ROLE OF COUNSELING ON MEDICAL ADHERENCE AND GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT:

BACKGROUND: Diabetes Mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. It is the leading cause of of end stage renal disease, non-traumatic limb amputation and adult blindness. The studies have shown that complications of DM can be prevented by the proper control of blood glucose, which is dependent on the patient's adherence to medication, life style modification, frequent monitoring of blood glucose etc. and can be influenced by proper education and counseling of the patient. The patients with DM should receive education about exercise, care of DM during illness and medications to lower plasma glucose[1]. This study aims to assess the impact of patients counseling on the medication adherence in type 2DM.

METHOD: This is a prospective randomized study that includes 100 patients with type 2 DM in the out-patient department of internal medicine in a tertiary care teaching hospital, north Kerala. After getting informed consent, they were kept in two groups by simple randomization technique and were assessed and followed at 4 weeks interval. Data related to the medication adherence was collected using Morisky Medication Adherence Scale questionnaire (MMAS-8).

RESULTS: Out of 100 patients 33% were male and 67% female. Both baseline and 1st follow up showed a low adherence value (<6) both in control and intervention group. In the second follow up most of the patients in intervention group showed a moderate adherence (6-8), whereas control group did not show any improvement.

CONCLUSION: It can be concluded that there is a stastically significant improvement in the adherence level after patient counseling and education. Knowledge about the disease and treatment has improved the patient's adherence to medication.

KEYWORDS: Type 2 DM, Medication Adherence, Patients Counseling.

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INTRODUCTION: Diabetes mellitus (DM) is a group of metabolic disorders of fat, carbohydrate and protein metabolism that results from defects in insulin secretion, insulin action (sensitivity) or both, and results in chronic complications including micro vascular, macro vascular and neuropathic disorders.[2] Type 2 diabetes is a heterogenous disorder caused by a combination of genetic factors, related to insulin secretion, insulin resistance and environmental factors such as obesity, unsatisfactory diet, sedentary life style, lack of exercise and increasing urbanization. Type 2 DM is a common form of idiopathic diabetes and is characterized by lack of insulin to prevent ketoacidosis.[3]

India leads the world with over 30 million individuals affected by this deadly disease earning the dubious distinction of being termed as the "Diabetes Capital of the World".[4] Diabetes is a global problem with devastating human, social and economic impact. The estimated worldwide prevalence among adults in 2010 was 285 million (6.4%) and is predicted to rise in 2030 by around 439 million (7.7%).[3]

Type 2 diabetes, which is more prevalent (more than 90% of all diabetic cases) and the main driver of the Diabetes epidemic, now affects 5.9% of the world's adult population with almost 80% of the total in developing countries. Nowhere is the Diabetes epidemic more pronounced than in India as the World Health Organization (WHO) reports show that 32 million people had diabetes in the year 2000. The International Diabetes Federation (IDF) estimates the total number of Diabetic subjects to be around 40.9 million in India and this is further set to rise to 69.9 million by the year 2025.[5]

Patient counseling is a process that improves patient's ability to cope up and make informed decisions regarding their disease and medication and motivates the patients to change their dietary habits and life style, which are harmful for their current health status.[6] The patient plays an active role and is able to make decisions, learn practical skills for the treatment and can be continuously involved in the day to day management of Diabetes. The Diabetes education programs should be combined with counseling and psychological intervention if they are to be really effective. Psychological care will enhance educational and medical intervention.[7]

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Diabetes is a chronic condition that has considerable impact on the life of each individual patient. The principal task of the health care team is to give each patient knowledge, self-confidence and motivation.[8] Studies have confirmed that the complications of Diabetes can be reduced by proper control of blood glucose. The proper control is dependent on the patient's adherence to medication, life style modifications, frequent monitoring of blood glucose, etc. and can be influenced by proper education and counseling of the patient.[9]

MATERIALS AND METHODS: A written informal consent was taken from the patient or caregiver, in a prescribed format. Patients who met the inclusion criteria were enrolled for the study. A prospective, randomized study was carried out in 100 patients of the Internal Medicine department. The 100 patients were kept in two groups by simple randomization technique (odd and even numbers) i.e., 50 in control and 50 in intervention groups. The control and intervention group patients' socio-demographic details, their FBS and PPBS, HbA1c and other data related to medication adherence were collected by using MMAS-8. They were asked to come for follow up at one month interval. The intervention group patients were counseled on various aspects like disease, drugs and their management and also provided disease and drug patient information leaflets at the baseline. But the control groups were not counseled, only asked to come for follow up from the date of enrolment to one month. The same method was adopted for FBS, PPBS, HbA1c and Medication Adherence Scale in the first and second follow ups. The obtained data was recorded and subjected for suitable statistical analysis.

