EPIDEMIOLOGICAL STUDY OF TYPE 2 DIABETES MMELLITUS, IT'S COMPLICATIONS AND THE IMPACT OF PHARMACISTS INTERVENTION IN QUALITY OF LIFE OF DIABETIC PATIENTS: A HOSPITAL – BASED STUDY

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ABSTRACT

Background: Diabetes is a chronic, metabolic disease characterized by elevated levels Of blood glucose which leads overtime to serious damage to the heart blood vessels, Eyes, kidney and nerves. Type 2 diabetes is becoming more common at an alarming Rate. The disease can be controlled with the right lifestyle and dietary adjustments, as Well as strict adherence to antidiabetic medication. Complications of diabetes include Nephropathy, retinopathy, neuropathy, cardiovascular etc. Diabetic patients QoL is Reduced in general independent of gender. The QoL is critical because it is a potent Measure for predicting a persons ability to manage disease and sustain health.

Objective: To identify the patients with type 2 DM and its complications and implement Preventive intervention by the pharmacist based on individual requirements and assess QoL.

Methodology: Observational, prospective, population based study.

Result: In the study period 150 patients were enrolled in the study. Out of this 67 (45%) were male patients and 83 (55%) were female patients .The DQoL Questionnaire scores show significant improvement after the intervention of patient Counselling among test population and there was no significant improvement among Control population. The epidemiology of diabetes was studied and cardiovascular Disease was found to be the most common complication in our study population .On Comparing HbA1c levels there was an improvement among patients due to pharmacist Impact.

Conclusion: There was an overall improvement in the quality of life among diabetics Patients. The Hba1c levels among test group showed an improvement after pharmacist Intervention. The intervention of health educational programs by the health care team Is very essential for a better understanding and management of the disease for the Patients in achieving their health care goals.

Keywords: DM, diabetes mellitus, DQoL questionnaire, complications, patient

Counselling

BACKGROUND

Diabetes mellitus is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose in the blood, which in turn damage many of the body's systems, in particular the blood vessels and nerves. Impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG) refer to levels of blood glucose concentration above the normal range, but below those which are diagnostic for diabetes. Subjects with IGT and/or IFG are at substantially higher risk of developing diabetes and cardiovascular disease than those with normal glucose tolerance. The benefits of clinical intervention in subjects with moderate glucose intolerance is a topic of much current interest. (World Health Organization, 1997).

According to the International Diabetes Federation's most recent figures from 2019, an Estimated 463 million adults worldwide have diabetes. Diabetes prevalence is steadily Rising; prior estimates from 2017 placed the number of diabetics at 425 million. By 2030, the number is expected to nearly double. Type 2 diabetes accounts for 85-90 Percent of all diabetes cases. Increases in total diabetes prevalence rates are mostly due To an increase in type 2 diabetes risk factors, such as increased longevity and being Overweight or obese.. diabetes is found all across the world, but it is more prevalent (particularly type 2) in wealthy countries[9]. However, the biggest rise in prevalence is Occurring in low- and middle-income nations, such as Asia and Africa, where the Majority of patients will most likely be found by 2030. The rise in incidence in Developing nations coincides with urbanisation and lifestyle changes, such as more Sedentary lives, less physically demanding jobs, and the global nutrition transition, Which is characterised by greater consumption of foods that are high in calories but low In nutrients (often high wound in sugar and saturated fats, sometimes referred to as the Western Pattern diet). The risk of developing type 2 diabetes has been linked to poorer Socioeconomic status in a number of nations.

The main complications of Diabetes includes nephropathy, retinopathy, neuropathy, cardiovascular etc. Nephropathy is clinically described as the development of proteinuria followed by a decline in glomerular filtration rate over a long period of time, often 10 to 20 years if untreated, the uremia that ensuses is fatal. Neuropathy is a major contributor two diabetics—related healing issues, erectile dysfunction, and cardiovascular problems and it can cause damage to the spinal chord and higher central nervous system. Diabetes is linked to a threefold increased risk of myocardial infarction compared to the general population, and CVD is responsible for more than half of diabetic mortality. Renal dysfunction, along with dyslipidemia, poor glycemic control, and persistent blood pressure rises, is a major risk factor for early CVD in people with type 2 diabetes.

