Assessment of Drug Utilization Pattern, Prevalence and Risk Factors for the Development of Diabetic Retinopathy among Type 2 Diabetic Patients in A South Indian Tertiary Care Hospital: A cross-sectional observational study

Madhavi Mannam¹, Lavanya Nalluri¹, Ravindrababu Pingili², Jaidev Sudagani³, Naveenbabu Kilaru*⁴
¹Department of Pharmacy Practice, KVSRS Siddhartha College of Pharmaceutical Sciences, Vijayawada-520010, Andhra Pradesh, India
²Department of Pharmacology, KVSRS Siddhartha College of Pharmaceutical Sciences, Vijayawada-520010, Andhra Pradesh, India
³Endocrinologist, Santhi Endocrine and Diabetes Hospital, Vijayawada-520010, Andhra Pradesh, India
⁴Department of Pharmaceutics and Pharmaceutical Biotechnology, KVSRS Siddhartha College of Pharmaceutical Sciences, Vijayawada-520010, Andhra Pradesh, India

Article History:
Received on: 05.09.2019
Revised on: 08.12.2019
Accepted on: 15.12.2019

Keywords:
Type 2 diabetes, Prevalence, Risk factors, Diabetic Retinopathy, Metformin

ABSTRACT
Diabetic retinopathy (DR) is a leading cause of visual impairment and blindness in the working-age population across the globe. The objective of the present study was to assess the drug utilization pattern, risk factors and prevalence of diabetic retinopathy in patients with type 2 diabetes mellitus in a south Indian tertiary care hospital. A cross-sectional observational study was conducted on 745 subjects (386 with diabetic retinopathy and 359 without diabetic retinopathy). Prevalence of diabetic retinopathy was measured and risk factors for the development of diabetic retinopathy were determined by calculating odds ratios using graph-pad prism statistical software and drug utilization pattern was assessed. Retinopathy was significantly higher in the subjects who are married, uneducated, housewives, urban residents, no income group and risk factors were comorbidities (other diseases, hypertension, endocrine diseases, history of cardiovascular diseases, HbA1c, high serum creatinine, duration of diabetes (5-10 years and >10 years, physical inactivity, junk foods (weekly once and weekly twice), soft drinks occasionally and tea/coffee (daily twice). Metformin (38.21%), combination of Insulin Iso-phane and Insulin Regular (16.75%), Insulin Regular (15.18%), combination of Glimepiride and Metformin (11.51%), Glimepiride (7.85%), combination of Metformin and Vildagliflozin (7.85%) were most commonly prescribed antidiabetic drugs to the T2DM patients with retinopathy.

INTRODUCTION
With 387 million people diagnosed with diabetes mellitus worldwide and a prevalence of 8.2% as per the Diabetes atlas 2014, diabetes mellitus has become a global burden (Fernandes et al., 2016; Guariguata et al., 2014). Diabetic retinopathy (DR) is a leading cause of visual impairment and blindness in the working-age population across the globe (Cheung et al., 2010; Klein, 2007). In 2010, of an estimated 285 million people worldwide with
diabetes, over one-third have signs of DR, and a third of these are afflicted with vision-threatening diabetic retinopathy (VTDR), defined as severe non-proliferative DR or proliferative DR (PDR) or the presence of diabetic macular edema (DME) (Yau et al., 2012; Lee et al., 2015). Without treatment, 50% of patients with proliferative diabetic retinopathy will become blind within 5 years (Resnikoff et al., 2004; Burgess et al., 2013). The risk factors of DR can be broadly divided into modifiable and non-modifiable factors. The modifiable risk factors include hyperglycemia, hypertension, hyperlipidemia and obesity. In contrast, the duration of diabetes, puberty and pregnancy are the non-modifiable risk factors for DR development and progression (Ting et al., 2016). The overall prevalence of DR and VTDR in T2DM was 34.6% and 10.2%, respectively. With the increasing number of people with diabetes, the number of DR and vision-threatening DR (VTDR), which includes severe non-proliferative DR, proliferative DR (PDR) and diabetic macular edema (DME), has been estimated to rise to 191.0 million and 56.3 million, respectively by 2030. The World Health Organization (WHO) defines “drug utilization” as the marketing, distribution, prescription and use of the drugs in a society considering its medical, social, and economic consequences (Ashutosh et al., 2017). Drug utilization studies help to assess whether the drug treatment is rational or not and to determine rational drug use, especially in poorer and rural populations (Mandal et al., 2016). This study was conducted with an objective to screen the type 2 diabetes patients in order to determine the prevalence of diabetic retinopathy and to determine the risk factors that are responsible for the development of diabetic retinopathy and to assess the drug utilization pattern.

MATERIALS AND METHODS

For this purpose, a cross-sectional observational study was carried out at the outpatient department of a tertiary care hospital by following the method developed by (Cui et al., 2017). The study was initiated after approval by the Institutes Ethical Review Committee. The protocol approval number was KVSRS/IEC/PG/231/2017.

Selection of participants

Patients of either sex diagnosed with or without T2DM of any duration (as per ADA guidelines) and willing to participate were included in the study. A total of 745 patients (359 patients with T2DM and 386 patients with diabetic retinopathy) were enrolled in the study.

Inclusion criteria

Patients of either sex diagnosed with type 2 diabetes mellitus of any duration, established as per American Diabetes Association (ADA) guidelines. Patients who are visiting a public endocrine hospital in six months would be recruited.

Exclusion criteria

Patients with incomplete case reports. Patients having type 1 diabetes mellitus, gestational diabetes and maturity-onset diabetes of the young were excluded from the study.

Data collection

Physicians were requested to report the clinical and biochemical data not exceeding 6 months before the observation. The information regarding demographics (age, sex), socioeconomic and lifestyle characteristics (smoking, alcohol consumption) was collected by interviewing the participant. Biochemical parameters were derived from the latest laboratory investigation reports documented in the clinical records. Socioeconomic status was assessed using the modified Kuppuswamy’s scale, which considers the education qualification, occupation of the family head and family income per month of the participant. The diagnosis of diabetic retinopathy was made by an ophthalmologic examination that included fundoscopy or retinal photography and measurement of visual acuity, carried out by an ophthalmologist. All the relevant data were collected in a predesigned paper case record form with the prior consent of the participant. Data were collected from a total of 745 patients (359 patients with T2DM and 386 patients with diabetic retinopathy).

