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IMPACT OF PATIENT COUNSELING ON BLOOD GLUCOSE LEVELS OF DIABETES MELLITUS PATIENTS

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ABSTRACT

Diabetes Mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia. A good metabolic control can be achieved by appropriate drug therapy as well as strict diet control, periodical monitoring of blood glucose, and patient education regarding lifestyle modifications and drug therapy adherence. Pharmacists play a vital role in patient education. A Prospective Observational study was conducted for a period of 6 months at Rajiv Gandhi Institute of Medical Sciences on known T2DM patients, we aimed to assess the impact of patient counseling on the patient's blood glucose levels. On daily basis patients who are visiting the general medicine department were screened as per the eligibility criteria after obtaining informed consent. At baseline all the subjects were assessed for their disease status along with the blood glucose levels and counseling was provided at monthly once for 3 months, finally the same data was assessed at the end of the study and compared. A total of 200 subjects were completed the study among them 130 (65%) were females, and 127 were in between 41-60 years. There is a statistical significant decrease was found in patient's blood glucose levels and the average RBS, FBS, PPBS values of before and after patient counseling are (249.86 ± 37.702 Vs 199.71 ± 29.92), (150.47 ± 11.98 Vs 127.79 ± 10.47) and (161.61 ± 8.86 Vs 135.23 ± 7.18) respectively. With this study we conclude that clinical pharmacist's education shown the significant improvement in controlling blood glucose levels and the management disease condition.

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INTRODUCTION

Diabetes Mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia, and associated with abnormalities in carbohydrate, fat, and protein metabolism which results in chronic complications including micro and macro vascular. [1]

According to the International Diabetes Federation (IDF) data, diabetes affected 382 million people worldwide in 2013, and is expected to rise 592 million by 2035. 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 [2]. By 2030 India will become the largest number of diabetic people that every fifth person with diabetes will be an Indian followed by china and U.S.A [3].

A good metabolic control can be achieved by drug therapy; may be with Monotherapy with Metformin, or as well as any other hypoglycemic drug, but only for a limited period of time. For this reason, after a few years from diagnosis most type2 diabetic patients require combination therapy in order to reach therapeutic goals. Metformin monotherapy failure leads to the addition of treatment options like sulphonylureas, glinides, thiazolidinediones, acarbose, glucagon-like peptide-1 (GLP-1) analogues, dipeptidyl peptidase IV (DPP-IV) inhibitors, or insulin [1].

According to National Health and Nutrition Examination Survey reports 37.0% of DM patients have adequate disease control. Diabetes imposes a large economic burden on the individual, national healthcare system and economy. In 2010 the expected Healthcare expenditures on diabetes are 11.6% of the total healthcare expenditure in the world. However, this economic burden can be reduced by implementing many inexpensive, easy-to-use interventions, most of which are cost-effective [4].

Over the past 2-3 decades, pharmacist's role has changed from dispensing medicine against prescription and dispensing OTC medicine to the development of new medicine, involving in therapy setting in a multidisciplinary team and ultimately focusing on improving the patient's quality of life through implementation of pharmaceutical care plans, this plan includes the achievement of positive outcomes by influencing the cure, elimination or reduction of symptoms, arresting or slowing the disease and its progress effectively at an early phase.

To accomplish pharmaceutical care plan successfully patient counseling is vital, which involves patients and their care takers. Patient counseling is interactive in nature and involves a one-to–one interaction between a pharmacist and a patient and/or caregiver. In this process pharmacist provides the patient's specific information through oral, written and/or using counseling aids. Generally this information includes drug route of administration, dose, frequency and its intended use along with specific precautions and side effects, storage; regarding disease and its clinical manifestations, etiology, risk factors and complications and their management, along with the lifestyle modifications to be done, dietary changes. The ultimate purpose of counseling is to assess awareness and provide information on safe and appropriate use of medications, thereby enhancing therapeutic outcomes. [5-7]

Several studies have reported the positive impact of clinical pharmacists counseling on glycemic control and quality of life outcomes in diabetic population. Studies such as Diabetes Control and Complication Trail (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS) have conclusively demonstrated that normalization of blood glucose significantly reduces the risk of complications [8].

As the prevalence and incidence of DM and its complications is being rising at a tremendous phase, healthcare system should implement and test the new approaches to trim down this, so, with this motto and supportive information we hypothesized to find the impact of clinical pharmacist's intervention through counseling in helping patients to cope up with their disease and make informed decisions regarding management and medication [9].

