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# A Prospective Study on Comparison of Severity of Depression Among Patients with Type II Diabetes, taking Oral Hypoglycemic Agents Versus Insulin in a Tertiary care Hospital , South India.

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## ABSTRACT

Depression is commonly found as a co-morbid condition in patients with diabetes. The co-existence of depression is associated with poor glycaemic control and low medication adherence. The objective of this study was to assess and compare the severity of depression in patients with Type II diabetes taking OHA versus Insulin. A prospective observational study conducted among 200 diabetic patients for a period of 6 months in the general medicine department of a tertiary care hospital, with established T2DM satisfying inclusion and exclusion criteria were evaluated for depression by using Hamilton Depression Rating scale (HAMD) with the help of physician. Finally comparing the severity of depression among patients taking OHA versus Insulin. Out of 200 diabetic patients, 124 (62%) patients were depressed. About 22% patients shows moderate depression ,followed by mild depression (20%), severe (10.5%) and very severe(9.5%). Mild-Moderate level of depression is more prevalent in diabetics than in general population. Majority of the patient taking OHA had no depression ( normal, 51%) followed by mild depression (19.6%), moderate (17.6%), and only 11.8% shows severe/ very severe depression. Patients on insulin showed that 27.5% have severe or very severe depression followed by moderate (26.3%), mild (22.5%), and 23.8% have no depression. Depression is more common in patients with diabetes mellitus. Study shows that depression is more prevalent in patients taking Insulin as compared to those using OHA.

**Keywords:** Diabetes, Depression, Insulin, Oral Hypoglycemic Agents (OHA)

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## INTRODUCTION

Diabetes is a chronic condition caused by an absolute lack of insulin or relative lack of insulin as a result of impaired insulin secretion and action [1]. Depression is commonly found as a co-morbid condition in diabetes. Co-existence of depression is associated with poor symptom control, increased suffering, health care expenditure, disability, decreased quality of life, reduced clinical outcomes and greater risk of death. The objective of this study was to assess and compare the severity of depression in patients with Type II diabetes taking OHA versus Insulin. Depression may exert its negative effect through hormonal, neuronal, or immune system changes that directly affect the body's ability to produce or use insulin [2]. The relationship between diabetes and depression have been argued to be essentially bidirectional. Both physiological and behavioral factors seem to play a role in the relationship between depression and diabetes. Depression is potentially related to impaired glucose tolerance. Depression impedes the adoption of effective cell management behaviours (including physical activity, appropriate self monitoring of blood glucose, foot care) through a decrease in social motivation, probably leading to poor glycemic control and decreased medication adherence. The coexistence of diabetes and depression is associated with significant morbidity, mortality and increased healthcare expenditures [3]. Identification and management of depression are important aspects of diabetes care. Self-administered or professionally administered instruments, such as PHQ-9& HAMD are useful adjuncts to the clinical interview in the identification of depression[4]. Both pharmacologic and psychotherapeutic interventions have demonstrated efficacy in patients with diabetes and depression[5-6]. Both the disease and drug related factors contribute to the development of depression. Antidepressant is the treatment of choice in primary care settings. Psychotherapy combined with psychoeducational interventions seem to be cost-effective and yield beneficial results, both on mental health outcomes as well as diabetes management and glycaemic control [7].

## MATERIALS AND METHOD

A prospective observational study conducted in the General Medicine Department of Cosmopolitan Hospital Thiruvananthapuram , for a period of 6 months( From December 2015-May2016) after getting clearance from Institution Human Ethical Committee and all procedures followed are adhered to ICMR's guidelines for biomedical research on human participants (2006). 200 patients with Type II Diabetes satisfying both inclusion and exclusion criteria were recruited in the study . Informed consent was directly obtained from the patients and screened for depression by using HAM-D ( Hamilton Depression Rating scale) with the help of physician. HAM-D scale

contains 21 questions and scoring is based on the first 17. A score of 0-7 = normal, 8-13 = Mild depression, 14-18 = Moderate depression, 19-22 = Severe depression and 23 or greater show Very severe depression. A structured interview, detailed history, and all available medical and treatment history were also reviewed.

**Inclusion criteria**:

The subjects diagnosed with Type 2 DM of age above 18yrs and on anti-diabetic treatment > 6months were *included* in the study.

**Exclusion criteria**:

Subject with Type I DM, other psychiatric disorders other than depression, pregnant women, patients with incomplete medical records and patients who are not willing to participate in the study were *excluded* from the study.

**Sample Size Calculation**

$$n = \frac{Z_{\infty}^2 \, p(1-p)}{d^2}$$

Where;

n = Sample size

$Z_{\infty}$ = Z statistics for a level of confidence

P = Estimated proportion of an attribute present in the population

d = Level of precision

- In the present study: -

P = 0.25 (Prevalance of depression among DM patients)

d = 25% of p = 0.063

$Z_{\infty}$ = 1.96 for $\infty = 0.05$

$$N = \frac{(1.96)^2 \times (0.25) \times (0.75)}{(0.063)^2} = 185$$

**Data Analysis**

All the data entered was analyzed using SPSS version 16 .Descriptive statistics were calculated for all variables. Mean and Standard deviation was calculated for qualitative variables like age, gender, duration of diabetes, HbA1C, and presence of depression. Associated co-morbidities and complications are also assessed. Chi square test was used to determine difference in the level of depression in patients with DM Type II, on either insulin and oral hypoglycemic medications. A p-value < 0.05 was considered significant.