Statistical Analysis

In the descriptive statistical analysis, categorical variables were expressed as numbers and percentages. For categorical variables, the tests of significance analysis, we applied a Chi-Square test or Fisher Exact test. For all analysis, P<0.05 was regarded as statistically significant. The odds ratio with 95% confidence intervals was calculated using univariate regression analysis. Data were analyzed using a statistical tool Graph pad prism software (version 5.0).

RESULTS AND DISCUSSION

A total of 745 subjects (359 with type 2 diabetes and 386 with diabetic retinopathy) were included in the study and the clinical characteristics of T2DM were presented in Table 1.
Table 1: Biochemical and clinical characteristics of patients with type 2 diabetes mellitus (N = 359)

| Variable                        | Patients with T2DM N (%) |
|---------------------------------|--------------------------|
| **Gender**                      |                          |
| Male                            | 155 (43.2)               |
| Female                          | 204 (56.8)               |
| **Age**                         |                          |
| 0-20 years                      | 0 (0.3)                  |
| 21-40 years                     | 83 (23.2)                |
| 41-60 years                     | 217 (60.6)               |
| Above 60 years                  | 57 (15.9)                |
| **Marital Status**              |                          |
| Unmarried                       | 16 (4.5)                 |
| Married                         | 343 (95.5)               |
| **Education**                   |                          |
| Un Educated                     | 131 (36.5)               |
| Educated                        | 228 (63.5)               |
| **BMI (Kg/m2)**                 |                          |
| <25 Kg/m2                       | 114 (31.8)               |
| >25 Kg/m2                       | 245 (68.2)               |
| **Body Weight (Kg)**            |                          |
| <50                             | 5 (1.3)                  |
| 50-70                           | 161 (45)                 |
| >70                             | 192 (53.6)               |
| **Nature of Work**              |                          |
| Not working anywhere            | 41 (11.4)                |
| Private job                     | 93 (25.9)                |
| Govt. job                       | 39 (10.8)                |
| Daily labor                     | 38 (10.6)                |
| Housewife                       | 148 (41.3)               |
| **Locality**                    |                          |
| Rural                           | 105 (29.2)               |
| Urban                           | 254 (70.7)               |
| **Monthly Income**              |                          |
| No income                       | 170 (47.5)               |
| Below 25000                     | 115 (32.1)               |
| Above 25000                     | 73 (20.4)                |
| **Co-morbidities**              |                          |
| No                              | 131 (29.4)               |
| HTN                             | 138 (30.8)               |
| History of CVDs                 | 7 (1.56)                 |
| Endocrine diseases              | 59 (13.2)                |
| Other diseases                  | 112 (25.1)               |
| **HbA1C**                       |                          |
| <7                              | 141 (44.2)               |
| 7-9                             | 109 (34.2)               |
| >9                              | 69 (21.6)                |
| **Fasting Blood Glucose (mg/dL)**|                        |
| 70-80                           | 10 (3)                   |
| 80-120                          | 92 (27.6)                |
| 121-160                         | 107 (32)                 |
| 161-200                         | 71 (21.3)                |
| >200                            | 54 (16.2)                |

Continued on next page
Table 1 continued

| Postprandial blood glucose levels (mg/dL) |  |
|-----------------|---|
| 90-110          | 3(1) |
| 111-130         | 9(3) |
| 131-150         | 33(10.9) |
| 151-200         | 165(54.6) |
| >200            | 92(30.5) |

| Random Blood Glucose (mg/dL) |  |
|-----------------------------|---|
| 80-100                      | 0 |
| 101-120                     | 0 |
| 121-140                     | 0 |
| 141-160                     | 2(13.3) |
| 161-200                     | 1(6.7) |
| >200                        | 12(80) |

| HDL (mg/dL)                  |  |
|------------------------------|---|
| Not available                | 54(20.1) |
| Normal                       | 130(48.3) |
| Low                          | 55(20.4) |
| High                         | 30(11.2) |

| Triglycerides (mg/dL)        |  |
|------------------------------|---|
| Not available                | 54(20.5) |
| Normal                       | 109(41.5) |
| Low                          | 8(3) |
| High                         | 92(35) |

| Total Cholesterol (mg/dL)    |  |
|------------------------------|---|
| Not available                | 54(19.6) |
| Normal                       | 151(54.7) |
| Low                          | 6(2.2) |
| High                         | 65(23.6) |

| LDL (mg/dL)                  |  |
|------------------------------|---|
| Not available                | 57(20.8) |
| Normal                       | 163(59.4) |
| Low                          | 9(3.3) |
| High                         | 45(16.5) |

| Urea (mg/dL)                 |  |
|------------------------------|---|
| Not available                | 72(36.4) |
| Normal                       | 78(39.4) |
| Low                          | 0 |
| High                         | 48(24.2) |

| Serum creatinine (mg/dL)     |  |
|------------------------------|---|
| Not available                | 45(12.6) |
| Normal                       | 305(85.2) |
| Low                          | 5(1.4) |
| High                         | 3(0.8) |

| Duration of T2DM (Years)     |  |
|------------------------------|---|
| <5                           | 172(47.9) |
| 5-10                         | 111(30.9) |
| >10                          | 76(21.2) |

| Following T2DM education    |  |
|------------------------------|---|
| Yes                          | 282(79.2) |
| No                           | 74(20.8) |

T2DM, Type 2 Diabetes Mellitus; BMI, Body Mass Index; HTN, Hypertension; CVDs, Cardiovascular Diseases; HbA1C, Glycated hemoglobin; HDL, High-Density Lipoproteins; LDL, Low-Density Lipoproteins
Table 2 and Table 3 show the socio-demographic and lifestyle characteristics of subjects with and without diabetic retinopathy, respectively. The prevalence of diabetic retinopathy was significantly higher in the subjects who are married (98.2%, P=0.0371), uneducated (69.9%) patients, nature of work (housewives 47.6%, P=0.0227), urban residents (60.6% P=0.0037), no income group (65.5%) and risk factors were comorbidities (other diseases 40.41%, P=0.0001, HTN 31.1%, P=0.0001, endocrine diseases 8.57%, P=0.0223, history of CVDs 48.4%, P<0.0001), no physical activity (63.3%), habit of taking junk foods (weekly once 19.9%, weekly twice 13.2%, P=0.0001), soft drinks (occasionally 24.9%, P=0.0073), tea/coffee (daily twice without sugar 38.1%, P=0.0465), HbA1c (7-9% 39.3%, P=0.0018, >9% 31.9%, P=0.0001), high serum creatinine (14.8%, P=0.0001), duration of diabetes (5-10 years 37.8% >10 years 37.3%, P=0.0001). Gender, age, BMI, body weight, monthly income, blood glucose levels, food habits, the habit of smoking, alcohol, stress levels are not significantly associated with the development of diabetic retinopathy.

