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IMPACT OF MEDICATION ADHERENCE AND PHARMACEUTICAL CARE ON GLYCEMIC CONTROL IN PATIENTS WITH TYPE II DIABETES MELLITUS

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ABSTRACT

This study aimed to determine the impact of medication adherence and pharmaceutical care on glycemic control in patients with type II diabetes mellitus. Retrospective and Prospective observational study was done at mallige hospital among 150 patients for the period of 6 months. (DSMQ) Scale Scoring Tool and Self-reported questionnaire tool used to assess diabetes self management activities associated with glycemic control in common treatment regimens for people with Type 2 Diabetes. Data were analyzed using SPSS software and Anova test was done to check if the means of groups are statistically significant or not. In the study 116 (77.3%) of patients were taking the anti-diabetic drug as advised by the doctor and 34(22.7%) were not taking medicines regularly. The HbA1c test score of 68 patients were found to be excellent in the range of (4- 6%)followed by 52 patients were found to be good(7-8%)and 30 patients found in the range of (9-14)belong to the poor condition. Various Diabetic complications such as diabetic ketoacidosis and hyperosmolar hyperglycemic nonketotic coma observed in non adherent patients. The Cronbach alpha is used to measure the internal consistency, the Cronbach alpha of DSMQ was found to be 0.858, thus reliability statistics of DSMQ found to be better. P value was found to be ($p<0.05$)which is statistically significant. The correlation of DSMQ and HbA1c was conducted in the study, the correlation R= -0.646 states that as DSMQ score decreases the glycosylated hemoglobin gets higher in value. Overall, patients with good medication adherence have better glycemic control compared with non-adherent ones. This study emphasizes the need for creating more awareness among the general practitioners and clinicians and patients on the importance of medication adherence and pharmaceutical care by conducting more continued medical education programs on drug therapy.

KEYWORDS: Diabetes-self management questionnaire, glycated hemoglobin, Type II diabetes mellitus, Cronbach alpha.

INTRODUCTION

Diabetic prevalence has been rising more rapidly in low and middle income countries than in high income countries. Almost half of the deaths are attributable to high blood glucose before the age of 70 years.[1] Medication adherence is the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider.[2] Antihyperglycemic agents, strict diet control and exercise have a good role in glycemic control. Treatment efficacy mainly depends upon medication efficacy and proper medication adherence to the therapeutic regimen. Poor adherence to the anti diabetic medications leads to poor glycemic control. Studies found out that poor adherence to prescribed regimens can result in increased rate of mortality and morbidity. There are several methods to assess adherence in the routine clinical setting. Lack of knowledge, multiple comorbidities, complexity, adverse drug effect, cost of the drug, polypharmacy, lack of finance are the reasons for non-adherence.[3] Adherence can be assessed by using a simple three or four point likert scale. Here, in our study we used a four point likert scale by using DSMQ. Physicians, pharmacists and other healthcare professionals have a proper role in medication adherence. Pharmacist have the key role in explaining the information of drug which are prescribed (what, why, when, how, and how long). More sophisticated techniques for assessing adherence include measurements of medications in urine or blood samples, electronic monitors, and the use of pills that emit a small electrical signal triggered by gastric acid. However, these are not available for routine clinical practice and may not be feasible in primary care. Assisting patients to deliver their medicine properly would be a better achievement to reduce the rate of morbidity and risk of prolonged hospitalization. Involving patients in decision making

could improve medication adherence.[2]

MATERIALS AND METHODS

STUDY SITE & STUDY DESIGN

This was a retrospective and prospective observational study including 150 sample sizes carried out at mallige hospital, bangalore in india. The study included patients with Type II diabetes mellitus and written informed consent was obtained from enrolled patients. Demographic data, medical history, drug history recorded and documented. Assessment of adherence done using DSMQ and self reported questionnaire.

STUDY CRITERIA

INCLUSION CRITERIA

- Patients with HbA1c in between 6.5% and 11%
- Adult human with T2DM/adult onset diabetes
- Gender (both male and females)
- Patients with BMI>22
- Age >25 years
- Patients with any comorbidities
- Patients receiving at least one antidiabetic drug
- Patients on insulin therapy
- Patients with RBS>120 mg/dl

EXCLUSION CRITERIA

- Pregnant women and lactating /nursing a child
- Patients who are not willing to participate in the study.
- Patients attending OPD
- Patients with incomplete information
- Patient with type 1 DM
- Patient with gestational diabetes