## RESULTS AND DISCUSSION

200 diabetic patients, with type 2 DM were recruited in the study; 80 (40%) of those patients were on insulin, 102 (51%) patients were managed on oral hypoglycaemic medications and 18 patients were using both (Table1 ). About 68 (34%) patients were in the age range of 51- 60 years. 57 (28.5%) patients in the age range of 61-70 years, 41 (20.5%) patients in the age range of >70 years, and 43 (17%) patient in the age range of <50 years with a mean age of 60.6 ± 11.2. 44.5% were females and 55.5% were males. 29% of diabetics were alcoholic, 35% were smokers and 47% don't have any history of alcoholism or smoking. Majority of the diabetics (41%) have a duration of diabetes of 5- 10 years, followed by 10-15 yrs (18%), <5 yrs (17.5%), 15-20yrs (16%) and > 20 yrs(7.5%) with a mean duration of 11.4 ± 7.8. About 67% of subjects shows family history of diabetes but 33% were not. Incidence of diabetes is more prevalent in patients with normal bodyweight (54%) followed by over weight (33.5%) obese (10%) and very less in Underweight patients (2%) with a mean BMI of 24.8 ± 3.3. (62.5%) had an HbA1C level of 5.7 followed by 7-9 (16%), 9-11 (11.5%), >11 (7%) and <5 (3%). Majority have a mean HbA1C of 7.2 ± 2. The most common complication in diabetic subjects was found to be Retinopathy(21%) followed by Infections (15.54%),Coronary Artery Disease (14.58%), Ischemic Heart Disease (11.8%), Nephropathy (9.11%), Stroke (7.29% ), Neuropathy (7%), Diabetic foot ulcer (7%), Cellulitis (4.55%), Diabetic ketoacidosis (1.21%) and Peripheral Vascular Disease (1%).

**Table1 Percentage distribution of the sample according to mode of therapy**

| Mode of therapy | Count | Percent |
|---|---|---|
| OHA | 102 | 51.0 |
| Insullin | 80 | 40.0 |
| Both | 18 | 9.0 |