Diabetes mellitus has a negative impact on quality of life, affecting the renal system, vision loss, heart problems, erectile dysfunction and peripheral neuropathies. Studies on QoL help identify shortcomings and needs, and compare the impact of different treatment regimes on wellbeing and satisfaction. Quality of life (QoL) in diabetic patients is decreased, regardless of gender. This is

due to a variety of lifestyle problems, such as nephropathy, vision loss, heart problems, erectile dysfunction and peripheral neuropathies. Patients suffering from diabetes have a poor quality of life, but have higher QoL than those with other chronic illnesses. The study on QoL helps in the evaluation of the physiologic functioning of a patient, identification of specific short comings and the needs of patients at different stages of the disease, and comparing the impact of different treatment regimes on a patient's wellbeing and satisfaction. Diabetes is a chronic illness, so there is a need for assessing the QoL of patients at regular intervals. Diabetes mellitus causes a range of lifestyle issues, including nephropathy, eyesight loss, cardiac issues, erectile dysfunction, and peripheral neuropathies. Patients with diabetes have a lower quality of life than those without the disease, but a slightly better quality of life than those with other chronic illnesses. Diabetes can diminish the amount and quality of any connection, family life, and travel restrictions, as well as raise financial stress. Studies on QoL aid in the evaluation of a patient's psychological functioning and the identification of specific problems. Because diabetes is a chronic illness, patients' quality of life must be assessed on aFrequent basis. Diabetes complications affect the organ system and are responsible for The bulk of the disease's morbidity and mortality. The Quality of Life (QoL) is critical Because it is a potent measure for predicting a person's ability to manage disease and Sustain long-term health and well-being.

MATERIALS AND METHOD

This six month prospective observational population based study was conducted in general medicine department at PK DAS INSTITUTE OF MEDICAL SCIENCES. This study was undertaken by assessing patient characteristics and their QoL by using a modified DQoL questionnaire. The inclusion criteria were Type 2 diabetes patients above 18 years of age or older and agreed to sign the informed consent form ,patients who were regularly keeping up with appointments. Pregnant and breast feeding women ,pediatrics, critically ill-patients, unwilling patients were excluded from the study. The study was approved by IEC of Nehru college of Pharmacy and PKDIMS. The required data were accessed from 6 months period with and without intervention. Screening of patients was done based on eligibility criteria and patients were enrolled to the study and data collection was done. Patient case notes, laboratory investigation reports, which was entered into a suitably designed patient data collection form. The study population was randomized into two groups- Control group and intervention group. The patient characteristics accessed in this study comprises of gender, age, duration of disease, complications, co morbidities. The quality of life of each patients was accessed using modified DQoL questionnaire filled out by each patients during baseline first and second intervention. Epidemiology of Type 2 diabetes mellitus was assessed. The modified DQoL questionnaire was provided to the Test and control group. Their HbA1c values was noted. Patient information leaflets were provided to the test population. The leaflets consists of how to take care of diabetics, diet plan, physical activity and medicines for diabetes. Conducting the first follow up (1 month) and second follow up (after 3 months) using the same questionnaire. The change in quality of life and changes in hbA1c levels are compared by using the result of baseline and second review among both test and control group. The control group was provided with pharmacist intervention only during the second follow up. The epidemiology of diabetes incidence and prevalence of complications was also recorded. The significance of pharmacist

intervention was analysed by comparing the QoL scores of test and control group using paired T test. The data was entered into Microsoft Excel 2007 and all analyses was performed using SPSS version21.0, p value< 0.05 was considered significant.