STUDY PROCEDURE

The data was collected in a proforma and google forms which included the demographic details, past medication history, comorbid condition, CGMrecords, RBSlevels, lab investigation and therapeutic data including name, dose, duration, and frequency of drugs. The entire data collected was entered in Microsoft excel sheet for analysis of results later. Here the ***Diabetes Self Management Questionnaire (DSMQ) Scale Scoring Tool*** is used to assess diabetes self management activities of 150 patients associated with glycemic control in common treatment regimens for people with Type 2 Diabetes. Respondents are asked to rate to which extent each statement applies to one's self management during the past 6 months. A **four- point Likert type rating scale** was chosen here, {applies to me very much; applies to to a considerable degree; applies to me to some degree; does not apply to me. The DSMQ contains 7 positively and 9 negatively keyed items (with view to effective self management); negatively keyed items have to be reverse scored so that higher values indicate more effective self-management.

Raw scores	Inverse scores to be summed
Applies to me very much =3 points	= 0 points
Applies to me to a considerable degree = 2 points	= 1 points
Applies to me to some degree = 1 points	=2 points
Does not apply to me = 0 points	=3 point

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS Statistics. Descriptive statistics, reliability analysis, cronbach alpha, Regression analysis and P-Anova test were done. P value of <0.05 was considered statistically significant.

RESULTS

DISTRIBUTION BASED ON "FACTORS ASSOCIATED WITH PATIENT ADHERANCE TO ANTI-DIABETIC MEDICATIONS"

1. GENDER DISTRIBUTION

Table 1: Frequency Distribution of Patient Gender.

GENDER					
		Frequency	Percent	Valid Percent	Cumulative Percent
	Male	86	57.3	57.3	57.3
	Female	64	42.7	42.7	100.0
	Total	150	100.0	100.0	

Out of 150 patients included in the study, 64 (42.7%) were females and 86 (57.3%) were males.

2. AGE DISTRIBUTION OF PATIENTS

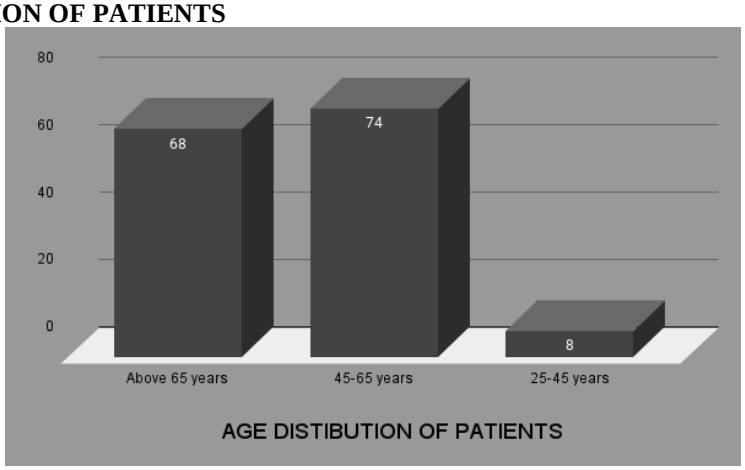

Figure 1: Bar Graph Representation For Patient Age Distribution.

Out of 150 patient's majority 74 (49.33%) of them were found in the age group between 45-65 years, followed by 68 (45.33%) in the age group above 65 years, 8 (5.33%) in the age group between 25-45.

3. DISTRIBUTION OF " DURATION OF DIABETES"

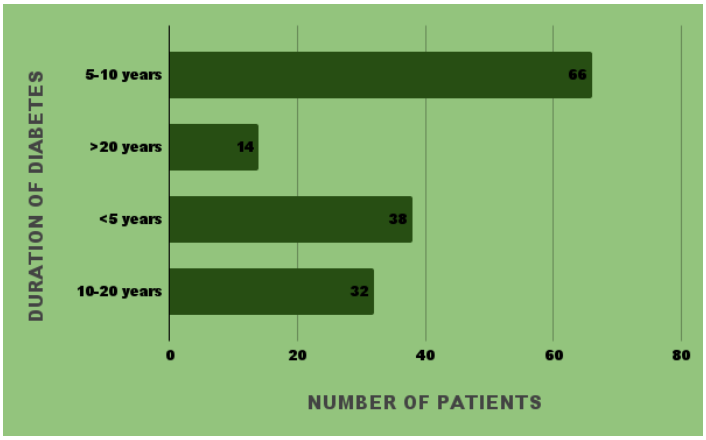

Figure 2: Bar Graph Representation of Duration of Diabetes.