Univariate regression analysis was performed to determine the odds ratios for the modifiable and non-modifiable risk factors for T2DM (Table 4). The analysis showed that married (OR, 2.526; 95% CI, 1.026 to 6.214, P=0.0371), poorly educated (OR, 0.2468; 95% CI, 0.1818 to 0.3352, P<0.0001), house wives (OR, 0.6068; 95% CI, 0.3941 to 0.9344, P=0.0027), urban residents (OR, 0.6364; 95% CI, 0.4688-0.8639, P=0.0037) and risk factors were co-morbidities (other diseases OR, 4.650; 95% CI, 3.281 to 6.501, P=0.0001), hypertension (OR, 2.642; 95% CI, 1.868 to 2.373, P=0.0001), Endocrine diseases (OR, 1.685; 95% CI, 1.075 to 2.641, P=0.0223), history of CVD (OR, 8.117; 95% CI, 3.451 to 19.09, P<0.0001), duration of diabetes (5-10 years OR, 2.357; 95% CI, 1.659-3.348, P<0.0001 and with duration >10 years (OR, 3.395; 95% CI, 2.336-4.933, P<0.0001), HbA1c (7-9% OR, 1.774; 95% CI, 1.235 to 2.547, P=0.0018; >9% OR, 2.275; 95% CI, 1.529 to 3.386, P<0.0001), high serum creatinine (OR, 11.55; 95% CI, 3.415 to 39.10, P<0.0001), physical inactivity (OR, 0.5558; 95% CI, 0.4146 to 0.7450, P<0.0001), junk foods weekly once (OR, 3.287; 95% CI, 2.049 to 5.274, P<0.0001) and weekly twice (OR, 2.935; 95% CI, 1.709 to 5.038, P<0.0001), soft drinks occasionally (OR, 1.642; 95% CI, 1.141 to 2.364, P=0.0073), tea/coffee (daily twice without sugar OR, 1.598; 95% CI, 1.006 to 2.539, P=0.0465).

The drug utilization pattern was assessed and presented the results in Table 5. Metformin (38.21%), combination of Insulin Isophane and Insulin Regular (16.75%), Insulin Regular (15.18%), combination of Glimepiride and Metformin (11.51%), Glimepiride (7.85%), combination of Metformin and Vildagliptin (7.85%) were most commonly prescribed anti-diabetic drugs to the T2DM patients with retinopathy. The present study's results suggested that subjects who are married, uneducated patients, nature of work (housewives), urban residents, no income group and risk factors were comorbidities (other diseases, HTN, endocrine diseases, history of CVDs), no physical activity, habit of taking junk foods (weakly once, weakly twice), soft drinks (occasionally), tea/coffee (daily twice without sugar), poor glycemic control, high serum creatinine, duration of diabetes are major risk factors for the development of retinopathy complication.

Marital status

The present study's results revealed that marital status (98.2%, P=0.0371) was significantly associated and was the major risk factor for diabetic retinopathy (OR, 2.526; 95% CI, 1.026 - 6.214). Therefore, further studies are needed to evaluate the exact impact of marital status on risk for diabetic retinopathy.

Education

Education is one of the risk factors for the development of diabetic retinopathy. (Martinell et al., 2016) conducted a study on Prevalence and risk factors for diabetic retinopathy at diagnosis (DRAD) in patients recently diagnosed with type 2 diabetes (T2D) or latent autoimmune diabetes in the adult (LADA) and concluded that DRAD prevalence in patients recently diagnosed with T2DM or is 12%. Low educational levels and low beta-cell function at diagnosis are risk factors for DRAD (Martinell et al., 2016). The present study's results also supported that educational status was significantly associated with (69.9%, P<0.0001) and a risk factor for the development of diabetic retinopathy.

Nature of work

The present study's results revealed that housewives (47.6%, P=0.0227) were significantly associated and was the major risk factor for diabetic retinopathy (OR, 0.6068; 95% CI, 0.3941-0.9344). Therefore, further studies are needed to evaluate the exact impact of the nature of work on risk for diabetic retinopathy.

Urban residence

The present study's results revealed that urban residents (60.6%, P=0.0037) were significantly associated and was the major risk factor for diabetic retinopathy (OR, 0.6364; 95% CI, 0.4688-0.8639).
Table 2: Socio-demographic characteristics of diabetic patients with (N=254) or without diabetic retinopathy (N= 359)

| Variable                  | Patients with T2DM N (%) | Patients with T2DM and retinopathy N (%) | P-Value     |
|---------------------------|--------------------------|-----------------------------------------|-------------|
| Gender                    |                          |                                         |             |
| Male                      | 155 (43.2)               | 99 (39)                                 | Ref         |
| Female                    | 204 (56.8)               | 155 (61)                                | 0.2985      |
| Age                       |                          |                                         |             |
| 0-20 years                | 1 (0.3)                  | –                                       | Ref         |
| 21-40 years               | 83 (23.2)                | 20 (7.9)                                | 0.6239      |
| 41-60 years               | 217 (60.6)               | 152 (59.8)                              | 0.4031      |
| Above 60 years            | 57 (15.9)                | 82 (32.3)                               | 0.2328      |
| Marital Status            |                          |                                         |             |
| Unmarried                 | 16 (4.5)                 | 3 (1.2)                                 | Ref         |
| Married                   | 343 (95.5)               | 251 (98.8)                              | 0.0211*     |
| Education                 |                          |                                         |             |
| Uneducated                | 131 (36.5)               | 155 (61)                                | Ref         |
| Educated                  | 228 (63.5)               | 99 (39)                                 | <0.0001***  |
| BMI (Kg/m2)               |                          |                                         |             |
| <25 Kg/m2                 | 114 (31.8)               | 62 (24.5)                               | Ref         |
| >/=25 Kg/m2               | 245 (68.2)               | 191 (75.5)                              | 0.0511      |
| Body Weight (Kg)          |                          |                                         |             |
| <50                       | 5 (1.3)                  | 5 (2)                                   | Ref         |
| 50-70                     | 161 (45)                 | 112 (44.3)                              | 0.5714      |
| >70                       | 192 (53.7)               | 136 (53.7)                              | 0.5897      |
| Nature of Work            |                          |                                         |             |
| Not working anywhere      | 41 (11.4)                | 57 (22.5)                               | Ref         |
| Private job               | 93 (25.9)                | 45 (17.7)                               | <0.0001***  |
| Govt. job                 | 39 (10.8)                | 14 (5.5)                                | 0.0002***   |
| Daily labour              | 38 (10.6)                | 25 (9.8)                                | 0.0221*     |
| Housewife                 | 148 (41.2)               | 113 (44.4)                              | 0.0120*     |
| Locality                  |                          |                                         |             |
| Rural                     | 105 (29.2)               | 130 (51.2)                              | Ref         |
| Urban                     | 254 (70.8)               | 124 (48.8)                              | <0.0001***  |
| Monthly Income            |                          |                                         |             |
| No income                 | 170 (47.5)               | 148 (58.3)                              | Ref         |
| Below 25000               | 115 (32.1)               | 87 (34.2)                               | 0.4382      |
| Above 25000               | 73 (20.4)                | 19 (7.4)                                | <0.0001***  |
| Co-morbidities            |                          |                                         |             |
| No                        | 131 (29.4)               | 37 (8.6)                                | Ref         |
| HTN                       | 138 (30.8)               | 161 (37.44)                             | <0.0001***  |
| History of CVDs           | 7 (1.56)                 | 34 (7.90)                               | <0.0001***  |
| Endocrine diseases        | 59 (13.2)                | 41 (9.53)                               | 0.0009***   |
| Other diseases            | 112 (25.1)               | 157 (36.51)                             | <0.0001***  |

