

Prevalence of Co-morbidities in Type 2 Diabetes Mellitus Patients, the Awareness Level and the Impact of Pharmacist's Patient Education Program

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ABSTRACT

Diabetes mellitus, it is a very dangerous non communicable disease which results in the death of millions usually in the developed countries. Diabetes mellitus along with the co-morbidities has been reported as the fifth leading cause of death, and the studies show that most often the developed countries where the people are less bothered about their food habits are most affected. There are 3 main types of diabetes: Type I, Type II, and Gestational diabetes mellitus. Type II is the most common form of diabetes and accounts for 90 to 95% of Diabetes cases. Chronic hyperglycemia without proper management can also lead to various short term and long term secondary complications, both of small and big, vascular nature which may be determined as the main cause of mortality and morbidity in type 2 diabetic patients all over the world. The study conducted strictly observed the diabetes affected people in a particular area and the co-morbidities were studied in a very detailed and elaborate manner and a pharmacist counseling and education program was conducted for the patients the statistical reports about studies clearly says that the program and studies had a positive effect on the co-morbidities and other factors like HbA_{1c} level, etc.

Keywords: Co-morbidity, diabetes mellitus, HbA_{1c} level, hyperglycemia, pharmacist patient counseling

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INTRODUCTION

Diabetes mellitus (DM) is one of the most common non-communicable disease (NCDs) globally. It is the 7th or 8th leading cause of death in most developed countries and there is substantial evidence that it is epidemic in many economically developing and newly industrialized countries [1,2]. According to international diabetes federation (IDF) 6th edition of Diabetes Atlas, it is indicated that the number of people living with diabetes is expected to rise from 382 million in 2013 to 592 million by 2035. IDF has also estimated that about 65.1 million people in India are living with diabetes. There are 3 main types of diabetes: Type I, Type II, and Gestational diabetes mellitus. Type II is the most common form of diabetes and accounts for 90 to 95% of Diabetes cases. Chronic hyperglycemia without proper management can also lead to various short term and long term secondary complications, both of small

and big, vascular nature which may be determined as the main cause of mortality and morbidity in type 2 diabetic patients all over the world [3].

CO-MORBIDITY

Co-morbidity is defined as the occurrence of one or more chronic conditions in the same person with an index-disease, occurs frequently among patients with diabetes. Currently, integrated diabetes care programs focus on diabetes-related co morbidities like cardiovascular diseases, retinopathy, nephropathy and diabetic foot [4].

However, patients with diabetes do not only have diabetes-related co morbidity but also have non diabetes-related co morbidity, such as depression and musculoskeletal diseases. With the on-going population aging of Western societies, not only the number of patients with diabetes is expected to increase, but also the number of patients

with diabetes with co morbidity. This implies that the current single disease management approach is not applicable to a large part of the patients with diabetes in the future [5].

Co-morbidity among patients with diabetes is associated with considerable consequences for health care and related costs. Co-morbidity has been shown to intensify health care utilization and to increase medical care costs for patients with diabetes. However, most studies have been focused on one health care service, mainly hospital care, or limited their analyses to one additional co morbid disease. In addition previous studies on multidisciplinary health care utilization were based on self-reported questionnaires instead of health care registration data.

DIABETIC RETINOPATHY

Diabetic Retinopathy (DR) is a vascular disorder affecting the microvasculature of the retina. Diabetic Retinopathy [DR] is a complication of diabetes and a leading cause of blindness. It occurs when diabetes damages the tiny blood vessels inside the retina, the light-sensitive tissue at the back of the eye [6]. The patient having diabetic retinopathy might not notice any changes to the vision at first. But over time, diabetic retinopathy can get worse and cause vision loss. Diabetic retinopathy usually affects both eyes [7]. It is estimated that diabetes mellitus affects 4 per cent of the world's population, almost half of whom have some degree of DR at any given time. Diabetic Retinopathy (DR) occurs both in type 1 and type 2 diabetes mellitus and has been shown that nearly all type 1 and 75 per cent of type 2 diabetes will develop Diabetic Retinopathy (DR) after 15 yrs duration of diabetes as shown in earlier epidemiological studies 2, 3. In the western population, Diabetic Retinopathy (DR) has shown to be the cause of visual impairment in 86 percent of type 1 diabetic patients and in 33 per cent of type 2 diabetic patients In India with the epidemic increase in type 2 diabetes mellitus as reported by the World Health Organization (WHO), diabetic retinopathy has been becoming a very important cause of visual disability and other visual problems. Visual disability from diabetes is a big public health problem. This morbidity is largely preventable and curable [8].