Patients were categorized according to duration of diabetes. Out of 150 patients, the majority 66 (44%) were found in between 5- 10 years, followed by 38 (25.3%) were less than 5 years, and 32 (21.33%) were found in between 10 -20 years and 14(9.33%) found greater than 20 years.

4. MEDICATION HISTORY OF PATIENTS

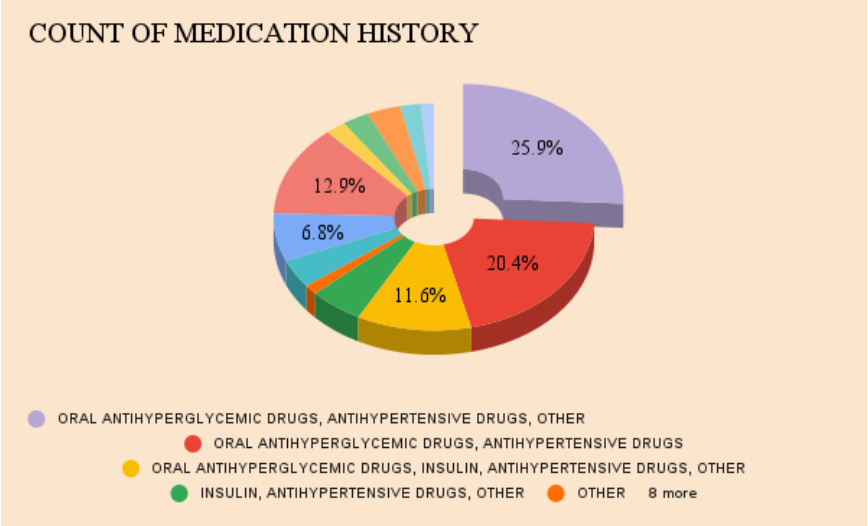

Figure 3: Pie Graph Representation Of Count Of Medication History.

Out of 150 patients enrolled in the study, majority (25.9%) of patients were taken combination therapy of oral antihyperglycemic drugs,anti-hypertensive drugs and others followed by (20.4%) patients were taken oral antihyperglycemic drugs and anti- hypertensive drugs and (11.6%) patients were taken oral antihyperglycemic drugs,insulin,anti-hypertensive drugs and other medication.

5.*RESULTS OF "SELF REPORTED QUESTIONNAIRE FOR MEDICATION ADHERENCE ON GLYCEMIC CONTROL"*

Table 2: Descriptive Statistics Of Questionnaire On Medication Adherence.

STATISTICS		
	N	
	Valid	Missing
Do you take the anti-diabetic drug as advised by your doctor?	150	0
If not, what is the reason?	34	116
Do you make your own modification in the dose of drug prescribed?	150	0
Do you regularly monitor your blood glucose level?	150	0
Did your physician give information on your drug?	150	0
Do you have good knowledge on your anti-diabetic drugs prescribed for you?	150	0
Do you feel comfortable in asking questions to your doctors?	150	0

Out of 150 patients, 116 (77.3%) were belongs to the category "YES" and cumulative percent found to be 22.7% and followed by 34 (22.7%) were belongs to the category "NO" and cumulative percent found to be 22.7 %.

Table 2.1: Frequency Table Distribution Of "Question 2".

Q2: If not, what is the reason?					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	lack of finance	2	1.3	5.9	5.9
	Interferes with my meal plan	1	.7	2.9	8.8
	Taking them since many years	5	3.3	14.7	23.5
	Feeling the drug is not effective	2	1.3	5.9	29.4
	I forget	10	6.7	29.4	58.8
	Side effects	2	1.3	5.9	64.7
	Feeling the dose given is high	1	.7	2.9	67.6
	Multiple medication	9	6.0	26.5	94.1
	Poor family support	2	1.3	5.9	100.0
	Total	34	22.7	100.0	
Missing	System	116	77.3		

Out of 150 patients, 34 (22.7%) belonged to the category of not taking medicines regularly. The reason for not taking the medications regularly are due to lack of finance(1.3%), interferes with meal plan (0.7%), taking them since many years (3.3%), feeling the drug is not effective(1.3%), I forget(6.7%), side effects(2%), feeling the dose given is high(0.7%), multiple medications(6.0%), and poor family support(1.3%).

6. RESULTS ON "DIABETES SELF-MANAGEMENT QUESTIONNAIRE" (DSMQ)

Table 3: Descriptive Statistics Table Distribution of Dsmq Data.