Continued on next page
Table 2 continued

| Variable                          | Patients with T2DM N (%) | Patients with T2DM and retinopathy N (%) | P-Value   |
|----------------------------------|--------------------------|------------------------------------------|-----------|
| Diastolic Blood Pressure         |                          |                                          |           |
| <90 mmHg                         | 281 (78.3)               | 203 (79.9)                               | Ref       |
| >/=90 mmHg                       | 78 (21.7)                | 51 (20)                                  | 0.6219    |
| HbA1C                            |                          |                                          |           |
| <7                               | 141 (44.2)               | 52 (21.8)                                | Ref       |
| 7-9                              | 109 (34.2)               | 100 (42)                                 | <0.0001***|
| >9                               | 69 (21.6)                | 86 (36.1)                                | <0.0001***|
| Fasting Blood Glucose (mg/dL)    |                          |                                          |           |
| 70-80                            | 10 (3)                   | 2 (0.9)                                  | Ref       |
| 80-120                           | 92 (27.6)                | 54 (24)                                  | 0.1572    |
| 121-160                          | 107 (32)                 | 62 (27.6)                                | 0.1610    |
| 161-200                          | 71 (21.3)                | 41 (18.2)                                | 0.1678    |
| >200                             | 54 (16.2)                | 66 (29.3)                                | 0.0113*   |
| Post prandial blood glucose levels (mg/dL) | | | |
| 90-110                           | 3 (1)                    | 1 (0.5)                                  | 0.6885    |
| 111-130                          | 9 (3)                    | 5 (2.3)                                  | 0.9423    |
| 131-150                          | 33 (10.9)                | 12 (5.6)                                 | 0.6143    |
| 151-200                          | 165 (54.6)               | 98 (45.4)                                | 0.2834    |
| >200                             | 92 (30.5)                | 100 (46.3)                               | Ref       |
| Random Blood Glucose (mg/dL)     |                          |                                          |           |
| 80-100                           | 0                        | 4 (5.2)                                  | 0.3259    |
| 101-120                          | 0                        | 5 (6.5)                                  | 0.2729    |
| 121-140                          | 0                        | 2 (2.6)                                  | 0.4857    |
| 141-160                          | 2 (13.3)                 | 8 (10.4)                                 | 0.9807    |
| 161-200                          | 1 (6.7)                  | 9 (11.7)                                 | 0.4635    |
| >200                             | 12 (80)                  | 49 (63.6)                                | Ref       |
| HDL (mg/dL)                      |                          |                                          |           |
| Not available                    | 54 (20.1)                | 84 (37.8)                                | Ref       |
| Normal                           | 130 (48.3)               | 73 (32.9)                                | <0.0001***|
| Low                              | 55 (20.4)                | 51 (23)                                  | 0.0470*   |
| High                             | 30 (11.2)                | 14 (6.4)                                 | 0.0008*** |
| Triglycerides (mg/dL)            |                          |                                          |           |
| Not available                    | 54 (20.5)                | 85 (38.5)                                | Ref       |

Continued on next page
Table 2 continued

| Variable                        | Patients with T2DM N (%) | Patients with T2DM and retinopathy N (%) | P-Value       |
|---------------------------------|--------------------------|-----------------------------------------|---------------|
| Normal                          | 109 (41.5)               | 46 (20.8)                               | <0.0001***    |
| Low                             | 8 (3)                    | 2 (0.9)                                 | 0.0108*       |
| High                            | 92 (35)                  | 88 (39.8)                               | 0.0293*       |
| Total Cholesterol (mg/dL)       |                          |                                         |               |
| Not available                   | 54 (19.6)                | 82 (36.8)                               | Ref           |
| Normal                          | 151 (54.7)               | 78 (35)                                 | <0.0001***    |
| Low                             | 6 (2.2)                  | 1 (0.4)                                 | 0.0161*       |
| High                            | 65 (23.6)                | 62 (27.8)                               | 0.0617        |
| LDL (mg/dL)                     |                          |                                         |               |
| Not available                   | 57 (20.8)                | 82 (37.1)                               | Ref           |
| Normal                          | 163 (59.4)               | 71 (32.2)                               | <0.0001***    |
| Low                             | 9 (3.3)                  | 4 (1.8)                                 | 0.0496*       |
| High                            | 45 (16.5)                | 64 (28.9)                               | 0.9649        |
| Urea (mg/dL)                    |                          |                                         |               |
| Not available                   | 72 (36.4)                | 120 (59.1)                              | Ref           |
| Normal                          | 78 (39.4)                | 22 (10.8)                               | <0.0001***    |
| Low                             | 0                       | 0                                       | ——            |
| High                            | 48 (24.2)                | 61 (30.1)                               | 0.2656        |
| Serum creatinine (mg/dL)        |                          |                                         |               |
| Not available                   | 45 (12.6)                | 7 (2.8)                                 | Ref           |
| Normal                          | 305 (85.2)               | 175 (68.9)                              | 0.0009***     |
| Low                             | 5 (1.4)                  | 0                                       | 0.3811        |
| High                            | 3 (0.8)                  | 72 (28.3)                               | <0.0001***    |
| Duration of T2DM (Years)        |                          |                                         |               |
| <5                              | 172 (47.9)               | 59 (23.2)                               | Ref           |
| 5-10                            | 111 (30.9)               | 101 (39.8)                              | <0.0001***    |
| >10                             | 76 (21.2)                | 94 (37)                                 | <0.0001***    |
| Following T2DM education        |                          |                                         |               |
| Yes                             | 282 (79.2)               | 180 (70.9)                              | Ref           |
| No                              | 74 (20.8)                | 74 (29.1)                               | 0.0177*       |