DIABETIC NEUROPATHY

Diabetic neuropathies are a group of nerve disorders that may be caused by Diabetes mellitus (DM). Nerve damage throughout the body may be observed in Diabetes mellitus (DM) patients over time and this is a critical condition. In some cases for some people nerve damage may occur without any symptoms while for some others the damage may be followed with symptoms such as tingling, pain, or numbness loss of feeling in the hands, arms, feet, and legs [9]. These nerve damage or disorders may affect every organ in the body, including important organs like the heart, digestive tract, and sex organs. Neuropathy is observed in about 60 to 70 % of Diabetes Mellitus patients, People with diabetes can develop nerve problems at any time without any prediction, but risk rises with neuropathy are seen in people who have had diabetes for at least 25 years. In people who have problems in controlling their blood glucose, also called blood sugar, those with high levels of blood fat and high BP and those who are overweight, diabetic neuropathies appear to be more common and chronic [10].

DIABETIC NEPHROPATHY

Diabetic Nephropathy is the leading cause of kidney disease in patients starting renal replacement therapy and affects 40% of type 1 and type 2 diabetic patients. It increases the risk of death, mainly from cardiovascular causes, and is defined by increased urinary albumin excretion (UAE) in the absence of other renal diseases. Diabetic nephropathy is categorized into stages: micro albuminuria (UAE 20 g/min and 199 g/min) and macro albuminuria (UAE 200g/min). Hyperglycemia, increased blood pressure levels, and genetic predisposition are the main risk factors for the development of diabetic nephropathy. Elevated serum lipids, smoking habits, and the amount and origin of dietary protein also seem to play a role as risk factors. Screening for micro albuminuria should be performed yearly, starting 5 years after diagnosis in type 1 diabetes or earlier in the presence of puberty or poor metabolic control in patients with type 2 diabetes; screening should be performed at diagnosis and yearly thereafter [11].

HYPERTENSION

Hypertension is more prevalent in patients with diabetes than in the non-diabetic population, and early identification and effective management of hypertension is paramount in the care of people with diabetes. Adults with both diabetes and hypertension have more renal disease and atherogenic risk factors than the general population, including dyslipidemia, elevated fibrinogen and left ventricular hypertrophy. Having both diabetes and hypertension has been shown to double the risk of cardiovascular events, cardiovascular mortality and total mortality [12].

HYPERLIPIDEMIA

Hypercholesterolemia is a disorder characterized by high levels of blood cholesterol. Cholesterol is manufactured primarily in the liver and then carried to the cells throughout the body by low-density lipoprotein (LDL). Because cholesterol and other fats do not dissolve in water, they cannot travel through the body unaided. Lipoproteins are particles formed in the liver to transport cholesterol and other fats through the bloodstream [13].

PHARMACIST'S ROLE IN MANAGEMENT OF DIABETES

Pharmacists are an integral part of the health care delivery system in the America and are the most accessible health care peoples in most communities. The Pharmacists may help bridge the education gap, since it is has been reported that only 30% of patients receive formal diabetes education. The Pharmacists are uniquely positioned to provide diabetes education since patients with diabetes see their pharmacists seven times more often than they see their primary care physician [14].

Almost all medically managed patients with Diabetes interact on an ongoing basis with a pharmacist. As such, pharmacists may have a profound influence on improving the lives of the patients with diabetes whom they see in their daily practice. The role of the pharmacist in DSMT is well established. Common practice sites where DSMT is provided include community pharmacies, ambulatory care settings, hospitals, long-term care facilities, rehabilitation facilities, and physician offices. Other sites may include, but are not limited to, the Public

Health Service (e.g., Indian Health Service) clinics, Community Health Centers, and private consulting practices. Numerous studies have shown that pharmacist interventions improve medication adherence, treatment outcomes, and quality of life for patients with diabetes. Studies have also shown that pharmacists have demonstrated cost savings by providing diabetes care in community settings as well as in Veterans Health Administration Clinics. Pharmacists have even build up d a business model to provide pharmacy services. [15,16].