Descriptive Statistics					
Item 16 Questionnaire	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
I check my blood glucose levels with care and Attention	150	1	3	2.58	.571
The food i choose to eat makes it easy to achieve optimal blood sugar Levels	149	1	3	2.83	.566
I keep all doctors appointments recommended for my Diabetes	148	1	3	2.20	.571
I take my diabetes medication as prescribed	149	2	3	2.91	.283
Occasionally I eat lot of sweets or other foods rich in carbohydrates	149	2	3	2.91	.283
I record my blood sugar levels regularly	150	0	3	2.45	.879
I tend to avoid diabetes- related doctors Appointments	149	2	3	2.92	.273
I do regular physical activity to achieve optimal blood sugar	149	2	3	2.32	.466

Levels					
I strictly follow the dietary recommendations given by my doctor or diabetes specialist	148	2	3	2.37	.485
I do not check my blood sugar levels frequently enough would be required for achieving good blood glucose control	150	2	3	2.97	.162
I avoid physical activity, although it would improve my diabetes	146	0	3	2.27	.602
I tend to forget to take or skip my diabetes medication	150	1	3	2.32	.522
Sometimes i have real food binges	150	0	3	2.61	.633
Regarding my diabetes care, i should see my medical practitioner more often	149	0	3	2.72	.761
I tend to skip planned physical activity	150	0	3	2.18	.646
My diabetes self-care is poor	149	1	3	2.32	.521
Valid N (listwise)	138				

7. RELIABILITY STATISTICS

Reliability refers to the consistency of a measure. Here, cronbach's alpha is used to measure the internal consistency, that is how closely related a set of items is. The general rule of thumb is that a cronbach's alpha of 0.70 and above is good, 0.80 and above is better, and 0.90 and above is best.

Table 4: Result on Reliability Statistics.

Reliability Statistics		
Cronbach's Alpha	**Cronbach's Alpha Based on Standardized Items**	**N of Items**
.858	.890	16

The cronbach' alpha of DSMQ was found to be 0.858 and cronbach's alpha based on standardized items was found to be 0.890, which indicates reliability statistics of DSMQ were found to be better.

8. RESULTS OF ANOVA TEST

The anova test is done to check if the means of groups are statistically significant or not.

Table 5: ANOVA distribution Table.

ANOVA						
		Sum Of Squares	**Df**	**Mean Square**	**F**	**Sig**
Between People		201.906	137	1.474	58.677	0.000
Within People	**Between Items**	184.717	15	12.314		
	Residual	431.283	2055	.210		
	Total	616.000	2070	.298		
Total		817.906	2207	.371		
Grand Mean = 2.55						

Here F [137, 15, 2055] = 58.677 and the P value is found to be ($p < 0.05$) which is statistically significant. The low p value shows that the effect is large or that the result is of major theoretical, clinical, or practical importance.

9. RESULTS OF DIABETES CLINICAL CHARACTERISATION

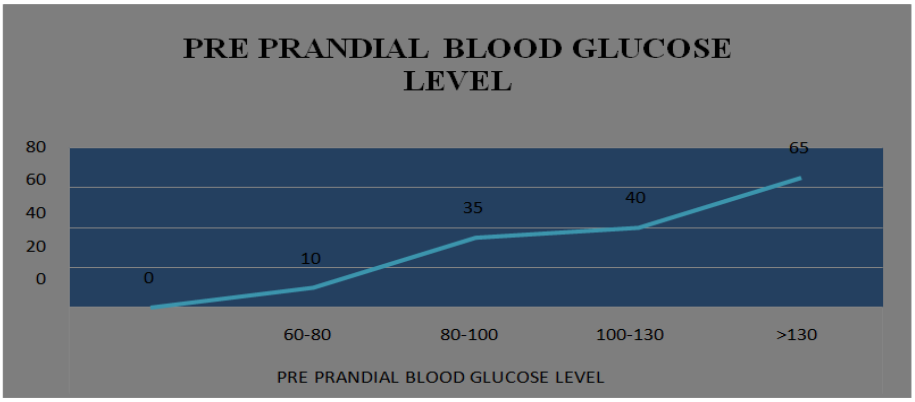

Figure 3: Line Graph Distribution of Pre – Prandial BG Level.