T2DM, Type 2 Diabetes Mellitus; BMI, Body Mass Index; HTN, Hypertension; CVDs, Cardiovascular Diseases; HbA1C, Glycated hemoglobin; HDL, High-Density Lipoproteins; LDL, Low-Density Lipoproteins
Table 3: Food and lifestyle characteristics of diabetic patients with (N=254) or without diabetic retinopathy (N=359).

| Variable                      | Patients with T2DM N (%) | Patients with T2DM and retinopathy N (%) | P-value   |
|-------------------------------|---------------------------|------------------------------------------|-----------|
| Food habits                   |                           |                                          |           |
| Vegetarian                    | 60 (16.7)                 | 37 (14.6)                                | Ref       |
| Mixed                         | 299 (83.3)                | 217 (85.4)                               | 0.4732    |
| Physical activity             |                           |                                          |           |
| No physical activity          | 176 (49)                  | 165 (64.9)                               | Ref       |
| Regular exercise              | 183 (50.9)                | 89 (35)                                  | <0.0001***|
| Habit of smoking              |                           |                                          |           |
| No                            | 320 (89.1)                | 218 (85.8)                               | Ref       |
| Yes                           | 22 (6.1)                  | 18 (7.1)                                 | 0.5781    |
| Past smoker                   | 17 (4.7)                  | 18 (7.1)                                 | 0.2039    |
| The habit of drinking alcohol |                           |                                          |           |
| No                            | 304 (85.1)                | 221 (87)                                 | Ref       |
| Yes                           | 44 (12.3)                 | 25 (9.9)                                 | 0.3526    |
| Past alcoholic                | 9 (2.5)                   | 8 (3.2)                                  | 0.6834    |
| The habit of taking junk foods|                           |                                          |           |
| No                            | 180 (50.3)                | 123 (48.6)                               | Ref       |
| Weekly once                   | 31 (8.7)                  | 16 (6.3)                                 | 0.3931    |
| Weekly twice                  | 23 (6.4)                  | 18 (7.1)                                 | 0.6860    |
| Weekly thrice and more        | 28 (7.8)                  | 23 (9.1)                                 | 0.5455    |
| Occasionally                  | 96 (26.8)                 | 73 (28.9)                                | 0.5824    |
| The habit of taking fruits /fruit juices |               |                                          |           |
| No                            | 66 (18.5)                 | 62 (24.5)                                | Ref       |
| Weekly once                   | 27 (7.5)                  | 17 (6.7)                                 | 0.2604    |
| Weekly twice                  | 35 (9.8)                  | 22 (8.7)                                 | 0.2145    |
| Weekly thrice & more          | 125 (34.9)                | 57 (22.4)                                | 0.0023**  |
| Occasionally                  | 105 (29.3)                | 96 (37.8)                                | 0.9047    |
| The habit of taking soft drinks|                           |                                          |           |
| No                            | 272 (76.2)                | 163 (64.1)                               | Ref       |
| Weekly once                   | 6 (1.7)                   | 6 (2.4)                                  | 0.3773    |
| Weekly twice                  | 5 (1.4)                   | 2 (0.8)                                  | 0.6291    |
| Weekly thrice & more          | 14 (4)                    | 2 (0.8)                                  | 0.0417*   |
| Occasionally                  | 60 (16.8)                 | 81 (31.9)                                | <0.0001***|
| The habit of taking tea/coffee|                           |                                          |           |
| No                            | 55 (15.3)                 | 29 (11.5)                                | Ref       |
| Daily once without sugar      | 54 (15)                   | 32 (12.6)                                | 0.7151    |
| Daily twice without sugar     | 110 (30.6)                | 107 (42.3)                               | 0.0208*   |
| Daily thrice without sugar    | 58 (16.2)                 | 35 (13.9)                                | 0.6671    |
| Daily once with sugar         | 25 (6.9)                  | 16 (6.3)                                 | 0.6226    |
| Daily twice with sugar        | 37 (10.3)                 | 24 (9.5)                                 | 0.5518    |
| Daily thrice with sugar       | 20 (5.6)                  | 10 (4)                                   | 0.9061    |
| Situations at working places  |                           |                                          |           |
| No stress                     | 181 (50.4)                | 127 (50)                                 | Ref       |
| Stress                        | 178 (49.6)                | 127 (50)                                 | 0.9188    |
Table 4: Univariate regression analysis of modifiable and non-modifiable risk factors for the development of retinopathy in patients with type 2 diabetes mellitus.

