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Research Article

**EVALUATION OF ANTI-DIABETIC THERAPY, OUTCOMES  
AND IMPACT OF PATIENT COUNSELING ON QUALITY OF  
LIFE IN TYPE-2 DIABETES MELLITUS IN A TERTIARY  
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**Abstract:**

*Diabetes Mellitus is a health problem worldwide. The most effective anti-diabetic drugs currently available include insulin and newer insulin preparations, sulphonylureas, biguanides, meglitinides, thiazolidinedione, alpha-glycosidase inhibitors, incretins, glucomannan. However, the future therapies will need to focus on those patients who do not respond well to these treatments and who account for 50% of the health care costs of Diabetes Mellitus. Drug development for diabetes mellitus has been directed at improving currently available drugs and finding new compounds. The chemical entities able to target the metabolic disorder. The main aim of this article is This was a prospective observational study, conducted over 6 months period from April 2011 to September 2011, for assessing the impact of patient counseling on quality of life in type 2 diabetes mellitus in a tertiary care teaching hospital.*

**Key words:** *Diabetes Mellitus, Insulin, sulphonylureas, alpha-glycosidase inhibitors*

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**INTRODUCTION:**

Diabetes mellitus is a hetero-genous metabolic disorder characterized by chronic hyperglycemia with insulin hypo-secretion or insulin insensitivity [1]. About 1 million new cases occur each year, and diabetes is the direct or indirect cause of at least 200,000 deaths each year. Diabetes is one of the oldest known diseases. An Egyptian manuscript from 1550 BCE mentions the phrase “the passing of too much urine.” The great Indian physician Sushruta (6th century B.C) identified the disease and classified it as *Medhumeha* [2].

Type-II diabetes mellitus is less common in non-Western countries where the diet contains fewer calories and daily caloric expenditure is higher. However, as people in these countries adopt Western lifestyles, weight gain and type-II diabetes mellitus are becoming virtually epidemic.

At least 171 million people currently have diabetes, and this figure is likely to more than double to 366 million by 2030. The top 10 countries, in numbers of people with diabetes, are currently India, China, the United States, Indonesia, Japan, Pakistan, Russia, Brazil, Italy, and Bangladesh.

India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed the “diabetes capital of the world”. According to the Diabetes Atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India currently around 40.9 million is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken [3].

**Type-I Diabetes:** Type-I diabetes is believed to be an autoimmune disease. The body's immune system attacks the cells in the pancreas that produce insulin. A predisposition to develop type-I diabetes may run in families, but a genetic cause is much more common for type-II diabetes. Environmental factors, including common unavoidable viral infections, may also contribute. Type-I diabetes is most common in people of non-Hispanic, Northern European descent (especially Finland and Sardinia), followed by African Americans, and Hispanic Americans. It is relatively rare in those of Asian descent. Type-I diabetes is slightly more common in men than in women.

**Type –II diabetes:** Type-II diabetes has strong genetic links, meaning that type-II diabetes tends to run in families. Several genes have been identified and more are under study which may relate to the causes of type-II diabetes. Risk factors for developing type-II diabetes include the following: High blood pressure, High blood triglyceride levels, Gestational diabetes, High-fat diet, High alcohol intake, Sedentary lifestyle aging: Increasing age is a significant risk factor for type-II diabetes. Risk

begins to rise significantly at about age 45 years, and rises considerably after age 65 years. In addition, an in utero environment resulting in low birth weight may predispose some individuals to develop type-II diabetes mellitus [4].

Depending upon etiology of diabetes mellitus hyperglycemia may result from the following: Reduced insulin secretion, Decreased glucose use by the body, increased glucose production.

**Pathogenesis of type1 diabetes mellitus:** Destruction of beta cells mass, usually leading to absolute insulin deficiency. Pathogenesis of type-IA diabetes is explained on the basis of 3 mutually interlinked mechanisms.

**Pathogenesis of type-II diabetes mellitus:** The basic metabolic defect is either a delayed or impaired insulin secretion or insulin resistance.

**Genetic factors:** A person with 1- parent having diabetes type-II is at an increased risk of getting diabetes, but if both parents have type-II diabetes the risk on the offspring rises to 40%.

**Constitutional factors:** Obesity, Hypertension, Low physical activity [5].

**Insulin resistance:** Receptor and post receptor defects, impaired glucose utilisation, increased hepatic synthesis of glucose [6-8].