RESULT

In this study,the target population obtained during the study were 150 outbof which 75 were taken as control group (not given any intervention) and the other 75 were taken as test group (given intervention). after first and second follow up patient population declined to 132.

Characteristics of patient (n=150)

		Percent
Age (years)	<30	2%
	31-40	6%
	41-50	11%
	51-60	26%
	61-70	32%
	71-80	19%
	>81	7%
Gender	Females	55%
	Males	45%
Duration of disease	0-5	20%
(years)	5-10	24.6%
	10-15	25.3%
	15-20	17.3%
	>20	10

The mean age of T2DM patients was 65.5 by age, more than half of the patients were in the age range 61-70. Among the 150 patients, most (55%) were females and 45% was males.

By duration of disease, it was found that most of the patients has suffered from diabetes for more than 5 years. Nearly 25% of the population has diabetes for more than 10 years. Only 20% has suffered from the disease for 0-5 years.

The QoL of patients with T2DM (n=150) in test and control groups.

QoL in test group

QoL	Mean ±10	Mean	t value	P value
		deviation		
Baseline	30.08±8.3			
		6.7	6.5	0.001
1 st Review	24.08±2.2			
1st review	24.08±2.2			
		11.97	4.2	0.001
2 nd review	12.11±1.5			
Baseline	30.08±8.3			
		18.6	18.6	0.001
2 nd review	12.11±1.5			

The utilisation of pharmacist intervention for the management of patients withb type 2 DM has improved the quality of life of the patients as shown in the table, the quality of life score before pharmacist intervention and after intervention shows a significant difference (mean deviation 18.6). The following result was observed from the comparative study in the test population, whereas when the significant difference in the baseline and second review of the control population was evaluated, it was not significant (mean deviation 4.49). This concludes that the application of the pharmacist intervention has improved QoL in diabetic patients.

QoL in control group

QoL	Mean±sd	Mean Deviation	t value	P value
Baseline	29.95±4.5			
		3.1	4.3	<0.05

1 st review	26.81±7.0			
1 st review	26.81±7.0			
		1.3	2.8	0.006
2 nd review	25.45±8.2			
Baseline	29.95±4.5			
		4.49	5.5	<0.05
2 nd review	25.45±8.2			

Comparison of HbA1c values in test and control

	Test		control	
HbA1c	Mean ±10	p	mean	P value
Test				
Baseline	9.61±1.3	2.5	15.7	<0.05
2 nd review	7.1 ±0.5			
Control				
Baseline	10.20 ±1.8	0.524	14	<0.05
2 nd review	9.67±1.8			

On comparing the Hba1c on test and control population, the test population shows a significant improvement (mean deviation 2.5) .

Epidemiology of type 2 diabetes mellitus in the study centre

Total number of	1516
IP patients treated	
Number of patients	359
treated for	
Type 2 diabetes	
Mellitus	
Prevalence	17%

Out of 1516 people visiting PKDIMS , the number of patients treated for Type2 DM was found to be 359. The prevalence was 17%.

DISCUSSION

DM is defined as a chronic condition characterised by hyperglycemia and due to impaired insulin secretion with or without insulin resistance. DM is a endocrine disorder . the prevalence of type 2 DM is raising . this has been ascribed to raise in obesity , sedentary lifestyle and a grawing minority population, among other factors. lack of knowledge negligence and poor adherence to medications are key factors for poor disease management.

Study conducted by Ronald <u>C.W.Ma</u> et al [52], more than 440 million people worldwide are effected by DM. The epidemiological study suggest that approximately 11% of population has diabetes. Our study shows that 17% of patients are diagnosed with diabetes among 1516 of total patients visiting our hospital.

Patients with type 2 DM were having more than one complication, our study shows that cardiovascular disease 95(35.7%) is the most common complication among the patients with type 2 DM .On the contrary , the study conducted by Oshin Mantaro [21], showed that peripheral neuropathy is the most common complication .

In our study on comparing HbA1c level before and after intervention showed improvement in test group and there is no significant improvement in control group. However findings similar to ourstudy were reported in the study conducted by R.Adepu et al. [50].