**Severity of Depression In Patients With Type Ii Diabetes Mellitus**

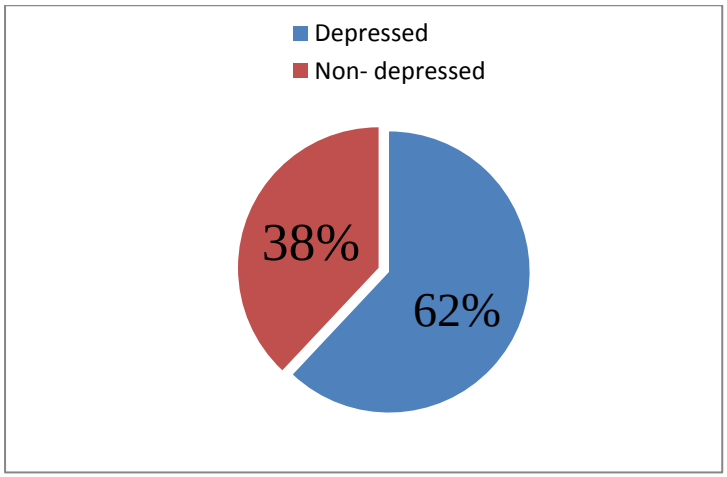


**Figure 1 Distribution of depressed versus non depressed patients**

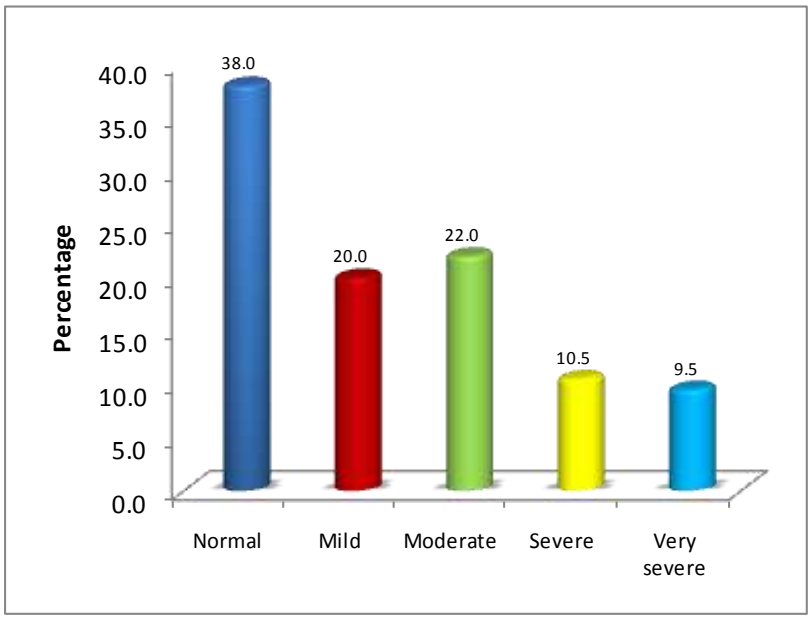


**Figure 2: Distribution of sample according to severity of depression**

Figure1and Figure 2 shows that out of 200 diabetic patients, 124 (62%) patients were depressed. About 22% patients shows moderate depression, followed by mild depression (20%), severe(10.5%) and very severe(9.5%). Mild-Moderate level of depression is more prevalent in diabetics than in general population. Females gender and diabetics with complications and associated co- morbidities are associated with high risk of developing depression. In a Cross Sectional Study conducted by Irum Siddique et.al [8] (2014) shows that depression was present among 53% of the patients. The severity of Depression was: mild in 20% of the surveyed population, moderate in 23% and severe in 10% of subjects [9].

**Comparison Severity of Depression In Diabetics Taking OHA Vs Insulin**

**Table 2: Percentage distribution of association of depression with mode of therapy**

| Mode of therapy | Normal(%) | Mild(%) | Moderate(%) | Severe/ Very severe (%) | $\chi^2$ | P |
|---|---|---|---|---|---|---|
| OHA | 52 (51) | 20 (19.6) | 18 (17.6) | 12 (11.8) | 19.38** | 0.004 |
| Insulin | 19 (23.8) | 18 (22.5) | 21 (26.3) | 22 (27.5) | | |
| Both | 5 (27.8) | 2 (11.1) | 5 (27.8) | 6 (33.3) | | |

Table 2 shows that majority of the patient taking OHA had no depression ( normal, 51%) followed by mild depression (19.6%), moderate (17.6%), and only 11.8% shows severe/ very severe depression. Patients on insulin showed that 27.5% have severe or very severe depression followed by moderate (26.3%), mild (22.5%), and only 23.8% have no depression. Patients on both insulin and OHA shows severe / very severe depression (27.5%), followed by moderate (26.3%), mild (22.5%), and 27.8% don't have any depression. Our result is contrary to the study done by Irum

Siddique et.al [8]. (2014) Conducted Cross Sectional Study Entitled "Frequency Of Depression In Patients With Diabetes Mellitus Type II From District Headquarter Hospital, Pakistan" in his study, Patients with DM type II, who were on oral hypoglycemic medications, found to be at a higher risk of developing Depression as compared to patients on insulin. Our result is supported by a previous study conducted by Noh JH et al[10] concludes that the patients on insulin show significantly higher frequency of depressive symptoms compared to oral diabetic group.

**Table 3: Association of depression with selected variables**

| | | **Normal** | **Mild** | **Moderate** | **Severe/ Very severe** | **$\chi^2$** | **P** |
|---|---|---|---|---|---|---|---|
| Age | <=60 | 32 (37.6) | 15 (17.6) | 19 (22.4) | 19 (22.4) | 0.83 | 0.842 |
| | >60 | 44 (38.3) | 25 (21.7) | 25 (21.7) | 21 (18.3) | | |
| Gender | Male | 52 (46.8) | 25 (22.5) | 25 (22.5) | 9 (8.1) | 23.6** | 0.000 |
| | Female | 24 (27) | 15 (16.9) | 19 (21.3) | 31 (34.8) | | |
| Mode of therapy | OHA | 52 (51) | 20 (19.6) | 18 (17.6) | 12 (11.8) | 19.38** | 0.004 |
| | Insulin | 19 (23.8) | 18 (22.5) | 21 (26.3) | 22 (27.5) | | |
| | Both | 5 (27.8) | 2 (11.1) | 5 (27.8) | 6 (33.3) | | |
| Type of therapy | Monotherapy | 48 (34.3) | 33 (23.6) | 32 (22.9) | 27 (19.3) | 2.15 | 0.542 |
| | Combination therapy | 9 (31) | 4 (13.8) | 8 (27.6) | 8 (27.6) | | |
| Medication adherence | Low | 4 (13.8) | 5 (17.2) | 7 (24.1) | 13 (44.8) | 29.31** | 0.000 |
| | Medium | 16 (28.1) | 9 (15.8) | 16 (28.1) | 16 (28.1) | | |
| | High | 56 (49.1) | 26 (22.8) | 21 (18.4) | 11 (9.6) | | |

## CONCLUSION

This study concludes that majority of the diabetic patients were depressed. Patients on insulin shows high levels of depression as compared to those on OHA. Most of the patient taking OHA had no depression followed by mild depression (19.6%), moderate (17.6%), and only 11.8% shows severe/ very severe depression.

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