**Impaired insulin secretion:** Failure of  $\beta$ -cell function-Glucose toxicity, lipotoxicity [9-13].

**RESEARCH METHODOLOGY:****Place of Study:**

The prospective observational study was carried out at Rajeev Gandhi Institute of Medical sciences(RIMS), Kadapa, a 800 bedded multi-disciplinary tertiary care teaching hospital, under the guidance of Dr. P. Murali Madhav M.D in department of general medicine RIMS, Kadapa.

The study proposal was approved by the Institutional Review Board of P.R.R.M.C.P. Kadapa, and was approved by the Ethical Committee of RIMS, Kadapa.

**Study Design:**

This was a prospective observational study, conducted over 6 months period from April 2011 to September 2011, for assessing the impact of patient counseling on quality of life in type 2 diabetes mellitus in a tertiary care teaching hospital.

**Period of Study:** 6 months (April 2011 to September 2011).

**Method of Study:**

Patients were selected from both IP & OP and the patients are followed during the therapy with anti-diabetic agents. Relevant patient data needed for the study was obtained from: Patient data collection

proforma, Patient's prescriptions, Patient interview  
Patient counseling questionnaire form

#### Study Population:

Patients (250 cases approximate) with type 2 diabetes mellitus, who according to their physician, needed insulin treatment will be eligible for the study, including newly diagnose patients and those receiving oral hypoglycemic drugs with (or) without insulin(or)  $FBS \geq 129$  gm/dl (or)  $RBS \geq 200$  mg/dl (or)  $PPBS \geq 200$ .

**Patient Enrollment:** The patients selected for the study were from both the IP & OP departments.

#### Inclusion Criteria:

The study population are both men & women were included to participate if they had uncontrolled type-II diabetes mellitus, obese lower weight,  $FBS$  level  $\geq 129$  mg/dl &  $RBS \geq 200$  mg/dl, age group ( $>30$  yrs).

#### Exclusion Criteria:

Patients were excluded, if they were unable to comply with protocol requirements. The patients having end stage complications like renal failure, hepatic failure & cardiac failure. History of adverse reactions to sulfonyl ureas (or) metformin. History of drug (or) alcohol abuse. Clinically relevant medical (or) psychological condition.

#### KAP Questionnaire:

This contains 20 questions which measure knowledge, attitude, and practice of the patients about diabetes.

#### Source of Data:

All necessary and relevant base line information were collected on a standard "patient data collection proforma", which contains patient demographic

data, admitting/ provision diagnosis data, past medical/ medication history, social history, patient examination(general physical & systemic) data, laboratory data, treatment chart prescriptions & other verbal communication data with patient's.

All the collected information is analyzed by the following parameters: Based on demographic data of sex. Based on age group. Based on social habits (smoking, alcoholism). Effect of patient counseling on blood sugar levels. Effect of patient counseling on physical component summary (PCS).Effect of patient counseling on mental component summary (MCS).Based on comparison of  $FBS$  &  $RBS$ . Based on month-wise patient outcome. Based on % distribution of patients with respect to presenting symptoms. Based on % distribution of patients with respect complications.

% distribution of patient's based on single/mono drug therapy % distribution of patient's based on combination therapy, two drug combination. Three drug combination. Four drug combination. Based on incidence level of diabetes mellitus.

#### Statistical Analysis:

Student T-test was performed to calculate the P-value for the purpose of comparison of results by using software namely "Graph Pad prism".

#### RESULTS:

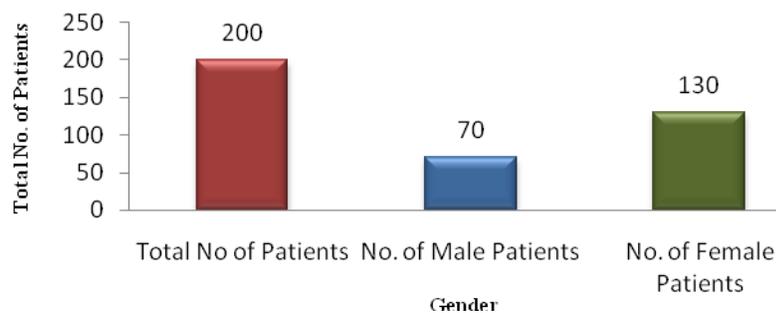
The prospective observational study was conducted for 6 months (April to September 2011) in south Indian teaching hospital RIMS, Kadapa. A total of 200 type-2diabetes mellitus patients were recruited under inclusion criteria upon received of ICF.

#### Patient Distributions Based on Demographic Data:

Out of 200 patients 130 (65%) females were found to be more when compared with males 70 (35%) which was represented in table-1 and figure-1.