In our study, a comparison of HbA1c levels of baseline and second review at different age groups shows improvement in patient age greater than 51-60 years, where as in a study conducted by Qinglin MA et al [51] shows that age is negatively corelated to HbA1c levels.

The quality of life among type 2 DM patients were improved in test group after patientcounselling than in control group. Same was the result for a study conducted by R.Adepu et al [50].

CONCLUSION

The study results revealed an overall improvement in the quality of life of patients with type 2 diabetes mellitus after a successful patient counselling program. The Modified DQoL Questionnaire was used to assess the quality of life and HbA1c levels. The prevalence of diabetes was studied, and cardiovascular disease was the most common complication. The study concluded that cardiovascular disease is the most common complication among the study population.

Educating diabetic patients regarding their illness is vital, because a successful DM treatment can be achieved only by focussing on lifestyle modifications along with drug therapy.

Our study suggests that pharmacists have to consider, giving emphasis on caring and giving follow up services to DM patients and also counselling services which will be beneficial for a successful treatment of the disease and preventing complications. Considering this , the patient information leaflets and other educational mediums should be provided for a better understanding and awareness on the disease. Hence, it is very important for healthcare teams to provide proper educational programs for the patients and the implementation of such a service to the community will help in the disease management.

REFERENCE

1. WHO - Diabetes Definition (Internet)

https://www.who.int/health-topics/diabetes

2.T. Dipiro, Robert L. Talbert pharmacotherapy a pathophysiologic approach, 2004;

7th edition, New York: McGraw-Hill;1335

3. Diabetes by Mayoclinic staff; October 30,22

https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444

4.Kohei KAKU, Pathophysiology of type 2 diabetes and its treatment policy, 2010, JMAJ 53(1): 41-46

5. Forbes J M, Cooper ME. *Mechanisms of diabetic complicatons*. Physio Rev. 2013 jan: 93(1):137-88

- 6. Roger Walker and Cate Whittlesea ; Clinical pharmacy and therapeutics ; 6th edition , 2007 685-709
- 7. K.D.Tripathi *Essentials of medical pharmacology*, New Delhi, 2013, 7th edition: 258-280 8. *Lifestyle changes for type 2 diabetes*, living with diabetes, 2019 (internet) https://www.diabetes.co.uk/lifestyle-changes-4-type2-diabetes.html
- 9. Epidemology of diabetes (internet)

FOUNDRY JOURNAL[ISSN:1001-4977] VOLUME 26 ISSUE 12

https://en.m.wikipedia.org/wiki/epidemology of diabetes

10. Diabetes in India-wikipedia(internet)

https://en.m.wikipedia.org/wiki/diabetes in India

12) R.Adepu et al (2007)"effect of patient counselling on quality of life in type 2 DM patients in two selected south Indian community pharmacies : A study "

https://www.ijpsonline.com/articles/effect-of-patient-counsellimng-on-quality-of-life-in-type-2-diabetes-mellitus-patienst-in-two-selected-south-indian-ciommunity-pharmacies.html/

13) Qinglin MA et al (2015) "Association between glycated hemoglobin A1c levels with age and gender in Chinese adults with no prior diagnosis of diabetes mellitus .

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4887772/#!po=33.8235

14) .Ronald .C.W.Ma et al (2018) " Epidemiology of diabetes and diabetic complications in china"

https://link.springer.com/article/10.1007/s00125-018-4557-7

15).N V Prasanth et al.,(2019) "A study on impact of patient counselling and education on quality of life in patients with metabolic syndrome".

https://www.sciencedirect.com/science/article/abs/pii/S2213398418300393

16) Ken Watkins et al., (2004) "Measurement of health-related QOL in diabetes mellitus". https://pubmed.ncbi.nlm.nih.gov/15612830/#:~:text=The%20DCP%20and%20DHP%20appear, populations%20(e.g.%20older%20adults)