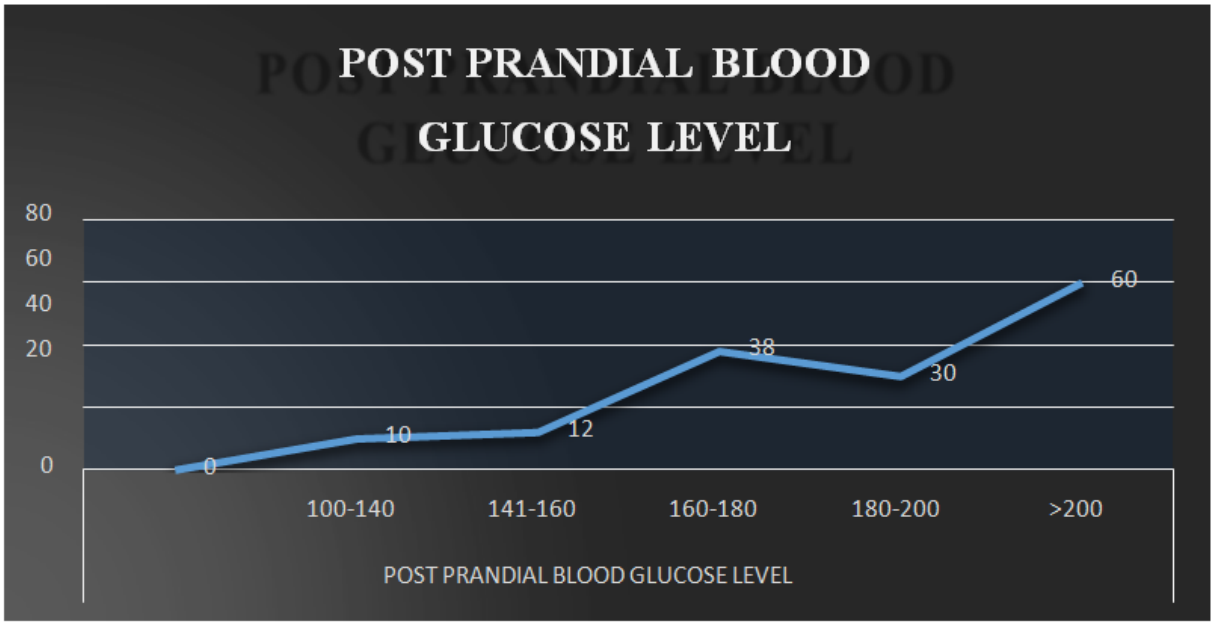

Figure 4: Line Graph Distribution Of Post – Prandial BG Level.

Out of 150 patients, pre – prandial blood glucose level of 65 patients belongs to > 130 mg / dl followed by 40 patients belongs in between 100-130 mg/dl and 35 patients belongs in between 80-100 mg/dl and 10 patients belongs in between 60-80 mg/dl. The post – prandial blood glucose level of 60 patients belongs to > 200 mg/dl followed by 30 patient belongs in between 180-200 mg/dl, 38 patients belong in between 160-180 mg/dl, 12 patients belong in between 141-160 mg/dl, 10 patients belongs in between 100-140 mg/dl.