| Variable                  | OR (95% CI)       | P-value   |
|---------------------------|-------------------|-----------|
| Gender                    |                   |           |
| Male                      | 1                 | Ref       |
| Female                    | 1.190 (0.8574 to 1.651) | 0.2985    |
| Age                       |                   |           |
| 0-20 years                | 1                 | Ref       |
| 21-40 years               | 0.7365 (0.02891 to 18.76) | 0.6239    |
| 41-60 years               | 2.103 (0.08505 to 52.02) | 0.4031    |
| Above 60 years            | 4.304 (0.1721 to 107.6) | 0.2328    |
| Marital Status            |                   |           |
| Unmarried                 | 1                 | Ref       |
| Married                   | 3.903 (1.125 to 13.54) | 0.0211*   |
| Education                 |                   |           |
| Uneducated Educated       | 1                 | Ref       |
|                           | 0.3670 (0.2635 to 0.5112) | <0.0001***|
| BMI (Kg/m2)               |                   |           |
| <25 Kg/m2                 | 1                 | Ref       |
| >/= 25 Kg/m2              | 1.433 (0.9974 to 2.060) | 0.0511    |
| Body Weight (Kg)          |                   |           |
| <50                       | 1                 | Ref       |
| 50-70                     | 0.6957 (0.1967 to 2.460) | 0.5714    |
| >70                       | 0.7083 (0.2011 to 2.495) | 0.5897    |
| Nature of Work            |                   |           |
| Not working anywhere      | 1                 | Ref       |
| Private job               | 0.3480 (0.2035 to 0.5952) | <0.0001***|
| Govt. job                 | 0.2582 (0.1243 to 0.5363) | 0.0002*** |
| Daily labour              | 0.4732 (0.2483 to 0.9020) | 0.0221*   |
| Housewife                 | 0.5492 (0.3432 to 0.8789) | 0.0120*   |
| Locality                  |                   |           |
| Rural                     | 1                 | Ref       |
| Urban                     | 0.3943 (0.2820 to 0.5513) | <0.0001***|
| Monthly Income            |                   |           |
| No income                 | 1                 | Ref       |
| Below 25000               | 0.8690 (0.6092 to 1.240) | 0.4382    |
| Above 25000               | 0.2990 (0.1723 to 0.5187) | <0.0001***|
| Co-morbidities            |                   |           |
| No                        | 1                 | Ref       |
| HTN                       | 4.131 (2.687 to 6.350) | <0.0001***|
| History of CVDs           | 17.20 (7.049 to 41.95) | <0.0001***|
| Endocrine diseases        | 2.460 (1.433 to 4.224) | 0.0009*** |
| Other diseases            | 4.963 (3.202 to 7.692) | <0.0001***|
| Systolic Blood Pressure   |                   |           |
| <140 mmHg                 | 1                 | Ref       |
| >140 mmHg                 | 1.522 (1.079 to 2.146) | 0.0164*   |
| Diastolic Blood Pressure  |                   |           |
| <90 mmHg                  | 1                 | Ref       |
| >90 mmHg                  | 0.9051 (0.6088 to 1.346) | 0.6219    |
| HbA1C                     |                   |           |
| <7                        | 1                 | Ref       |
| 7-9                       | 2.488 (1.638 to 3.779) | <0.0001***|
| >9                        | 3.380 (2.157 to 5.295) | <0.0001***|

Continued on next page
Table 4 continued

| Variable                                | OR (95% CI)                  | P-value |
|-----------------------------------------|------------------------------|---------|
| Fasting Blood Glucose (mg/dL)           |                              |         |
| 70-80                                   | 1                            | Ref     |
| 81-120                                  | 2.935 (0.6196 to 13.90)      | 0.1572  |
| 121-160                                 | 2.897 (0.6146 to 13.66)      | 0.1610  |
| 161-200                                 | 2.887 (0.6028 to 13.83)      | 0.1678  |
| >200                                    | 6.111 (1.283 to 29.10)       | 0.0113* |
| Post prandial blood glucose levels (mg/dL) |                              |         |
| 90-110                                  | 1                            | Ref     |
| 111-130                                 | 1.667 (0.1349 to 20.59)      | 0.6885  |
| 131-150                                 | 1.091 (0.1032 to 11.53)      | 0.9423  |
| 151-200                                 | 1.782 (0.1827 to 17.38)      | 0.6143  |
| >200                                    | 3.261 (0.3331 to 31.92)      | 0.2834  |
| Random Blood Glucose (mg/dL)            |                              |         |
| 80-100                                  | 2.273 (0.1146 to 45.09)      | 0.3259  |
| 101-120                                 | 2.778 (0.1437 to 53.69)      | 0.2729  |
| 121-140                                 | 1.263 (0.05689 to 28.02)     | 0.4857  |
| 141-160                                 | 0.9796 (0.1837 to 5.222)     | 0.9807  |
| 161-200                                 | 2.204 (0.2540 to 19.13)      | 0.4635  |
| >200                                    | 1                            | Ref     |
| HDL (mg/dL)                             |                              |         |
| Not available                           | 1                            | Ref     |
| Normal                                  | 0.3610 (0.2310 to 0.5640)    | <0.0001*** |
| Low                                     | 0.5961 (0.3572 to 0.9947)    | 0.0470*  |
| High                                    | 0.3000 (0.1459 to 0.6168)    | 0.0008*** |
| Triglycerides (mg/dL)                   |                              |         |
| Not available                           | 1                            | Ref     |
| Normal                                  | 0.2681 (0.1651 to 0.4354)    | <0.0001*** |
| Low                                     | 0.1588 (0.03249 to0.7765)    | 0.0108*  |
| High                                    | 0.6077 (0.3878 to 0.9523)    | 0.0293*  |
| Total Cholesterol (mg/dL)               |                              |         |
| Not available                           | 1                            | Ref     |
| Normal                                  | 0.3402 (0.2193 to 0.5277)    | <0.0001*** |
| Low                                     | 0.1098 (0.01285 to0.9377)    | 0.0161*  |
| High                                    | 0.6281 (0.3852 to 1.024)     | 0.0617  |
| LDL (mg/dL)                             |                              |         |
| Not available                           | 1                            | Ref     |
| Normal                                  | 0.3028 (0.1954 to 0.4693)    | <0.0001*** |
| Low                                     | 0.3089 (0.09070 to 1.052)    | 0.0496*  |
| High                                    | 0.9886 (0.5939 to 1.646)     | 0.9649  |
| Urea (mg/dL)                            |                              |         |
| Not available                           | 1                            | Ref     |
| Normal                                  | 0.1692 (0.09703 to 0.2951)   | <0.0001*** |
| Low                                     | 0.7625 (0.4728 to 1.230)     | 0.2656  |
| Serum creatinine (mg/dL)                |                              |         |
| Not available                           | 1                            | Ref     |
| Normal                                  | 3.689 (1.628 to 8.358)       | 0.0009*** |
| Low                                     | 0.5515 (0.02754 to 11.05)    | 0.3811  |
| High                                    | 154.3 (37.92 to 627.7)       | <0.0001*** |
| Duration of T2DM (Years)                |                              |         |