The pharmacists are able to build strong relationships with patients and become a reliable source of information. Pharmacists may also have ongoing communication with physicians and may serve as the 'bridge' between other health care providers and the patient, thus ensuring continuity of care. In addition, pharmacists may provide on-going recommendations to the patients and their providers to optimize diabetes care.

These factors position Pharmacists to profoundly impact the health outcomes and quality of life for their patients with diabetes. A variety of pharmacist interventions to improve diabetes outcomes have been reported by pharmacists in community pharmacies. These interventions included diabetes education and pharmacologic management to improve glycemic control as well as lowering blood pressure and cholesterol. These programs were done in collaboration with physicians, local formal diabetes education programs, and the patient's insurer. Pharmacist intervention was provided in concert with regular physician follow-up visits and formal diabetes education programs offered by local diabetes education Centers. Patients were either referred by their primary care providers or could self-refer for a pharmacist consultation to evaluate A1C and lipid results, blood pressure, and receive diabetes education [17].

The Pharmacists provided three one-hour sessions and quarterly follow-up visits to assess patient progress toward goals [18]. After each visit, the pharmacist sent a report of the patient's lab and blood pressure with Recommendations for drug therapy changes to the patient's physician. The Scope of

Practice for pharmacist diabetes educators defines a range of practice for the specialty, and provides a framework for appropriate and effective pharmacist practice in diabetes care. All pharmacists must be knowledgeable of the disease state and coexisting diseases, to provide safe, competent care to persons with, or at risk, for diabetes. Pharmacists providing diabetes care utilize established principles of education strategies, learning theory, and provide lifestyle counseling to help patients effectively manage their disease. Instruction is individualized for persons of all ages, incorporating cultural preferences, health beliefs, and preferred learning styles of the patient [19-21].

MATERIALS AND METHODS

This chapter comprises of study site, study population, study design, data collection and data analysis.

STUDY SITE

Study was carried out in the inpatient and outpatient department of **C.S.I Mission Hospital** located at Malappuram district Kerala having 100 beds and specialized in other, general, medicine, pediatric, dermatology and gynecology and a 24 hour working casualty.

Data were collected from in patient & out Patient files of general medicine department in that hospital and by interviewing the patients.

STUDY DESIGN

A prospective study with questionnaire used to evaluate type 2 Diabetes with co-morbidities and awareness levels.

STUDY PERIOD

The study was carried out from May 2013 to February 2014 (10 months)

STUDY POPULATION

The study population consists of 699 diabetic patients those who qualified the inclusion criteria.

STUDY CRITERIA

INCLUSION CRITERIA

- Patients with Type 2 Diabetes Mellitus was included in the study
- Both male and female included in the study
- Patients with existing co-morbidities

EXCLUSION CRITERIA

- Pediatric patient were excluded
- Emergency care patient excluded

- Pregnant women are excluded
- Mentally retarded patient excluded
- Type 1 diabetes mellitus was excluded
- Patient who have not been able to attend at least 3 visits to the hospital during the study period.

DATA COLLECTION

Permission was obtained from hospital administration and doctors to conduct the study in that Hospital. The study was carried using medical chart of 699 randomly selected patients who had been treated in the hospital and data was collected from prescription, current medication chart and laboratory records. Informed consent was obtained from the patients before the interview.

STUDY PROCEDURES

Research type was descriptive observational study. The data were collected from 699 cares of patient in first visit, second visit and third visit. In the first visit patient will sign informed patent consent form and asking questionnaire. The variables analyzed were general characteristics of the patient genders, Age, current, medical history and medicine prescribed during hospital hospitalization. The medication uses of patients during hospitalization were recorded. Also giving education and counseling to the patients regarding dietary changes, exercise, and importance of medication adherence etc. in first and second visit. The data collection of impact of pharmacist education program questionnaire is continuing in the final visit during this study.

Level-1

Based on the prescription of the diagnosis co-morbidities were identified.

Level -2

Interview to understand the awareness level of the patient on the co-morbidities

Level -3

Patient awareness program on co-morbidities was initiated

Level- 4

Follow up on same parameter to understand the impact of patient awareness program on the patient, the awareness level before and after pharmacist's patient education program was compared and the impact of

pharmacist patient's education program diabetes was co morbidities.