10. RESULTS OF HbA1C AND GLUCOSE

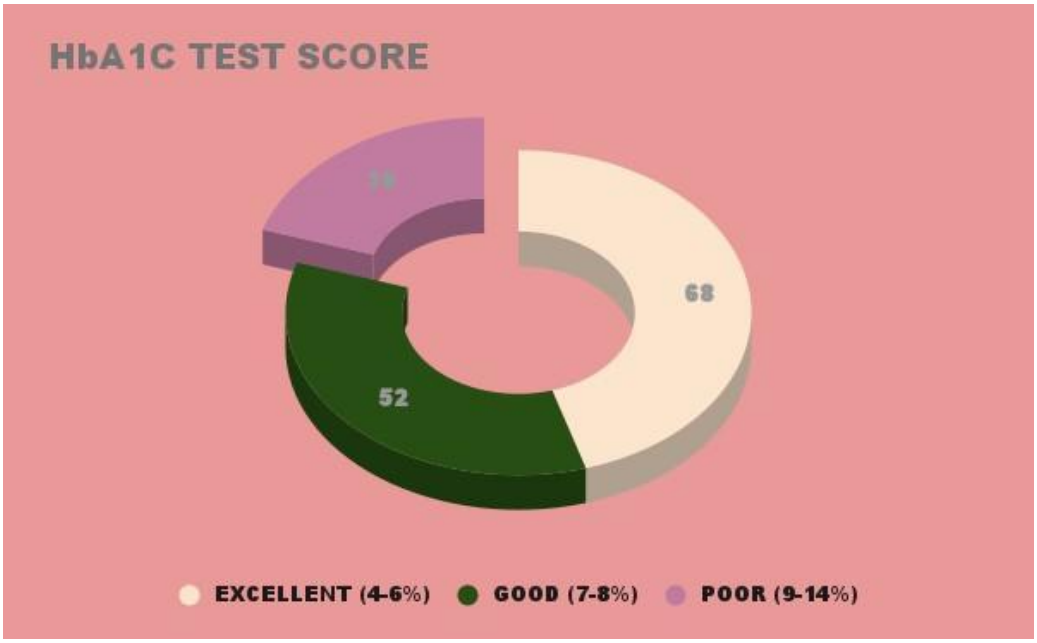

Figure 5: Pie Chart Representation Of HbA1c.

The HbA1c test score of 68 patients were found to be excellent in the range of (4-6%)followed by 52 patients were found to be good test scores in the range of (7-8%) and 30 patients found in the range of (9-14%) that belong to the poor condition. Poor HbA1c test score indicates persistently elevated blood glucose and severe complication might be occur. This is seen in the patients who are non-adherent to medication and obtained low score in DSMQ assessment (below the cut off score).

11. DISTRIBUTION OF COUNT OF GLUCOSE

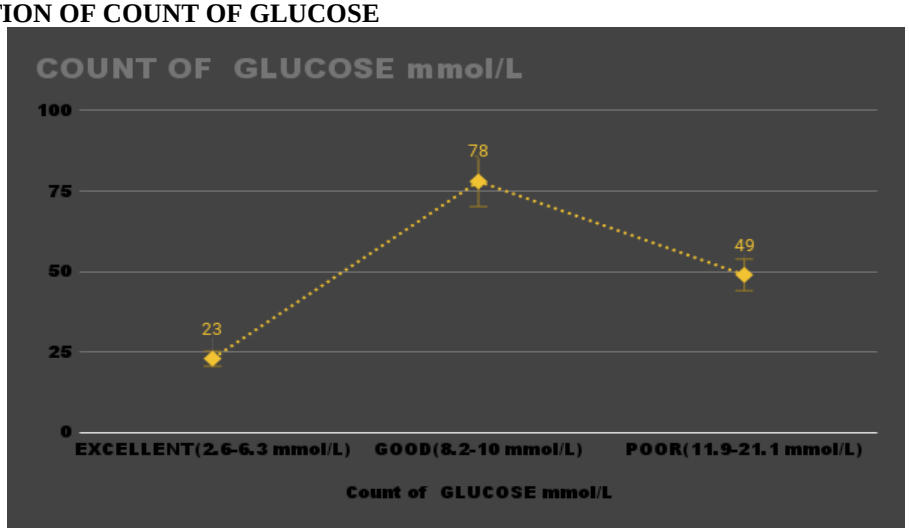

Figure 6: Line Graph Representation of Count of Glucose.

Out of 150 patients enrolled in the study, 23 patients are with EXCELLENT glucose level (2.6-6.3mmol/L) followed by 78 patients with GOOD glucose level (8.2 – 10 mmol/L) and 49 patients with POOR glucose level (11.9-21.1 mmol/l).The patients who follows the diabetic care and medication adherence properly fall under the category of Excellent glucose level with no diabetic complications.

12. RESULTS OF DIABETIC COMPLICATIONS

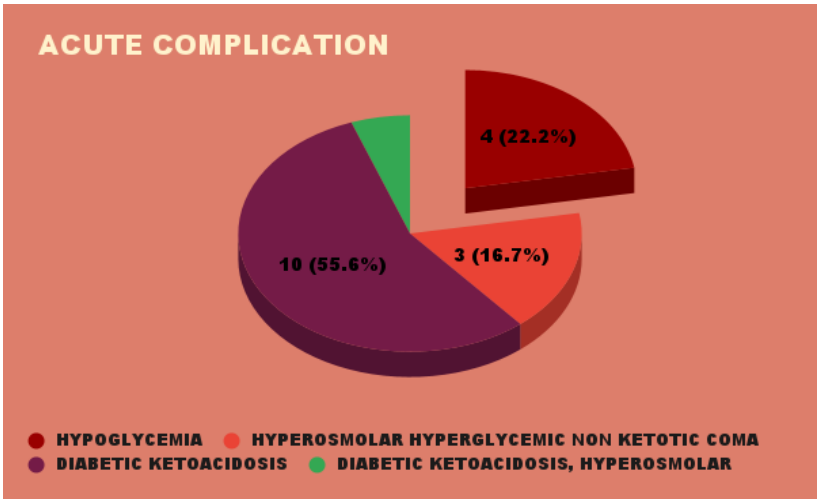

Figure 6: Pie Chart Representation of Acute Complications.