*Continued on next page*
| Variable                                      | OR (95% CI) | P-value       |
|----------------------------------------------|-------------|--------------|
| <5                                           | 1           | Ref          |
| 5-10                                         | 2.653 (1.778 to 3.958) | <0.001***   |
| >10                                          | 3.606 (2.362 to 5.504) | <0.001***   |
| Following T2DM education                     |             |              |
| Yes                                          | 1           | Ref          |
| No                                           | 1.567 (1.079 to 2.274) | 0.0177*     |
| Food habits                                  |             |              |
| Vegetarian                                   | 1           | Ref          |
| Mixed                                        | 1.177 (0.7538 to 1.838) | 0.4732     |
| Physical activity                            |             |              |
| No physical activity                         | 1           | Ref          |
| Regular exercise                             | 0.5188 (0.3727 to 0.7220) | <0.001***   |
| Habit of smoking                             |             |              |
| No                                           | 1           | Ref          |
| Yes                                          | 1.201 (0.6292 to 2.292) | 0.5781     |
| Past smoker                                  | 1.554 (0.7835 to 3.083) | 0.2039     |
| The habit of drinking alcohol                |             |              |
| No                                           | 1           | Ref          |
| Yes                                          | 0.7816 (0.4643 to 1.316) | 0.3526     |
| Past alcoholic                               | 1.223 (0.4643 to 3.220) | 0.6834     |
| The habit of taking junk foods               |             |              |
| No                                           | 1           | Ref          |
| Weekly once                                  | 0.7553 (0.3960 to 1.440) | 0.3931     |
| Weekly twice                                 | 1.145 (0.5930 to 2.212) | 0.6860     |
| Weekly thrice and more                       | 1.202 (0.6614 to 2.185) | 0.5455     |
| Occasionally                                 | 1.113 (0.7601 to 1.629) | 0.5824     |
| The habit of taking fruits/fruit juices      |             |              |
| No                                           | 1           | Ref          |
| Weekly once                                  | 0.6703 (0.3332 to 1.348) | 0.2604     |
| Weekly twice                                 | 0.6691 (0.3542 to 1.264) | 0.2145     |
| Weekly thrice & more                         | 0.4854 (0.3042 to 0.7746) | 0.0023**   |
| Occasionally                                 | 0.9733 (0.6245 to 1.517) | 0.9047     |
| The habit of taking soft drinks              |             |              |
| No                                           | 1           | Ref          |
| Weekly once                                  | 1.669 (0.5292 to 5.262) | 0.3773     |
| Weekly twice                                 | 0.6675 (0.1280 to 3.481) | 0.6291     |
| Weekly thrice & more                         | 0.2384 (0.05348 to 1.063) | 0.0417*    |
| Occasionally                                 | 2.253 (1.531 to 3.315) | <0.001***   |
| The habit of taking tea/coffee               |             |              |
| No                                           | 1           | Ref          |
| Daily once without sugar                     | 1.124 (0.6001 to 2.105) | 0.7151     |
| Daily twice without sugar                    | 1.845 (1.094 to 3.112) | 0.0208*    |
| Daily thrice without sugar                   | 1.144 (0.6186 to 2.117) | 0.6671     |
| Daily once with sugar                        | 1.214 (0.5607 to 2.627) | 0.6226     |
| Daily twice with sugar                       | 1.230 (0.6214 to 2.435) | 0.5518     |
| Daily thrice with sugar                      | 0.9483 (0.3923 to 2.292) | 0.9061     |
| Situations at working places                 |             |              |
| No stress                                    | 1           | Ref          |
| Stress                                       | 1.017 (0.7373 to 1.402) | 0.9188     |

T2DM: Type 2 Diabetes Mellitus; BMI: Body Mass Index; HTN: Hypertension; CVDs: Cardiovascular Diseases; HbA1C: Glycated hemoglobin; HDL: High-Density Lipoproteins; LDL: Low-Density Lipoproteins
Therefore, further studies are needed to evaluate the exact impact of urban residence on risk for diabetic retinopathy.

**Monthly income**

The present study’s results revealed that monthly income ($P<0.0001$) was significantly associated and was the major risk factor for diabetic retinopathy (OR, $0.1841; 95\% \text{CI}, 0.1082 - 0.3133$). Therefore, further studies are needed to evaluate the exact impact of monthly income on risk for diabetic retinopathy.

**Comorbidities**

Hypertension ($P<0.0001$) was positively associated with diabetic retinopathy. (Yau et al., 2012) conducted a study to examine the global prevalence and major risk factors for diabetic retinopathy (DR) and gave a conclusion that DR has the potential to be the leading cause of visual impairment and blindness worldwide and also concluded that poorer glycemic and blood pressure control are strongly associated with DR (Yau et al., 2012). Another study conducted by (Al-Rubeaan et al., 2015) also concluded that hypertension was the most significant risk factor. The present study’s results are also supported that hypertension (30.1%, $P < 0.0001$) was a risk factor for diabetic retinopathy (OR, $2.642; 95\% \text{CI}, 1.868-3.736$).

**Physical inactivity**

The present study’s results revealed that physical inactivity (63.3%, $P<0.0001$) was significantly associated and was the major risk factor for diabetic retinopathy. Therefore, further studies are needed to evaluate the exact impact of physical inactivity on risk for diabetic retinopathy.

**Junk foods**

The present study’s results revealed that habit of taking junk foods weakly once (19.9%, $P < 0.0001$), weakly twice (13.2 %, $P<0.0001$) was significantly associated and was the major risk factor for diabetic retinopathy (weekly once OR, $3.287; 95\% \text{CI}, 2.049 - 5.274$ and weekly twice OR, $2.935; 95\% \text{CI}, 1.709 -5.038$). Therefore, further studies are needed to evaluate the exact impact of the habit of taking junk foods on risk for diabetic retinopathy.

**Soft drinks**

The present study’s results revealed that the habit of taking soft drinks occasionally (24.9%, $P = 0.0073$) was significantly associated and was the major risk factor for diabetic retinopathy (OR, $1.642;95\% \text{CI}, 1.141-2.364$). Therefore, further studies are needed to evaluate the exact impact of the habit of taking soft drinks on risk for diabetic retinopathy.

**The habit of taking tea/coffee**

The present study’s results revealed that the habit of taking tea/coffee twice without sugar (38.1%, $P=0.0465$) was significantly associated and was the major risk factor for diabetic retinopathy (OR, $1.598; 95\% \text{CI}, 1.006-2.539$). Therefore, further studies are needed to evaluate the exact impact of the habit of taking tea/coffee on risk for diabetic retinopathy.