**Table1: Patient Distribution Based on Gender**

Total No. of Patients (%)	No. of Male Patients (%)	No. of Female Patients (%)
200 (100%)	70 (35%)	130 (65%)



**Fig 1: Graphical Representation of Patient Distribution Based on Gender**

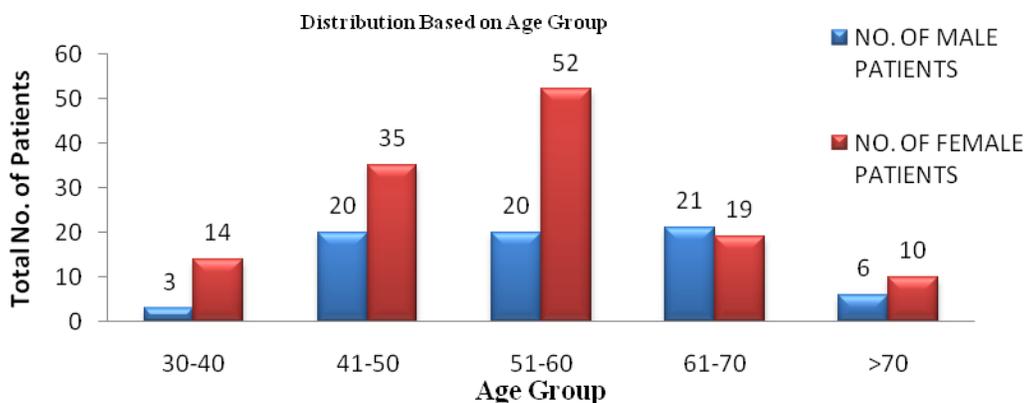
**Patient Distribution with Respect to their Age Groups:**

We categorized the patients respected to their age groups. Out of 200 patients majority 72 (36%) of them were found in between the age group 51-60

years, followed by 55(27.5%) in between the age group 41-50 years, 40 (20%) in between the age group 30-40 years, then finally 16 (8%) were >70 years which was represented in table-2 and figure-2.

**Table2: Patient Distribution with Respect to their Age Groups**

Age group of patients	No. of male Patients (%)	No. of female Patients (%)	Total No. of Patients (%)
30-40	3(17.62)	14(82.35)	17(8.5%)
41-50	20(36.36)	35(63.63)	55 (27.5%)
51-60	20(27.77)	52(72.22)	72 (36%)
61-70	21(52.5)	19(47.5)	40 (20%)
>70	6(37.5)	10(62.5)	16 (8%)



**Fig 2: Graphical Representation of Patient Distribution with Respect to their Age Groups**

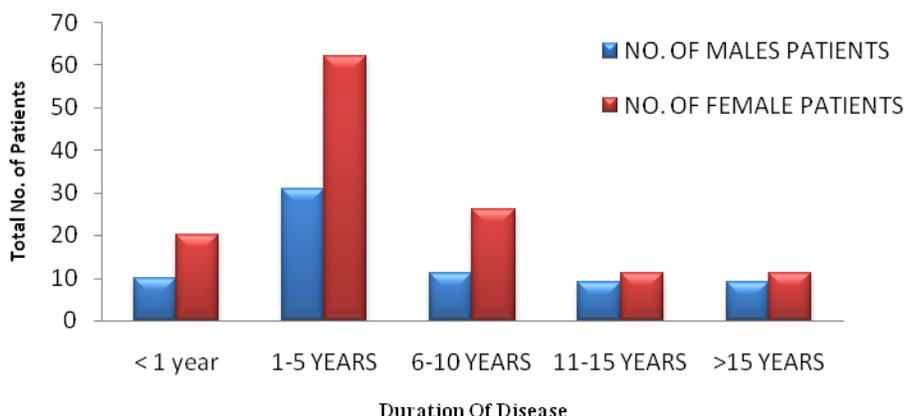
**Distribution of Patients Based on Duration of Disease:**

Out of 200 patients 93 (46%) were in between 1-5 years, followed by 37 (19%) were in between 6-10 years, 30 (15%) were in below 1 year, 20 (10%)

were between 11-15 years, and finally 20 (10%) were above 15 years results were shown in tables-3, 4 and figure-3, 4.