STATISTICAL TOOL

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using SPSSver: 17 2010

Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskal Wallis **chi-square test** was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

Qualitative responses were obtained for the 6 questions from the Study cases. In order to make a quantitative analysis, scores were given to the qualitative responses as follows.

RESULTS AND DISCUSSION

The study attended to estimate the quality of life in patient suffering from DM with co morbidities using question air. The improvements of the quality of life in DM patient with co morbidities are also analyzed in this study and the roll of pharmacist in

Table 1: Age and Sex Distribution

Age	N=699	% To Total	Female	Female %	Male	Male %
21-30	6	0.9	3	0.4	3	0.4
31-40	41	5.9	24	3.4	17	2.4
41-50	112	16.0	53	7.6	59	8.4
51-60	169	24.2	79	11.3	90	12.9
61-70	186	26.6	90	12.9	96	13.7
71-80	118	16.9	44	6.3	74	10.6
80-90	62	8.9	27	3.9	35	5.0
91-100	5	0.7	5	0.7	0	0
			325		374	

According to the graphical picture, male patients were more affected to type 2 diabetes mellitus than female patients. The chart says that about 53.5% of patients who attended the studies were males and about 46.5% were females.

BODY MASS INDEX (BMI) [22]: In (Table 2) an attempt is made to categories all the patients who took part in the studies on the basis of body mass index (BMI) for this, BMI range was divided in to five categories- below normal, normal, over wait, obesity class I and obesity class II. Male and female data were separately classified below these categories.

A total of 37 people came under the category

patient education program is also determined during the study. The impact of study and patient education program on those patients were also studied in detailed.

DEMOGRAPHICAL DATA

A total of about 1126 patients were randomly selected for this study, out of which about 862npeople were suffering from type 2 DM out of the 862 people 699 attended the further studies and patient education program. The rest were avoided due to lack of regular follow up, Final statistical analysis of the data was done for a total of 699 patients those who completed the study with regular follow up.

The table 1 shows the demographical data of the study conducted. It was noted that out of the 699 patients. The chart clearly describes about the total number of people who attended the program from different age groups and the chart also gives a clear cut idea about the number of male and female patients who attended the program from different age groups and also says about the percentage of males and females from different age groups who suffers from diabetes mellitus.

of below normal. Under the category of normal range 295 patients were added. The over wait category has 230 patients in which 114 are females and 116 are males, thus 20.6% of females and 16.6% of males are under this categories.

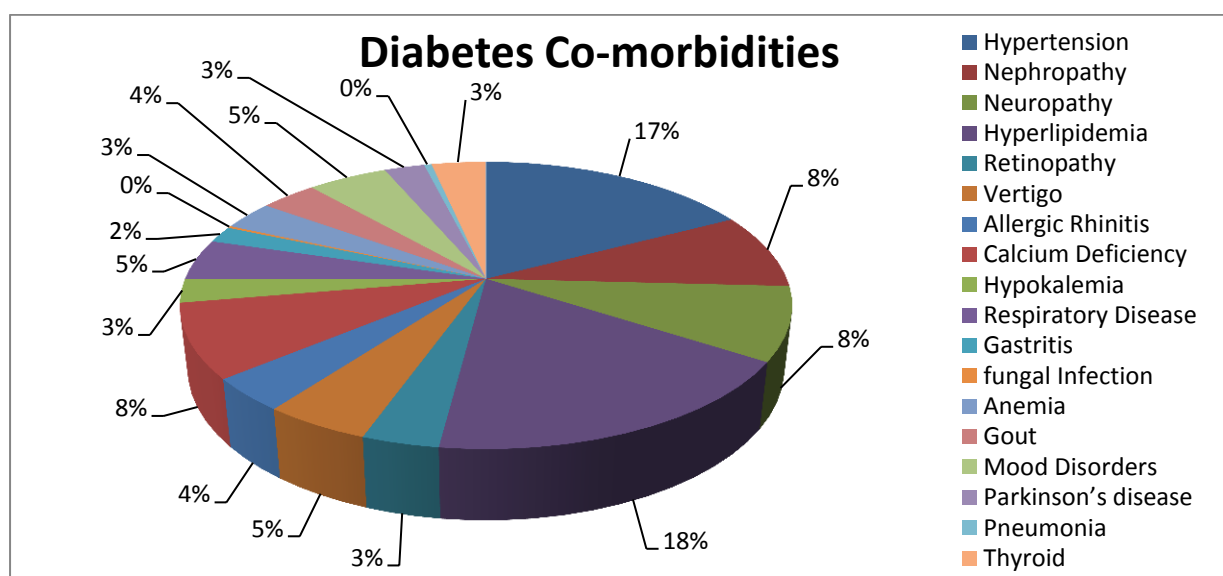
The obesity class one (class I) and obesity class two (class II) had 120 and 17 patients respectively, in which 50 females and 70 males were present in obesity class I and 10 females and 7 males were present in obesity class II. 7.2% of female and the 10% of males comes under obesity class one and 1.4% of females and 1% males come under obesity class II.

