RESEARCH ARTICLE

Overcoming Depression: The Role of Patient Counseling among Depressed Diabetic Patients

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ABSTRACT

A prospective open label study was performed for 6 months which included the follow up period of 2 months. Its demonstrated that patient counseling in diabetes depressed patients have shown to be significantly beneficial similar to a placebo effect. The use of the Hamilton Depression Rating Scale has also been investigated. In the District Government Head Quarters Hospital, Udhagamandalam, 125 patients with diabetes completed a questionnaire (Hamilton Depression Rating Scale) assessing diabetes monitoring, and depression. The levels of depression were measured in those who had evidence of poor disease control. (LDL $\geq$130 mg/dL, systolic blood pressure $\geq$140 mm Hg). The Body Mass Index, Fasting Blood Sugar, Post Prandial Blood Glucose, Low Density Lipoproteins, High Density Lipoproteins, Total Cholesterol were recorded at every visit. The results for the group I shown that the mean fasting blood glucose levels and post prandial glucose levels significantly reduced (p<0.0001) from baseline in Visit 4 (Mean difference: 11.63, SE of difference: 1.32),(mean difference: 13.80, SE of difference: 1.389) and Visit 8 (Mean: 24.86, SE of Difference 2.577),(mean difference: 31. 24, SE of difference: 3.09)   whereas the group II showed that the mean fasting blood glucose levels and post prandial blood glucose levels increased significantly. It was observed that the group which underwent patient counseling showed good outcome when compared to the group which didn't undergo patient counseling. Counseling enhances a better understanding of the disease, prescriptional medications as well as other factors thus bringing out a positive outcome in an individual's disease affected life.

KEYWORDS

Depression, Patient Counseling, Diabetes

INTRODUCTION

The etiology of depressive disorders is too complex to be totally explained by a single, social, developmental or biologic theory. Several factors appear to work together to cause or precipitate depressive disorders. Depression is caused due to the deficiency of either of four major brain chemicals: serotonin, GABA, dopamine and acetylcholine. In some cases deficiency of all of them. Depressed patients loose interest in activities that once were pleasurable, experience loss of appetite or overeating, have problems concentrating, remembering details, or making decisions and may contemplate or attempt suicide. Insomnia, excessive sleeping, fatigue, loss of energy, or aches, pains or digestive problems that are resistant to treatment may be present. Depressed

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mood is not necessarily a psychiatric disorder. Certain medications are known to cause depressed mood in a significant number of patients. These include Hepatitis C drug therapy and some drugs used to treat high blood pressure, such as beta-blockers or reserpine.

Depressed mood can be the result of a number of infectious diseases and physiological problems including hypoandrogenism (in men), Addison's disease, Lyme disease, multiple sclerosis, sleep apnea and disturbed circadian rhythm. Several years before the introduction of anti-depressants, the cause of depression was limited to decreased brain levels of the neurotransmitters NE,5-HT & DA, although the actual cause remains unknown. More recent insight into the possible mechanisms underlying depressive disorders comes from studies on brain- derived neurotrophic factor (BDNF).

The brain-derived neurotrophic factor is a growth factor protein that regulates the differentiation and survival of neurons. In addition to pharmacological interventions, patient counseling should be employed whenever the patient is able and willing to participate. The effects of patient counseling is considered to be additive.

The Hamilton Depression Rating Scale (HAM-D) has proven useful for many years as a way of determining a patient's level of depression before, during, and after treatment.[17] It generally takes 15-20 minutes to complete the interview and score the results. In the last 15 years in the United Kingdom there has been a very significant expansion of psychological treatments in primary care for depression, in particular primary care counseling.

In this study the role of patient counseling in diabetes patients with depression was investigated. The various counseling points enables the patients to comply with their diabetic medications thus leading to a promising outcome. This report strongly suggests that administration of patient counseling in depressed patients is considered a new therapeutic strategy for patients with diabetes.[1-16]

METHODOLOGY

Ethical Issues

Ethical approval for the study was obtained from Institutional Ethics Committee, JSS College of Pharmacy, Ootacamund (Ooty), Tamil Nadu, India.