We had tested our hypothesis through the following objectives:

- Assessing the patient's disease condition by measuring blood glucose levels and clinical manifestations before and after counseling.
- Educating patients in disease management periodically through oral and written information.

Research Methodology

Study Details

Place of study	: Department of General Medicine, Rajiv Gandhi Institute of Medical Sciences (RIMS), Kadapa.
Study duration	: 6 months
Study design	: Prospective Observational study
Study population	: Both old and new cases of Type 2 diabetes mellitus and receiving oral hypoglycemic drugs with (or) without insulin

Patient Enrollment

After obtaining the signed informed consent patients were selected from both the IP & OP departments as per eligibility criteria after obtaining the ethical approvals from the Institutional Review Board of Rajiv Gandhi Institute of Medical Sciences (IRB RIMS), Kadapa.

Inclusion Criteria

The study population are both men & women were included to participate if they had uncontrolled type-2 diabetes mellitus with FBS level FBS ≥ 129 gm/dl (or) RBS ≥ 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 drug (or) alcohol abuse.
- Clinically relevant medical (or) psychological conditions.

Method of Study

Patients who had visited to the general medical IP, OP wards were screened as per the eligibility criteria after obtaining the informed consent form. In first month, at baseline i'e before patient counseling laboratory parameters (FBS, RBS and PPBS) were noted. Patient counseling [5] was provided to the patients and then the patients were monitored closely for any changes in the blood glucose levels. The effect of patient counseling on the Type 2 DM was estimated by comparing the blood glucose parameters i'e FBS, PPBS and RBS before and after patient counseling.

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.

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

Demographic Data

TABLE 1 elucidates the demographics of the study subjects, Out of 200 patients 130 were females and males were 70. Majority i.e. 36 % were in between the age group 51-60 years, followed by 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, 59 (29.5%) are having social habits like alcoholism only 11.5 %, followed by 9.5 % are both alcoholics and smokers, finally 8.5 % were only smokers, 60 % subjects ere employers, 77 % were married, 71 % are illiterates, 61 % are residing in rural area, and 46% subjects are having the history of diabetes for 1-5 years, followed by 37 (19%) were in between 6-10 years and finally 20 (10%) were above 15 years.

TABLE 1 Demographic Data of the Study Subjects.

Gender	Number of patients (n=200)	Percentage (%)
Male	70	35
Female	130	65
Age		
30-40	17	8.5
41-50	55	27.5
51-60	72	36
61-70	40	20
>70	16	8
Employment status		0
Employed	119	59.5
Un Employed	45	22.5
Retired	36	18
Marital status		
Married	154	77
Unmarried	43	21.5
Divorced/widow	3	1.5
Educational status		0
Literate	142	71
Illiterate	58	29
Residence		
Rural	122	61
Urban	78	39
Social habits		
Alcoholics	23	11.5
Smokers	17	8.5
Alcoholics and smokers	19	9.5
Duration of the Disease		0
<1	30	15
1-5	93	46.5
6-10	37	18.5
11-15	20	10
>15	20	10

Diabetic Symptoms

The diabetic symptoms were shown in TABLE 2. We found here there is decrease in complaints of diabetic symptoms after patient counseling.

TABLE 2 Diabetic Symptoms reported by the study subjects.

	Number of patients	
Diabetic Symptoms	Baseline	Post counseling
Polyuria	117	81
Insomnia	59	45
Pruritis	47	32
Dizziness	24	12
Diarrhoea	14	08
Chest Pain	13	07

Diabetes Complications

Patients were monitored and interviewed regarding the complications, if any, and found 124 subjects developed complications among them, around 60 % of the study subjects found to have Hypertension followed by Neuropathy (10 %), Diabetic foot ulcer (8 %), Nephropathy (6 %), retinopathy (6 %) and other complications (10 %)

Drug Therapy

TABLE 3 explains about the type of therapy prescribed and it was found that 2-drug therapy was majorly used to treat the diabetic patients. We revealed that 2 classes of oral anti-diabetic drugs and 2 types of insulin were used to treat patients, according to our study biguanides (metformin) are majorly used. In combination therapy biguanides + Sulfonyl ureas were given to majority of patients and followed by insulin + biguanides.

TABLE 3 Type of Drug Therapy Prescribed.