The diabetic complications are found in the patients with low HbA1c levels and poor medication adherence. Out of 150 patients enrolled in the study, diabetic ketoacidosis, hyper osmolar hyperglycemic coma non ketotic coma is observed in 1 patient followed by HHNS is observed is 3 patients, hypoglycemia is observed in 4 patients and diabetic ketoacidosis is observed in 10 patients.

13. RESULTS OF CORRELATIONS

Table 6: Correlation Table of DSMQ and HbA1c.

Correlations			
		DSMQ	**HbA1C**
DSMQ	Pearson Correlation	1	-.646**
	Sig. (2-tailed)		.000
	N	26	26
HbA1C	Pearson Correlation	-.646**	1
	Sig. (2-tailed)	0.000	

	N	26	26
**. Correlation is significant at the 0.01 level (2-tailed).			

The total score is a global measure of diabetes self management and it comprises all the 16 questions. The cronbach' alpha of the questionnaire was found highly significant. Out of 150 patients enrolled in the study, 26 patients' DSMQ scores were found below the cut- off score 6. The population whose cut off score less than 6 is compared with the poor HbA1c level to know the relation between both variables. The strength of the relationship varies in degree based on the value of correlation coefficient. Pearson correlation R is found to be -0.646. The correlation is significant at the 0.01 level.

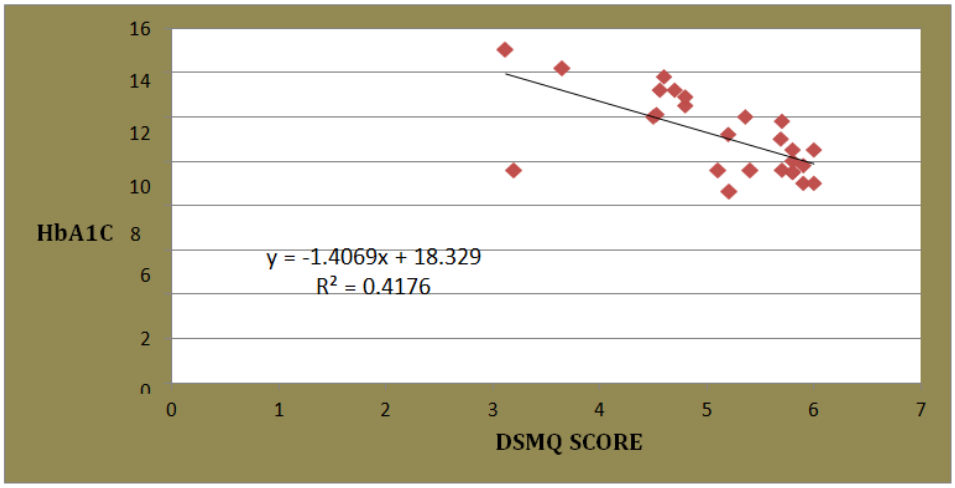

Figure 7: Scattered Plot Diagram Of Hba1c And DSMQ Scor.

Here the R square value is 0.4176 and Pearson correlation R is found to be -0.646. That means the value lies in between -0.6 and -1 that indicates a high degree of negative correlation. This correlation R = -0.646 states that as the DSMQ score decreases the glycosylated hemoglobin gets higher in value.

DISCUSSION

The data was collected from 150 patients using a specially designed data collection form. Out of 150 patients enrolled in the study from the inpatient department, Majority of patients 74(49.33%) of them were found in the age group between 45-65 years. 86(57.3%) were males and 64(42.7%) were females. Maximum distribution of duration of diabetes were found in between 5-10 years (44%). In the study 116 (77.3%) of patients were taking the anti- diabetic drug as advised by the doctor and 34(22.7%) were not taking medicines regularly. It was observed that 26 (17.3%) patients used to make their own modification in the dose of drug prescribed and the majority of patients 106 (70.7)were monitoring the blood glucose level regularly. It is remarkable that 135(90.0%) patients were getting information regarding the prescribed drugs from the physician and 128(85.3%) patients were having good knowledge regarding the anti-diabetic drugs prescribed for them. In the study 127(84.7%)patients were comfortable in asking questions to the physician. Diabetes self-management questionnaire (DSMQ) is used to assess diabetes self- management activities of 150 patients. The mean value and standard deviation found to be 2.32 and 0.521 for "My diabetes-self care is poor". Out of 150 patients, 34 (22.7%) belonged to the category of not taking medicines regularly. The reason for not taking the medications regularly are due to lack of finance(1.3%), interferes with meal plan (0.7%), taking them since many years (3.3%), feeling the drug is not effective(1.3%), I forget(6.7%), side effects(2%),feeling the dose given is high(0.7%), multiple medications(6.0%), and poor family support(1.3%).