Study Description

The District Government Head Quarters Hospital, Udhagamandalam is a 420 bedded hospital providing secondary healthcare to the people of Niligiri district. On an average about 180 out-patients and 20 in-patients are treated and admitted per day respectively. The hospital has various wards viz., intensive care unit, medical wards, surgical wards, pediatric wards and gynecology department. The study was a Prospective Open Label Study which included 125 subjects (expecting 20% drop out). The study was conducted for a period of 6 months which included a follow up period of 2 months.

Study Criteria

Eligibility

Age: 18- 80 years

Gender: Both

Accepts: No Healthy Volunteers

Inclusion Criteria

- Known Type 1 and Type 2 Diabetes Mellitus with or without comorbidities.

- Patients who are able to give consent for study participation.

- Patients with Hamilton score > 7.

- Only applicable to subjects who will participate in the subgroup: Be able and willing to participate in Intervention group (who will receive patient counseling) or Control group (who will not receive patient counseling).

Exclusion Criteria

- Participation in any other clinical study within one month prior/during this study period.

- Pregnancy and lactating women.

- Other types of Diabetes Mellitus.

- Patients with prolonged microvascular and macrovascular complications.

- Patient with significant hepatic and renal dysfunctions.

Source of Data

Patient Interview and Medical records.

Informed Consent and Patient Data Collection
Study details were explained in-person to the patients and written informed consent form was obtained from them. Patient's data including demographic, past medical and medication history, present medications, biochemical test results and other parameters that are available were collected in a structured data collection form. Those patients with Hamilton Scale >7 were taken into study.

Study Procedure

Subject enrollment and assessment of Demographic and social habits

The study was approved by Institutional Review Board, J.S.S College of Pharmacy, Udhagamandalam, Tamil Nadu.

Data Collection of the Subject

The study participants completed a demographic data collection form providing information about their sex, age, marital status, education, income level, type of diabetes, length of time since diagnosis of diabetes and presence of other specific health problems, family history, past medication and medical history and current treatment. The Hamilton scale scoring was performed and the data collected.

Allocation of patients into groups according to therapy

- Group I: Patients who received counseling.

- Group II: Patients who did not receive counseling.

Follow up visits (V)

There were totally of eight follow up visits each separated by a gap of 7 days. During the follow up visits the patients are assessed for the following

1. Glycemic control.

2. Possible symptoms or signs suggestive of hyperglycemia/ hypoglycemia.

3. Consumption of any other medicines, vitamins or herbs.

4. Problems in following diabetes care plan for the patients in pharmaceutical care intervention group.

5. Review of the patient medical diary.

6. Counseling of patients in the pharmaceutical care intervention group.

During the V_1 to V_7 follow up visits blood pressure, Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS), lipid profile and Hamilton scale were measured and at V_8 visit body weight, height, BMI, blood pressure, Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS), lipid profile and Hamilton scale were measured.

Patient Counseling

Patients in the pharmaceutical care intervention group received diabetic medication Counseling and depression counseling, printed educational material and instructions on dietary regulation, exercise and lifestyle modifications while the control group patients did not receive any counseling till the end of the study.

Disease Knowledge Counseling

The patients were given counseling on the disease knowledge. The counseling points include:

- What is diabetes?

- What is depression?

- Types of diabetes.

- The risk factors for diabetes

- How to identify the Hypoglycemia and Hyperglycemia?

- What are the signs and symptoms of diabetes?

- Importance of controlling and managing diabetes and depression.

- Complications of diabetes?

Patients were explained in detail about each of the above aspect of the disease with the help of information leaflet in Tamil and patient information on diabetes mellitus in English.

Dietary Modification Counseling

The dietary modifications suggested to the patients included reducing the intake of fats, increasing the intake of high-fiber carbohydrates, reducing the intake of refined sugars and salts, restricting alcohol consumption, spacing meals evenly (4-5 h apart), maintaining regular eating habits and eating fruits in moderate amounts (preferably raw and partially ripe fruits). The patient education material and dietary chart was prepared in Tamil for their convenience to the patients. The dietary chart contains information on the list of food items on vegetables, fruits, dairy products, poultry etc in measured quantities that can be consumed by diabetic patients. The dietary chart also includes the time table for consumption of food with periodic timing at specific interval stating the type and amount of food that can be consumed.

Life Style Modification Counseling

In the intervention group, the study subjects were advised to perform any one exercise regularly to improve blood sugar control, body weight control and to increase the sensitivity of insulin. The patients were advised to go for a walk for 30- 45 min at least three times a week.

