fasting blood glucose remains the primary test for the diagnosis of diabetes and pre-diabetes. Normal fasting glucose levels are between 80 and 100 mg/dl. In the present study, 92.4% of patients were found to be >100 mg/dl or FBS, of which 60.1% had FBG >126mg/dl. This strongly correlates with the increased age and male predominance data of the present study. This might be due to poor control or decreased adherence to prescribed medications.

Comorbidity can be defined as the coexistence of other medical conditions with an index disease (primary disease). T2DM often occurs on its own and is almost always accompanied by a co-

occurring condition. In the present study, 39.4% were found with a single comorbidity, and the most common comorbidity in the study was found to be HTN (19.2%). 28.8% of patients had dual comorbidity along with diabetes; the most prevalent dual comorbidity was found to be HTN with hyperlipidemia (8.6%). 11.05% were suffering from triple comorbidity, and 2.8% were found with quadruple comorbidity. 17.9% were not associated with any comorbidities, whereas in a study conducted by Shuvo et al. (2023, 41,4% of T2DM patients had two or more associated comorbidities. Most of the previous studies state that the most common comorbidities associated with diabetes are HTN and dyslipidemia. The existence of comorbidities accelerates diabetic progression, promotes physical and mental disorders, which lead to premature mortality, and also worsens diabetes related healthcare outcomes.

In the present study, 43.75% were found to have a single comorbidity, and the most common complication in the study was found to be DKD (21.1%). 8.17% of patients were found with dual complications, and neuropathy, along with DKD, was the most common dual complication (4.5%). Whereas in a study conducted by Sachan et al., 2021 of participants were found to have retinopathy, and 39.4% had neuropathy. It is observed that complications are seen as the duration of diabetes increases.

In the present study, the prescription pattern showed a high prevalence of combination therapy, with 54.3% of patients receiving two oral hypoglycemic agents (OHAs), and insulin was prescribed in 33.6% of cases, while 66.4% were not using insulin. The most prescribed class of drugs were found to be DPP-4 inhibitors (23.4%) and sulfonylureas (15.7%), whereas in a study conducted by Upadhyay D et al., 2007 reported a predominance of monotherapy or dual therapy, where biguanides (51.27%) and sulfonylureas (35.35%) were the main class of drugs, and 7.96% were prescribed with insulin. The differences in prescribing patterns could be attributed to the evolution of diabetes management guidelines, the increasing availability and acceptance of newer drug classes, and the growing emphasis on individualized therapy based on comorbidities and glycemic targets.

In the present study, the majority of participants (53.4%) were found to have medium adherence to the prescribed medications, while 27.4% of patients showed high medication adherence, and 19.2% showed low adherence. In a study conducted by Mahajan et al. (2023, a slightly higher rate of high medication adherence (41%) was observed. It is also observed that patients with better glycemic control and higher educational levels were more likely to adhere to their medication. This might be due to low physical activity and uncontrolled HbA1c levels.

In another study conducted by Allela et al. (2023 lower adherence rates were observed (6.5%). This study highlighted the strong link between low adherence and high HbA1c levels, which supports our finding that adherence is directly tied to fasting blood sugar control. Poor adherence was more common in patients with limited education and long disease duration, indicating a lack of adequate diabetes education and counselling.

The present study estimated the overall QoL of T2DM patients in the physical health, psychological, social relationship, and environmental domains, in which overall QoL was found to be moderate (50.5), and the most affected domain in moderate QoL was found to be the environmental domain. In a study conducted by Amin et al. (2022, similar trends were observed where overall QoL was found to be at or less than 50%. Decline in QoL scores in all domains

might be associated with a higher number of complications and comorbidities, as they could be negative determinants of QoL in T2DM individuals (Gebremedhin et al., 2019). Whereas a study conducted by Tamornpark et al. (2022 reported a good QoL in the environment (50.6%), young age, higher income, family support, regular exercise, disease knowledge, absence of complications, and government medical support might be the influences for good QoL (Chaudhari et al., 2024).

The present study shows a considerable proportion of patients exhibiting high levels of diabetes-related distress (DRD) according to the DDS-17 scale used in this study. In the present study, regimen-related (63.5%), interpersonal (63%), and emotional distress (61.5%) were prominent contributors to overall distress, whereas in a study conducted by Kintzoglanakis et al. (2024, 35.8% of the patients experienced moderate to high levels in RD. Patients were taking up to four different diabetes medications along with insulin, which might be a contributing factor for RRD. In another study conducted by Aziza et al. (2023, 57.5% of patients reported emotional distress, and 54% reported regimen-related distress. In the current study, the important findings were the significant relationships among marital status, place of residence, duration of diabetes, and diabetic distress. Being married may increase the chances of experiencing diabetes- related stress (Aljuaid et al., 2018)

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