Anova test is done to check if the means of groups are statistically significant or not. The P value is found to be ($p< 0.05$) which is statistically significant. The low p value shows that the effect is large or that the result is of major theoretical, clinical, or practical importance.

Out of 150 patients, pre – prandial blood glucose level of 65 patients belongs to > 130 mg / dl followed by 40 patients belongs in between 100-130 mg/dl and 35 patients belongs in between 80-100 mg/dl and 10 patients belongs in between 60-80 mg/dl. The post – prandial blood glucose level of 60 patients belongs to > 200 mg/dl followed by 30 patient belongs in between 180-200 mg/dl, 38 patients belong in between 160-180 mg/dl, 12 patients belong in between 141-160 mg/dl, 10 patients belongs in between 100-140 mg/dl. The HbA1c test score of 68 patients were found to be excellent in the range of 4-6 % followed by 52 patients were found to be good test score in the range of 7-8% and 30 patients found in the range of 9-14 % that belong to the poor condition.

Poor HbA1c test score seen in the patients who are poor in medication adherence and obtained low scores in

DSMQ assessment. The patients who follow the diabetic care and medication adherence properly fall under the category of Excellent glucose level with no diabetic complications. The diabetic complications is found in the patients with low HbA1c levels and poor medication adherence. Out of 150 patients enrolled in the study, diabetic ketoacidosis, hyper osmolar hyperglycemic coma non ketotic coma is observed in 1 patient followed by HHNK is observed is 3 patients, hypoglycemia is observed in 4 patients and diabetic ketoacidosis is observed in 10 patients. In the study, Serum ketone level is found <0.5 mmol/L in 11 patients followed by 8 number of patients with 0.6-1.5 mmol/L and 8 number of patients with > 1.5 mmol/L under the risk of ketoacidosis. The total score is a global measure of diabetes self-management and it comprises all the 16 question. The Cronbach' alpha of the questionnaire was found highly significant. Out of 150 patients enrolled in the study, 26 patients' DSMQ scores were found below the cut- off score 6. The population whose cut-off score less than 6 is compared with the poor HbA1c level to know the relation between both variables. The strength of the relationship varies in degree based on the value of correlation coefficient Significant 2 tailed test is conducted on the both variables. The scattered plot diagram has been done in the study between HbA1c and DSMQ score. Here the R square value is 0.4176 and Pearson correlation R is found to be -0.646. That means the value lies in between -0.6 and -1 that indicates a high degree of negative correlation. This correlation R = -0.646 states that as the DSMQ score decreases the glycosylated hemoglobin gets higher in value.

LIMITATIONS

- The study enrolled the patients only from one hospital and hence the impact of medication adherence and pharmaceutical care on the glycemic control in Type 2 DM patients cannot be generalized to the population of india.
- Study is only conducted in inpatients
- More sophisticated methods needs to be used to to assess the adherence pattern

CONCLUSIONS

Glycemic control is fundamental to the management of diabetes. This study evaluated the impact of medication adherence, pharmaceutical care on glycemic control in patients with type 2 diabetes mellitus. The assessment of medication knowledge is an important outcome measure in evaluating the effectiveness of diabetes education programmes. The result of the study can serve as baseline information for health care professionals and patients to further improve diabetic management. Pharmaceutical care programmes delivered by pharmacists are known to improve quality of patients. The assessment of medication knowledge is an important outcome measure in evaluating the effectiveness of diabetes education programmes. Adherence to therapies is a primary determinant of treatment success. Failure to adherence leads to worsening of disease, deaths and increased mortality rate and health cost. We could improve the medication adherence by patient education, dosing simplification and minimization of adverse effects, preparing a dosing card to the patients. Pharmaceutical care can be measured by collecting the patient data, identification of problems, establishing outcome goals through a good therapeutic plan, evaluating treatment alternatives by monitoring and modifying therapeutic plan, individualizing drug regimens and monitoring outcomes. This study emphasizes the need for creating more awareness among the general practitioners and clinicians and patients on the importance medication adherence and pharmaceutical care by conducting more continued medical education programs on drug therapy.

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