Counseling on Depression

- The patients were counseled that diabetes is one of the common disorder (prevalence > 70% in India and >171 million worldwide).

- The patients were given a chance to have an open discussion on all matters troubling him/her.

- On every follow up the pharmacist showed good listening session so that it would create

a good platform for the patient (by maintaining an empathic relationship).

Statistical Inference

GraphPad Prism Statistical Software Version 6.02 (Licensed Version) was used for statistical analysis.

RESULTS

To evaluate whether the patient counseling used in diabetes patients with depression have an influence in the depressive symptamology, we used the Hamilton Depression Rating Scale to measure the rate of depression. A total of 180 diabetes patients were screened using Hamilton depression scale, nearly 122 patients were found to have depression. All these patients were enrolled into the study and among those subjects 102 patients completed the study (drop out: 16.34 %). These subjects were further randomized into two groups (patient counseling and non-patient counseling).

The Prevalence of depression among diabetes is shown in the following figure 1. The severity of depression among Group I and Group II are shown in figure 2 & 3.
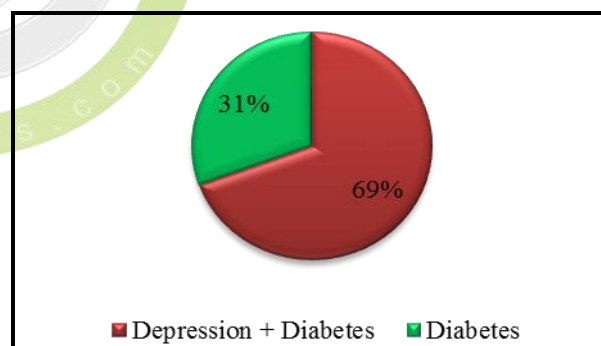

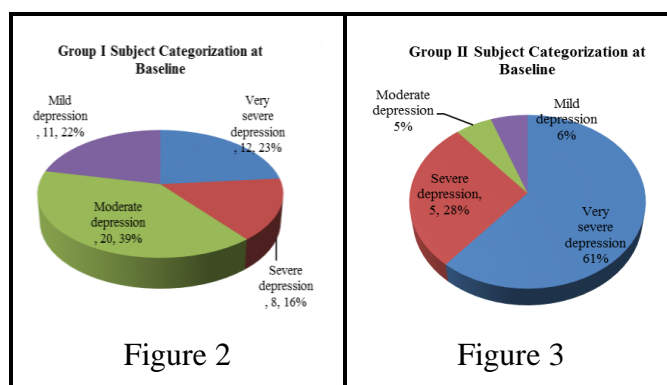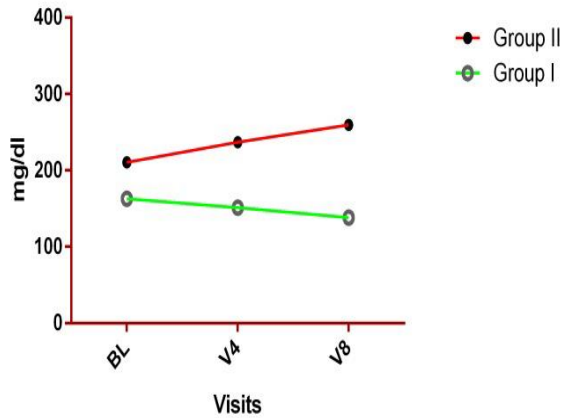Figure 1: Prevalence of Depression among diabetes

Fasting Blood glucose Levels
Group I Vs Group II

Figure 4   Mean Fasting Blood Glucose Levels Group I Vs Group II

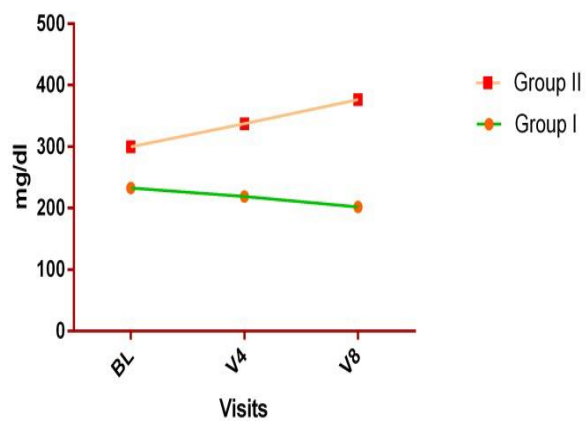|	Group I	Group II
Number of values	3	3
Minimum	138.0	210.6
Maximum	162.9	259.6
Mean	150.7	235.6
Std. Deviation	12.46	24.52
Std. Error of Mean	7.194	14.16
Lower 95% CI of mean	119.8	174.7
Upper 95% CI of mean	181.7	296.5
Coefficient of variation	8.27%	10.40%