**Table 3: Distributions of Patients Based on Duration of Disease**

Duration of Disease (Years)	No. of Male Patients (%)	No. of Female Patients (%)	Total No. of Patients (%)
<1	10(33.33)	20(66.67)	30(15%)
1-5	31(33.33)	62(66.67)	93(46%)
6-10	11(29.73)	26(70.27)	37(19%)
11-15	9(45)	11(55)	20(10%)
>15	9(45)	11(55)	20(10%)

**Based on Duration of Disease****Fig 3: Graphical Representation of Distributions of Patients Based on Duration of Disease****Table4: Distribution of Patients Based on Diabetic Symptoms**

Diabetic Symptoms	No. of Patients in Pre Counseling (%)	No. of Patients in Post Counseling (%)	Total No. of Patients (%)	P-Value
Poly uria	82 (60.74)	53(39.25)	135(46)	0.4681
Insomnia	44(60.27)	29(39.72)	73(25)	
Pruritis	34(60.71)	22(39.28)	56(19)	
Dizziness	9(69.23)	4(30.76)	13(5)	
Diarrhoea	5(83.33)	1(16.66)	6(2)	
Chest pain	5(83.33)	1(16.66)	6(2)	
Dental problem	2(100)	0	2(1)	

*The diabetic symptoms at baseline and after counseling*

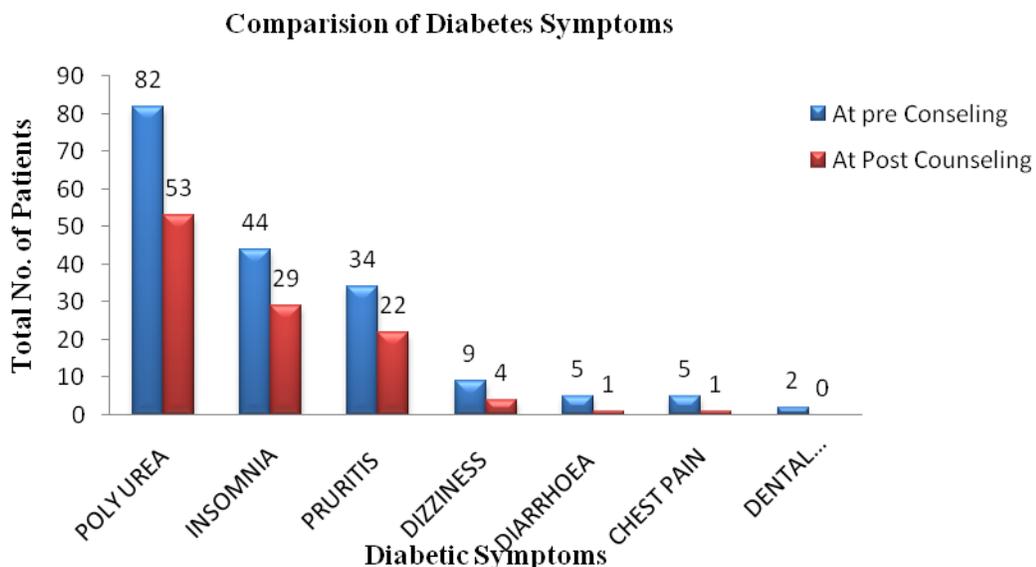


Fig 4: Graphical Representation of Comparison of Diabetic Symptoms

**Effect of Patient Counseling on Blood Glucose Levels**

At baseline, majority of patients 60 (57.69%) RBS values in between range of 241-280, after counseling majority of patients 151 (82.51%) in

between the RBS range of 200-240. The RBS values of the patients are high at baseline, after counseling the patients the same values were reduced shown in table-5 and figure-5.

**Table 5: Effect of Patient Counseling on RBS Values of Diabetic Patients**

RBS Range (mg/dl)	No. of Patients in Pre Counseling (%)	No. of Patients in Post Counseling (%)	Total No. of Patients (%)	P-Value
200-240	32(17.48)	151(82.51)	183(50%)	0.6771
241-280	60(57.69)	44(42.30)	104(28%)	
281-320	32(71.11)	13(28.88)	45(12%)	
>320	30(83.33)	6(16.66)	36(40%)	

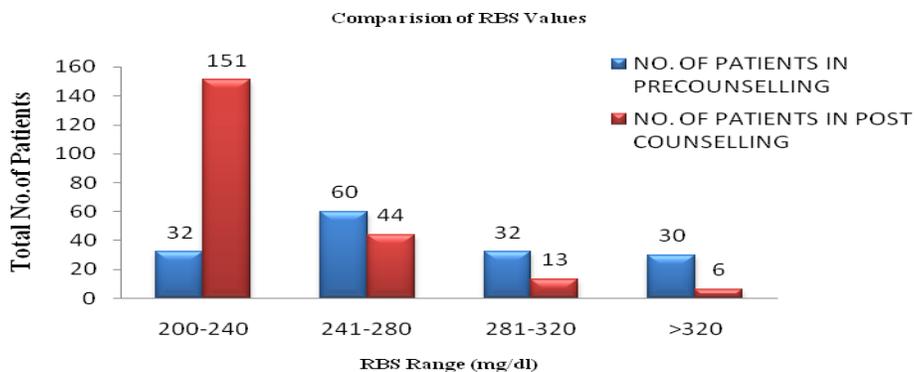


Fig 5: Graphical Representation of RBS Values of Diabetic Patients

**DISCUSSION:**

Scientific studies have suggested that, counseling has shown positive impact on health and decreased the mortality and morbidity. The present six months study demonstrated the influence of structured education on knowledge, attitude and practices, various domains of QOL and clinical and physiological parameters of diabetes mellitus.