Drug Regimen	**Total No. of Patients (%)**
MONOTHERAPY	44(22)
Metformin	23(52)
Human insulin actrapid	11(25)
Human insulin mixtard	7(16)
Glibenclamide	3(7)
2 DRUG THERAPY	129(65)
Biguanides + sulphonyl ureas	117(91)
Insulin + biguanides	12(9)
3 DRUG THERAPY	
Insulin+ Biguanides+ Sulfonyl Ureas	27(14)

Effect of Patient Counseling on Blood Glucose Levels

TABLE 4 explains about the blood sugar values which have been monitored at before and after the counseling with statistical significance and 95% CI values. There was significant decline in fasting blood glucose from baseline to post counseling was observed.

TABLE 4 Average blood sugar values of study patients.

Sl. No.	**Parameter**	**Average (SD)**		***P Value***	**95% CI**
		Pre-Counseling	**Post-Counseling**		
1	RBS (mg/dl)	249.86 (±37.702)	199.71 (± 29.92)	<0.0001	-53.99 to -46.31
2	FBS (mg/dl)	150.47 (± 11.98)	127.79 (± 10.47)	<0.0001	-24.11 to -21.24
3	PPBS (mg/dl)	161.61 (± 8.86)	135.23 (± 7.18)	<0.0001	-30.31 to -22.14

DISCUSSION

Scientific studies have suggested that, counseling has shown positive impact on health and decreased the mortality and morbidity. The present study demonstrated the influence of structured education on blood sugar levels and clinical and physiological parameters of diabetes mellitus.

Generally female especially working women may have tremendous stress as they have to manage both family and professional life, which is the trigger/risk factor for the development and progression this disease, in present study we observed that the occurrence of diabetes mellitus was more in females (65%) than in males (35%) similar results were reported by Gray C Brown et.al [10].

Diabetes is more prevalent above the age of 50 years as the normal physiological and morphological functioning may reduces in most of the human beings and triggers the incidence of majority of the diseases, in our study majority of patients (36%) were in between 51-60 years age group but Mahesh Gottipati et.al [11] reported that majority of patients 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.

Alcoholism and/or smoking are the serious threat factors for the development of illnesses in the body, further they limits the effect of the therapy also, with this study we found that maximum number of patients i.e. 30% had alcoholism and/or smoking as their risk factor.

In the present study 74 patients reported hypertension along with the DM, these results were supported by Mahesh Gottipati et.al [11] study. This indicates that hypertension is the common complication of DM.

As diabetes is the chronic metabolic diseases, with no permanent cure, and the risk increase with the diseases progressed for many years and management is only the choice, so proper awareness about the disease and its progression and how to identify and control the complications at an early stage, importantly balancing the blood sugar levels in safe range are most useful instructions in controlling their disease. In our study most of the patients i.e. 46% were suffering from DM since 1-5 years and many of them were newly diagnosed and about 10% patients were suffering from this disease above 15 years. Mahesh Gottipati et.al [11] reported that 48.89% patients were suffering from the disease more than 6 years, we found that there is a statistical significant decrease (<0.0001, with 95 % CI) was found in blood sugar levels from baseline to post counseling which is evidenced with decrease in diabetic symptom complaints. This shows the effectiveness of patient counseling in reducing the blood glucose levels. These results were supported by Bakyaraj R, Shareef J and S Palaian et.al [5, 12, 15-16].

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 [13] study. In combination therapy especially in oral therapy biguanides+ sulphonylureas combination was used most widely (69%) this was supported by Ismail AM et al [14] 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.

CONCLUSION

Diabetes is a chronic metabolic disease with serious complications and required close and continuous monitoring of patient's symptoms and blood sugar levels to reduce the disease related morbidity and mortality, with this present study we proved that, clinical pharmacist is the one of the important health care provider in managing chronic diseases like diabetes with proper education and outcome monitoring. Clinical pharmacist's education shown the significant improvement in controlling blood glucose levels and the management disease condition. Like dispensing pharmacist in every hospital setup, a clinical pharmacist must be available to the patients' especially for chronic disease conditions. To support our recommendations a well structured research should be carried out by the healthcare professions and department of health and family welfare.