**HbA1c**

Poor glycemic control was significantly associated with the development of diabetic retinopathy. Joanne et al., conducted a study to examine the global prevalence and major risk factors for diabetic retinopathy (DR) and gave a conclusion that DR has the potential to be the leading cause of visual impairment and blindness worldwide and also concluded that poorer glycemic and blood pressure control are strongly associated with DR [15]. In the present study, it was significant that poor glycemic control (7-9% (39.3%, $P=0.0018$, >9% (31.9%, $P<0.0001$) was a risk factor for development of diabetic retinopathy (7-9% (OR, $1.774; 95\% \text{CI}, 1.235-2.547$) and> 9% (OR, $2.275; 95\% \text{CI}, 1.529-3.386$). Other relevant studies were conducted by Donghyun et al. and Khalid et al. concluded that poor glycemic control was significantly associated with the development of diabetic retinopathy (Al-Rubeaan et al., 2015; Jee et al., 2013).

**Serum creatinine**

The present study’s results revealed that high serum creatinine levels (14.8%, $P <0.0001$) was significantly associated and was the major risk factor for diabetic retinopathy (OR, $11.55; 95\% \text{CI}, 3.415-39.10$). Therefore, further studies are needed to evaluate the exact impact of serum creatinine on risk for diabetic retinopathy.

**Duration of T2DM**

Joanne et al., 2015 conducted a study to examine the global prevalence and major risk factors for diabetic retinopathy (DR) and gave a conclusion that DR has the potential to be the leading cause of visual impairment and blindness worldwide and also concluded that longer diabetes duration was the significant risk factor. In the present study, it was significant that long-standing diabetes (5-10 years (37.8%, $P<0.0001$ and with duration >10 years (37.3%, $P <0.0001$)) was a risk factor for development of diabetic retinopathy (5-10 years (OR, $2.357; 95\% \text{CI}, 1.659-3.348$) and with duration >10 years (OR, $3.395; 95\% \text{CI}, 2.336-4.933$). Other relevant studies were conducted by Donghyun et al., Sadiq et al., Khalid et al., Rajiv et al., they also concluded that long-standing diabetes was significantly associated...
Table 5: Medication given for the patients with diabetic retinopathy

| S. No | Generic Name of Drugs                        | N (%)  |
|-------|---------------------------------------------|--------|
| 1     | Metformin                                   | 72 (47.05) |
| 2     | Glimepiride + Metformin                     | 47 (30.71) |
| 3     | Insulin Isophane + Regular Insulin          | 45 (29.41) |
| 4     | Teneligliptin                               | 16 (10.45) |
| 5     | Insulin Regular                             | 15 (9.80)  |
| 6     | Glimepiride                                 | 10 (6.53)  |
| 7     | Pioglitazone                                | 10 (6.53)  |
| 8     | Gliclazide + Metformin                      | 8 (5.22)   |
| 9     | Insulin Glargine                            | 7 (4.57)   |
| 10    | Gliclazide                                  | 6 (3.92)   |
| 11    | Sitagliptin + Metformin                     | 4 (2.61)   |
| 12    | Teneligliptin + Metformin                   | 4 (2.61)   |
| 13    | Metformin + Voglibose                       | 4 (2.61)   |
| 14    | Insulin Aspart                              | 4 (2.61)   |
| 15    | Glipizide + Metformin                       | 3 (1.96)   |
| 16    | Glipizamide + Metformin                     | 3 (1.96)   |
| 17    | Metformin + Vildagliptin                    | 3 (1.96)   |
| 18    | Lantus Insulin                              | 2 (1.30)   |
| 19    | Glimepiride + Metformin + Voglibose         | 2 (1.30)   |
| 20    | Glimepiride + Metformin + Pioglitazone      | 2 (1.30)   |
| 21    | Sitagliptin                                 | 2 (1.30)   |
| 22    | Acarbose                                    | 1 (0.65)   |
| 23    | Linagliptin                                 | 1 (0.65)   |
| 24    | Voglibose                                   | 1 (0.65)   |
| 25    | Dapagliflozin                               | 1 (0.65)   |
| 26    | Empagliflozin                               | 1 (0.65)   |

with the development of diabetic retinopathy (Hussain et al., 2013; Raman et al., 2014).

Drug utilization pattern

Sekhar et al. conducted a prospective observational study, including 181 patients for 6 months in Bankura Sammilani Medical College and gave a conclusion that metformin was the commonest drug used; glimepiride and metformin combination was the commonest combination therapy (Resnikoff et al., 2004). Our present study’s results revealed that Metformin, a combination of Insulin Isophane and Insulin Regular, a combination of Glimepiride and Metformin, Glimepiride, a combination of Metformin and Vildagliptin were most commonly prescribed anti-diabetic drugs to the T2DM patients with retinopathy.

CONCLUSION

Subjects who are married, uneducated patients, nature of work (housewives), rural residents, no income group and risk factors were comorbidities (other diseases, HTN, endocrine diseases, history of CVDs), no physical activity, habit of taking junk foods (weakly once, weakly twice), soft drinks (occasionally), tea/coffee (daily twice without sugar), HbA1c (7-9%, >9%), high serum creatinine, duration of diabetes (5-10 years, > 10 years) were significant risk factors for development of retinopathy. Metformin, a combination of Insulin Isophane and Insulin Regular, a combination of Glimepiride and Metformin, Glimepiride, a combination of Metformin and Vildagliptin were most commonly prescribed anti-diabetic drugs to the T2DM patients with retinopathy.

Key findings

1. The prevalence of diabetic retinopathy was found to be 31.28%.
2. Retinopathy prevalence was higher in females compared to males (P=0.2608).
3. The prevalence of retinopathy was significantly higher in the subjects who are married (98.2%,...
4. The prevalence of retinopathy was significantly higher in the subjects who are poorly educated (69.9%, P<0.0001) when compared to educated.

5. The prevalence of retinopathy was significantly higher in the subjects who are not doing any work when compared to others.

6. The major comorbidities for the development of retinopathy complications include hypertension (P<0.0001), history of cardiovascular diseases (P<0.0001), endocrine diseases (P=0.0223) and other diseases (P<0.0001).

7. Locality, physical inactivity, socioeconomic status, food habits, soft drinks, junk foods, the habit of taking tea/coffee are significantly associated with the development of retinopathy complications.

8. Poor glycemic control, serum creatinine levels are significantly associated with the development of retinopathy complications.

9. Duration of diabetes (>10 years, 37.3% P<0.0001, 5-10 years 37.8% P<0.0001) was significantly associated with the development of retinopathy complications.

10. Metformin, a combination of Insulin Isophane and Insulin Regular, a combination of Glimepiride and Metformin, Glimepiride, a combination of Metformin and Vildagliptin were most commonly prescribed anti-diabetic drugs to the T2DM patients with retinopathy.

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