In present study we observed that diabetes mellitus was more prevalent in females 65% than in males 35%. This may be due that majority of the patients were illiterate housewives leading sedentary life style, stress full life.

In our study majority of patients 36% were in between 51-60 years age group but Mahesh Gottipati *et.al* [14] reported that majority of patients 52.83% were in between 61-80 years. Both the studies reported that patients > 50 years of age were affected more, this may be due to the fact that, age is the risk factor for developing DM.

In our study we found that maximum number of patients 39% had alcoholism as their risk factor and this has to reduce to control the prevalence of DM.

In our study most of the patients 46% were suffering from DM since 1-5 years and many of them were newly diagnosed to have DM. and about 10% patients were suffering from this disease above 15 years. A proper education and counseling in this patients will improves the QOL and minimize the complications of the disease. Mahesh Gottipati *et.al* [14] reported that 48.89% patients were suffering from the disease more than 6 years.

Symptoms are a person's perception of an abnormal physical, emotional, or cognitive state. In the present study statistically there is no significant difference ( $p>0.05$ ) was found in number of complaints but clinically there is significant decrease was found between the diabetic symptom complaints at baseline and after counseling. This shows the effectiveness of patient counseling in reducing the blood glucose levels. These results were supported by Bakyaraj R *et.al* [15].

In the present study 74% patients reported hypertension along with the DM, these results were supported by Mahesh Gottipati *et.al* [14] study. This indicates that hypertension is the common complication of DM.

The measurement of blood glucose values in diabetes patients is necessary, we observed that blood glucose levels are high at baseline due lack of adequate knowledge of disease, may be due to their negligence towards health, after patient counseling there is a reduction was found but this decrease was not statistically significant ( $p>0.05$ ). These results were supported by Bakyaraj R. *et al* [15].

In the present study we observed that biguanides (Metformin) utilization was high as monotherapy in controlling blood glucose levels, this may be due to its advantage of no weight gain, and it was supported by Adhikari A.K. *et al* [16] study.

In combination therapy especially in oral therapy biguanides+ sulphonylureas combination was used most widely 69% this was supported by Ismail AM *et al* [17] study. Metformin + insulin combination was used for those patients got admitted into the wards with uncontrolled DM.

Three drug regimen including insulin was used in patients where immediate reduction in elevated blood glucose levels is needed.

In this study we observed both statistical and clinical significant improvement ( $p<0.05$ ) in patients knowledge, attitude and practice after counseling and same was observed in Mahesh Gottipati *et al* [14] study. The study assessed the level of knowledge, attitude and practice on diabetes. The KAP questionnaire consists of 20 questions regarding diabetes, its causes, symptoms, complications and lifestyle changes have given lot of information to the patients how to control the disease.

Quality of life is a concept increasing valued as an outcome variable in bio-behavioral research. In the present study most of the people 48.5% responded to physical components, followed by 36% people responded to mental components and considerable patients 15.5% responded to both physical and mental components.

Here we used short form-12 to assess the quality of life of patients at baseline and after counseling, by using physical components (total of 6 questions in that 2 from physical functioning, 2 from role physical, 1 from bodily pain, and 1 from general health) and mental components (total of 6 questions in that 2 from vitality, 1 from social functioning, 1 from role emotional, 2 from mental health).

**CONCLUSION:**

To sum up, poor knowledge leads to non-adherence to medication therapy, this eventually leads to poor blood glucose level control in diabetic patients. The present study revealed that the patients were unaware about the basic concept related to diabetes. The present study also concluded that chronic diseases like diabetes affect the quality of life of patients and the education has a major role in improving the health care outcomes like glycemic control and quality of life. It also improved the medication adherence behavior. Maintenance of diet and exercise improved the patient's enjoyment in day-to-day life activities and that has reduced the

morbidity and mortality rates. Clinical pharmacist imparted patient education through counseling improved Quality of life through knowledge and adherence to therapy.

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