List of Abbreviations

CI – Confidence Interval
FBS – Fasting Blood Sugar
IP – In Patient
OP – Out Patient
OTC – Over The Counter
PPBS – Post Pandrial Blood Sugar
RBS – Random Blood Sugar
T2DM – Type 2 Diabetes Mellitus
U.S.A – United States of America

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Conflict of Interest

None

REFERENCES

1. Joseph T Dipiro. Pharmacotherapy: A Pathophysiologic approach. 7th ed. The McGraw Hill Publishers; 2008 pp 147 and 1206
2. Diabetes [homepage on the Internet] National Institute of Diabetes and Digestive and Kidney Diseases [Cited on: 19.02.2017] Available from: https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/Pages/diabetes.aspx
3. Till Seuring, Olga Archangdidi, Marc Suhrcke. The Economic Costs of Type 2 Diabetes: A Global Systematic Review, Pharmacoeco. 2015; 33(8): 811-31.

4. Anna Paulade Sa Borges, Camilo Molinoguidoni, Osvaldo De Freitas, Leonardo Regis Leura Perusa, Economic Evaluation of Outpatients with Type 2 Diabetes Mellitus Assisted By A Pharmaceutical Care Service. Arq Bras Endocrinol Metab. 2011; 55(9): 686-91.
5. S Palaian, A Chhetri, M Prabhu, S Rajan, P Shankar. Role of Pharmacist in Counseling Diabetes Patients. The Internet J of Pharmacol. 2004 [cited 2011 Dec 12] Volume 4 Number 1. Available from: http://ispub.com/IJPHARM/4/1/3272.
6. Patlak M. New weapons to combat an ancient disease: treating diabetes". The FASEB J. 2002; 16 (14): 1853.
7. S.Z. Inamdar, R.V. Kulkarni, S.R Karajgi, F.V.Manvi, M.S.Ganachari, B.J.Mahendra Kumar. Medication Adherence in Diabetes Mellitus: An Overview on Pharmacist Role. Am J of Adv Drug Del. 2013; 1(3): 238-50.
8. R.Adepu, A.Rasheed, B.G.Nagavi. Effect of Patient Counseling on Quality of Life in Type-2 Diabetes Mellitus Patients in Two Selected South Indian Community Pharmacies: A Study. Ind J of Pharm Sci. 2007; 519-24.
9. Renuga E, Ramakrishnan Sr, Vanitha Rani N, Thennarasu P, Kannan G. Impact of Continuous Patient Counseling on Knowledge, Attitude, and Practices and Medication Adherence of Diabetic Patients Attending Outpatient Pharmacy Services, Asia J of Pharm Clin Res. 2016; 9(1): 364-69.
10. Gary C Brown, Melissa M Brown, Sanjay Sharma, Heidi Brown, Marvin Gozum, Paul Denton. Quality of Life Associated with Diabetes Mellitus in an Adults Population. J of Diab and its Compli. 2000; 14 (1): 18-24.
11. Mahesh Gottipati, Mohideen Abdul Kader M, Arunmozhy Barathiraja S, N V R Praveen Kumar T, S Balasubramaniyan, Manna P K. Role of Clinical Pharmacist in the Management of Diabetic patients. Pharmacie Globale (IJCP). 2011; 4 (07).
12. Bakyaraj R, Rajendran NN, Narmadha MP. Effect of Insulin Therapy in Type-2 Diabetes in Improving a Cell Function and Glycemic Control Compared with Oral Anti- Diabetic Agents with or without Insulin in Routine Clinical Practice. Ind J Pharm Pract. 2010; 3(1): 47-57.
13. Agarwal AA, Jadhav PR, Deshmukh YA. Prescribing pattern and efficacy of anti-diabetic drugs in maintaining optimal glycemic levels in diabetic patients. J of Basic and Clin Pharm. 2014; 5(3):79-83.
14. Ismail AM, Ingle VP, Senthamarai R, Jesima BA. Anti-diabetic Potentiality of Newer Oral Anti-hyperglycemic Combination Therapy over Conventional one. IJOPP. 2010; 3(4): 24-27.
15. Shareef J, Fernandes J, Samaga L, Bhat ML. Evaluating the Effect of Pharmacist's Delivered Counseling on Medication Adherence and Glycemic Control in Patients with Diabetes Mellitus. J Diabetes Metab. 2016; 7 (3).
16. Malathy R, Narmadha MP, Ramesh S, Alvin Jose M, Dinesh Babu N. Effect of a Diabetes Counseling Programme on Knowledge, Attitude and Practice among Diabetic Patients in Erode District of South India. J Young Pharm. 2011; 3(1): 65–72.

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