Table 2: BMI Distribution

Category	N=699	% to Total	Female	% to Total (F)	Male	% to Total (M)
below normal	37	5.3	18	2.6	19	2.7
Normal	295	42.2	131	18.7	164	23.5
Over weight	230	32.9	114	20.6	116	16.6
Obesity class I	120	17.2	50	7.2	70	10.0
Obesity class II	17	2.4	10	1.4	7	1.0
			325		374	

DIABETES CO-MORBIDITIES**Table 3: Diabetes Co-morbidities**

Sl no	Co-morbidity	Total count	% To Total	Female		Male	
				No of patients	% To Total	No of patients	% To Total
1	Hypertension	594	85.0	267	38.2	327	46.8
2	Nephropathy	291	41.6	175	25.0	116	16.6
3	Neuropathy	284	40.6	120	17.2	164	23.5
4	Hyperlipidemia	615	88.0	263	37.6	342	48.9
5	Retinopathy	118	16.9	52	7.4	66	9.4
6	Vertigo	163	23.3	87	12.4	76	10.9
7	Allergic Rhinitis	128	18.3	57	8.2	71	10.2
8	Calcium Deficiency	286	40.9	128	18.3	158	22.6
9	Hypokalemia	91	13.0	43	6.2	48	6.9
10	Respiratory Disease	158	22.6	76	10.9	82	11.7
11	Gastritis	64	9.2	33	4.7	31	4.4
12	fungal Infection	8	1.1	2	0.3	6	0.9
13	Anemia	112	16.0	44	6.3	68	9.7
14	Gout	122	17.5	60	8.6	62	8.9
15	Mood Disorders	173	24.7	88	12.6	85	12.2
16	Parkinson's disease	87	12.4	37	5.3	50	7.2
17	Pneumonia	16	2.3	6	0.9	10	1.4
18	Thyroid	118	16.9	71	10.2	47	6.7

**Figure 1: Prevalence of Co-morbidity**

According to the table it is clearly visible that hyperlipidemia is the most common co-morbidity affected to DM patients. It is found that 615 patient were affected to this particular problem, that is about 88.0% of DM patients who attended the studies had hyperlipidemia.

Hypertension is the next in the list. It is clear that about 594 patients, which are 85.0% of DM patients, were having the co-morbidity hypertension too. The table says about 291 patient were affected by nephropathy, about 41.6% calcium deficiency is the next most commonly occurring co-morbidity. About 286 were affected by this problem. That is about 40.9%.

The table next says about neuropathy, 284 were affected by the disease that is a total of 40.6%. then about 173 was victim of mood stabilizer. That is 24.7%. The next common co-morbidity, according to the table was vertigo, 163 were reported to be vertigo patents (23.3%). Respiratory diseases were the next and 158 patient that is 22.6% were affected to this problem.

Patient with allergic problem was 128 that make a percentage of 18.3. The next in the list is gout. 122 were victims of the disease, which is 17.5%. Retinopathy is the next in the list 118 patient suffered from the retinopathy. That is 16.9%. the table also says that thyroid deficiency also had the same number of affected patient that of retinopathy. That is 118 and 16.9%. About 112 people had anemic problem that is a total percentage of 16 % had anemia among the DM patient who were taken for the studies. Hypokalemia comes next in the list 91 patient were affected. That is about 13% had Hypokalemia.

PATIENT AWARENESS PROGRAM

Keeping these factors in mind. It is very necessary to organize a patient education program. Through which a detailed study about the DM patients and co-morbidities were conducted.