Fasting Blood glucose Levels
Group I Vs Group II

	Group I	Group II
Number of values	3	3
Minimum	201.7	299.8
Maximum	232.9	376.5
Mean	217.9	337.8
Std. Deviation	15.63	38.35
Std. Error of Mean	9.027	22.14
Lower 95% CI of mean	179.1	242.6
Upper 95% CI of mean	256.7	433.1
Coefficient of variation	7.18%	11.35%

Figure 5   Mean Post Prandial Blood Glucose Levels Group I Vs Group II

HAM D Score - Group I

Table Analyzed	HAM D
Column B	Group I Visit 8
vs.	vs.
Column A	Group I Baseline
Paired t test	
P value	< 0.0001
P value summary	****
Significantly different? (P < 0.05)	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=9.403 df=50
Number of pairs	51
How big is the difference?	
Mean of differences	-3.647
SD of differences	2.770
SEM of differences	0.3879
95% confidence interval	-4.426 to -2.868
R squared	0.6388
How effective was the pairing?	
Correlation coefficient (r)	0.8810
P value (one tailed)	< 0.0001
P value summary	****
Was the pairing significantly effective?	Yes

HAM D Score - Group II

Table Analyzed	HAM D
Column D	Group II Visit 8
vs.	vs.
Column C	Group II Baseline
Paired t test	
P value	< 0.0001
P value summary	****
Significantly different? (P < 0.05)	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=6.849 df=50
Number of pairs	51
How big is the difference?	
Mean of differences	2.745
SD of differences	2.862
SEM of differences	0.4008
95% confidence interval	1.940 to 3.550
R squared	0.4840
How effective was the pairing?	
Correlation coefficient (r)	0.8375
P value (one tailed)	< 0.0001
P value summary	****
Was the pairing significantly effective?	Yes

HAM D Score Group I vs Group II

Table Analyzed	HAM D GI VS GII
Column B	Group II
vs.	vs.
Column A	Group I
Unpaired t test with Welch's correction	
P value	0.0342
P value summary	*
Significantly different? (P < 0.10)	Yes
One- or two-tailed P value?	One-tailed
Welch-corrected t, df	t=3.860 df=1.861
How big is the difference?	
Mean ± SEM of column A	17.49 ± 1.820 N=2
Mean ± SEM of column B	26.30 ± 1.375 N=2
Difference between means	8.805 ± 2.281
90% confidence interval	1.793 to 15.82
R squared	0.8890
F test to compare variances	
F,DFn, Dfd	
P value	
P value summary	
Significantly different? (P < 0.10)	

Figure 6 HAM D Score
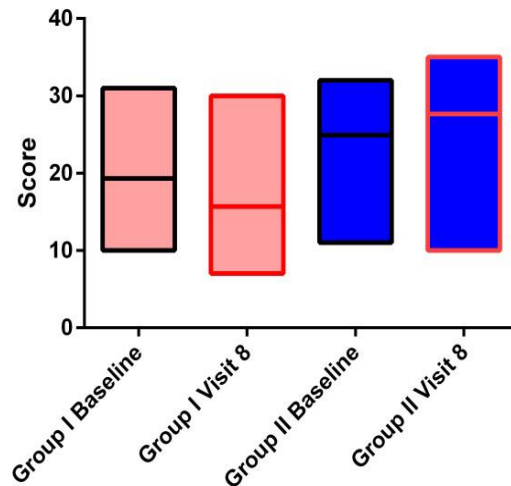
DISCUSSION

This study provides information about the effectiveness of patient counseling in overcoming depression among diabetes patients. The prevalence of depression among diabetes in Nilgiris population (both type 1 and type 2) is about 60 % this report is in favor of the work already published by Beekman AJ.[22] The rising number of depressed cases necessitates the importance of screening and management of depression among diabetes. However the present clinical setup focus much on management of diabetes and fails to address for screening and management of depression. Hence this present study is to develop simple counseling points which can be frequently given by pharmacist to the diabetes depressed subjects.[23]