The need for organizing such a program was to make the people aware about these diseases and its deadly effects which may be caused if not treated properly at proper time. In the program leaflets were created on the basis of the co-morbidities and distributed among the patients. Making them aware about the disease, for that counseling

program was also organized among the patient to used their knowledge about these co-morbidities and proper instructions were given to them.

From these studies and counseling it was clear that most of the patients were unaware about the co-morbidities, which can be affecting along with DM. Most of the peoples are not much bothered about these diseases which can be very dangerous in some cases if untreated. The people are mostly busy with their works and day to day activities while most of them are often forgetting to do maintaining a healthy life style. The changing of people towards western culture and fast foods etc. has become a good reason for such a large rate of DM patients and other dangerous co-morbidities which can accompany them. Patient education program conducted and the each and every data and values regarding co-morbidity, and the patients were recorded carefully before and after the program. Recorded values before and after the patient education program were compared carefully to determine whether there was any recordable changes in the data.

The result was that there was a significant decrease in the co morbidity range of the patients. After the program the percentage of people in each co morbidity change was decreased in a notable manner and it was also found that many patients who attended the program before to take proper steps to stay away from these co-morbidities and live a healthy life. Most of the people began to control their food and also began to do exercises.

From the dates and record the changes if was clear that most of the people were able to understand the importance of co-morbidities and their prevention steps. From the data if can also be clear that our program had a good impact on the patients and the program was a success.

The mean difference of different intervention (before and after the patient education program) can also be calculated from the table and the percentage can also be determined if necessary. The table distinctly describes about the 5 co-morbidities which includes retinopathy, nephropathy, neuropathy, hypertension and hyper lipidemia. The mean and SD are

described on the basis of the two patient education program. intervention, that is before and after the

THE IMPACT OF PHARMACIST'S PATIENT EDUCATION PROGRAM

Table 4: The impact of pharmacist's patient education program

Co-morbidities	Intervention	Mean	SD	P value	Significant
Retinopathy	before	3.63	1.26	0.0001	Significant
	after	4.71	1.87		
Nephropathy	before	3.64	1.44	0.0001	Significant
	after	4.64	1.40		
Neuropathy	before	2.91	1.08	0.0001	Significant
	after	4.28	1.03		
Hypertension	before	2.26	1.07	0.0001	Significant
	after	3.30	1.01		
Hyperlipidemia	before	1.89	1.03	0.0001	Significant

According to the table the mean value of retinopathy affecter patients before the patient education program was 3.632 and after was 4.71, the men difference was found to be 1.078. The calculated standard deviation was about 1.26 and 1.87 before and after the program respectively. The p value was calculated as 0.0001 and was found to be significant. In case of nephropathy the mean value was noted to be 3.64 before the program and 4.64 after, thus the mean difference is 1. The SD was recorded as 1.440 and 1.07 respectively before and after the program, the P value is 0.0001 and thus was found to be significant. The mean value is 2.907 and 4.283 for before and after intervention for neuropathy, the mean difference of the co-morbidity is 1.376 and the SD before the program was 1.82 and after was 1.035 for

neuropathy. The P value was found to be 0.0001 so it is significant.

Hypertension, very common and deadly co-morbidity among diabetes affected people. 2.259 was the mean value before and 3.303 was the value after patient education program, the mean difference was 1.044 and SD was 1.07 and 1.010 before and after respectively. It is significant and the P value was 0.0001.

In the case of hyper lipedemia the mean value is 1.894 and 2.937 with a difference of 1.042 the SD of the co-morbidity recorded is 1.038 before the patient education program and 0.946 after the program. The P value is 0.0001 and is significant. From the table it is clear that the P value of all the 5 co-morbidities was 0.0001. Since the P value is below 0.5 it can be said that all the co-morbidities described in the table are significant.