The results for the group I shown that the mean Fasting Blood Glucose Levels significantly reduced (p<0.0001) from baseline in Visit 4 (Mean difference: 11.63, SE of difference: 1.32) and Visit 8 (Mean: 24.86, SE of Difference 2.577) whereas the group II shown that the mean fasting blood glucose levels increased significantly (p<0.0001) from baseline at Visit 4 (mean difference: 26.08, SE of difference: 1.98) and Visit 8 (mean difference: 48.94, SE of difference: 4.31). On comparing the mean and coefficient of variation the group I (whom received patient counseling) showed betterment in controlling the disease. Similarly the results for the group I shown that the mean post prandial blood glucose levels reduced (p<0.0001) from baseline at Visit 4 (mean difference: 13.80, SE of difference: 1.389) and Visit 8 (mean difference: 31. 24, SE of difference: 3.09). Whereas the group II shown that the mean post prandial blood glucose levels increased significantly (p<0.0001) from baseline at Visit 4 (mean difference: 37.41, SE of difference: 3.537) and Visit 8 (mean difference: 76.73, SE of difference: 5.81). On comparing the mean and coefficient of variation the group I (whom received patient counseling) showed betterment in the disease symptomology. On overall these results are supporting to the reports of William A Rush.[24]

CONCLUSION

The principle conclusion of the study is that the pharmacist intervened counseling points can be beneficial to those diabetes patients who are suffering from depression. However further studies need to be performed with larger sample size and duration to find out the effect of duration of counseling on depression and diabetes self-care among Nilgiris population.

Table 1: Demographic and Metabolic Characteristics

Baseline Characteristics	Group I	Group II
Age mean (SD)	52.39 (5.90)	52.43 (6.21)
Sex % Men Women	31.4 68.6	45.0 55.0
Duration of Diabetes (months) Mean (SD)	52 (15.2)	45 (14.177)
BMI Mean (SD) Kg/m²	22 (4.1)	22.3 (3.9)
FBS Mean (SD) mg/dl	162.9 (23.87)	210.63 (67.71)
PPBS Mean (SD) mg/dl	232.94 (29.99)	299.80 (62.32)
TC Mean (SD) mg/dl	208 (48.9)	208.37 (49.42)
LDL Mean (SD) mg/dl	140.37 (47.38)	141.37 (45.38)
HDL Mean (SD) mg/dl	58.18 (18.31)	56.18 (16.41)
Ham D Score	18.45 (4.77)	25.78 (4.01)

BMI: *Body Mass Index,* **FBS**: *Fasting Blood Sugar,* **PPBS**: *Post Prandial Blood Glucose,* **LDL**: *Low Density Lipoproteins,* **HDL**: *High Density Lipoproteins,* **TC**: *Total Cholesterol.*

The rates of depression were significantly higher in women than in men with diabetes, a pattern that mirrors the female preponderance of depression observed in epidemiological surveys of the general population. The findings are similar to the earlier review of the diabetes literature by Gavard et al. [25] that included 18 studies. These investigators found that major depression was present in 14.7% and elevated depression symptoms in 26% of patients with diabetes. Thus, as many as one in every three individuals with diabetes has depression at a level that impairs functioning and quality of life, adherence to medical treatment, and glycemic control, and increases the risk of diabetes complications.

Table 2: Clinical Characteristics at final visit

Visit (V8)	Group I	Group II
FBS Mean (SD) mg/dl	138.02 (8.61)	259.59 (75.40)
PPBS Mean (SD) mg/dl	201.71 (13.76)	376.53 (68.56)
TC Mean (SD) mg/dl	166.27 (36.35)	182.24 (42.75)
LDL Mean (SD) mg/dl	99.37 (29.37)	115.22 (38.23)
HDL Mean (SD) mg/dl	65.67 (13.86)	63.22 (14.87)
Ham D Score	14.53 (4.57)	28.92 (3.034)

The findings of this review echo the observation, first made by Wolfgang et al [26] in 1999, that depression is associated with diabetes. The complex interactions of physical, psychological, and genetic factors that contribute to this association remain uncertain.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

ACKNOWLEDGMENTS

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