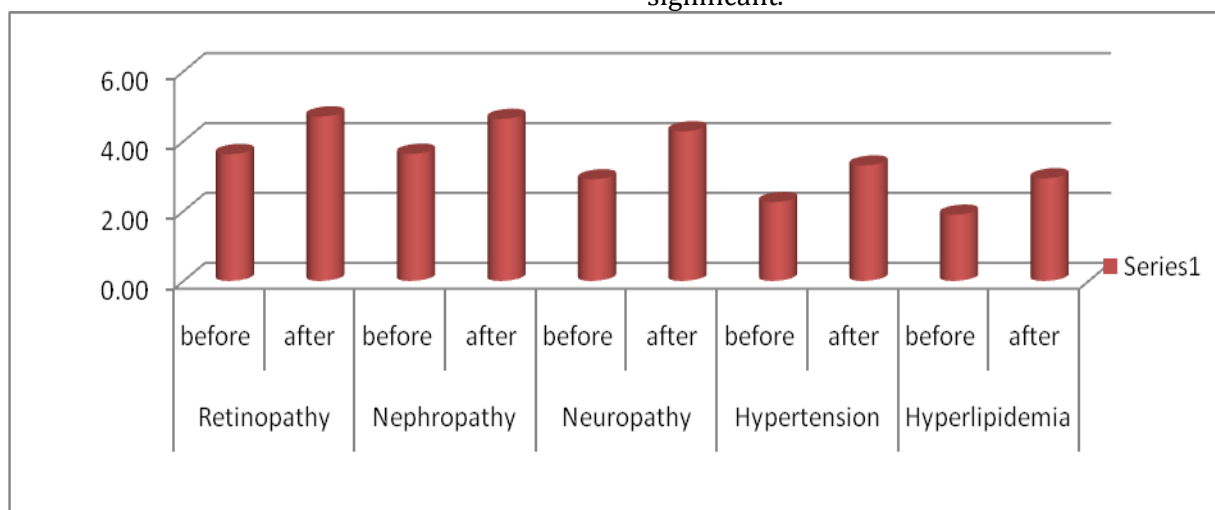


Figure 2: The impact of Pharmacist's Patient Education Program

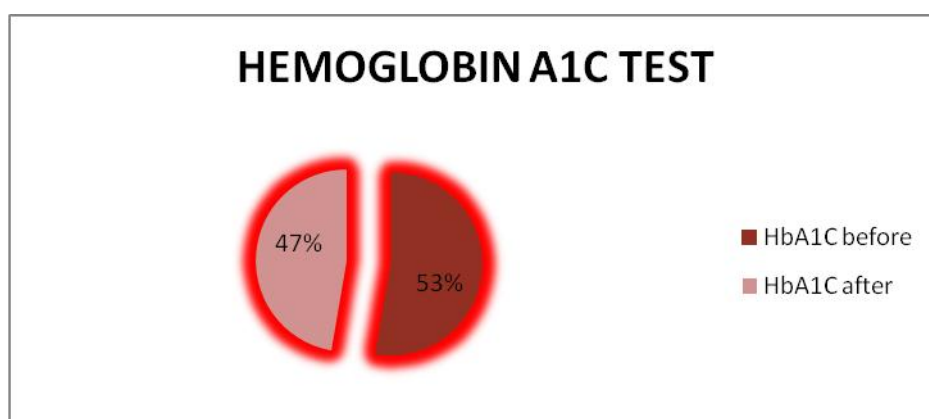
HEMOGLOBIN A1C TEST [23]**Table 5: HbA_{1c} test before and after patient education program**

Lab test	Grand Total	% To Total
HbA _{1c} before	5856.4	837.83
HbA _{1c} after	5255.3	751.83

The HbA_{1c} level data also has a significant impact by the clinical outcome of the studies and patient education program. It was found that the HbA_{1c} level before program was 5856.4, that is about 53%, and the level after the program was 5255.3, the percentage level was reduced to 47%. Thus the clinical outcome of the studies and patient education

program has reduced the % level of HbA_{1c} by 6%.

From these data, all these co-morbidities were significant and HbA_{1c} level has also reduced to a notable level due to patient education program, thus the program could make a remarkable effect on diabetes affected patient who were used for these studies.

**Figure 3: HbA_{1c} test before and after patient education program****CONCLUSION**

The main objective of the study was to study the prevalence of co-morbidities in type 2 DM. The awareness level of people and the impact of pharmacist patient education program were also studied in detail. Implementation of the patient education program on the co-morbidities among the type 2 DM patients was also an aim of the study conducted.

The impact of the patient education program on the awareness level of patient was found out. The significance level of the co-morbidities were found out, from these data it was seen that all the co-morbidities were having the P value of about 0.0001, which is below 0.05 thus it was determined that the intervention by the Pharmacist was significant & outcome was positive.

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