OBSERVATIONS: A total of 100 subjects in General Medicine OP department participated in the study. There were 33 (33%) males and 67 (67%) females. An MMAS-8 questionnaire was used to assess the medication adherence, and demographic details, laboratory results, drugs given, medical and medication history were documented using data entry sheet.

Gender	DM Control		DM Intervention	
	N	%	N	%
Male	18	36	15	30
Female	32	64	35	70
Total	**50**	**100**	**50**	**100**

Table 1: Distribution of gender details of Diabetes Mellitus patients

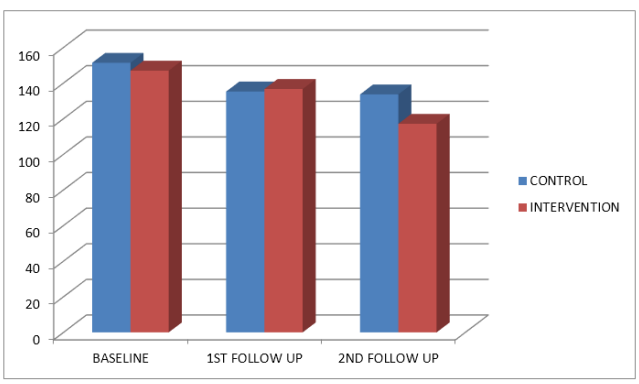
Table 1 shows the gender details of type 2 Diabetes Mellitus patients, out of 100 patients, 50 were in intervention group, in which males were 15 (30%) and females were 35 (70%). In control group out of 50 patients, 18 (36%) were male and 32 (64%) were females.

FBS (mg/dl)	CONTROL (Mean±SD)	INTERVENTION (Mean±SD)	P VALUE
Baseline	151.36±51.50	146.98±49.78	0.680
1st follow up	135.24±33.45	136.67±35.87	0.834
2nd follow up	133.63±32.51	117.12±22.31	0.041
Baseline Vs 1st follow up	t = 1.889; p = 0.061	t = 1.563; p = 0.102	-
Baseline Vs 2nd follow up	t = 2.334; p = 0.011*	t = 4.001; p < 0.001*	-

Table 2: Comparison Of Blood Sugar Parameter-Fbs (mg/dl)

* - Statistically significant results, SD- standard deviation.

DIAGRAM 1: COMPARISON OF BLOOD SUGAR PARAMETER -FBS (mg/dl)



The baseline values of control and intervention group are 151.36±51.50 and 146.98±49.78 respectively, with no significant difference. The first follow-up values of control and intervention group are 135.24±33.45 and 136.67±35.87 respectively. The second follow-up values were found to be highly significant, with control group 133.63±32.51 and intervention group 117.12±22.31.

PPBS (mg/dl)	CONTROL (mean±SD)	INTERVENTION (mean±SD)	P VALUE
Baseline	222.12±96.11	229.42 ± 94.7	0.462
1st follow up	197.81±62.88	191.61 ± 52.15	0.758
2nd follow up	201.43±68.45	166.32 ± 29.84	0.006
Baseline vs 1st follow up	t = 1.552; p = 0.113	t = 3.218; p = 0.002*	-
Baseline vs 2nd follow up	t = 0.843; p = 0.436	t = 4.001; p < 0.001	-

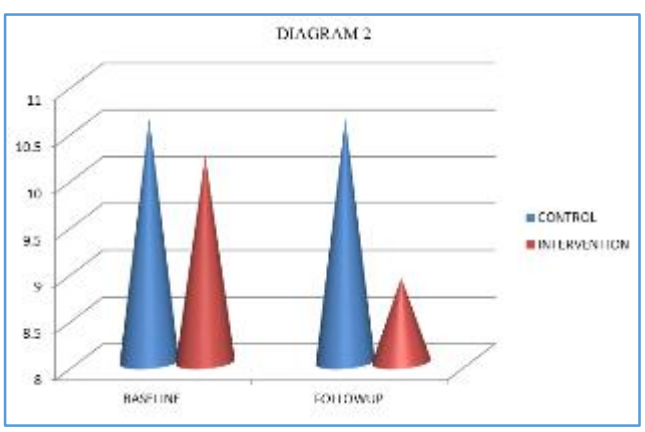
Table 3: Comparison of Blood Sugar Parameter-Ppbs (mg/dl)

The baseline PPBS levels of control and intervention group are 222.12±96.11 and 229.42±94.7 respectively. The first follow-up values of control and intervention group are 197.81±62.88 and 191.61±52.15 respectively. The second follow-up values of control and intervention group are 201.43±68.45 and 166.32±29.84 respectively. PPBS values of second follow up were found to be highly significant with a p value <0.001 when compared to baseline and first follow up.

HbA1c	CONTROL	INTERVENTION	P VALUE
Baseline	10.6	10.2	0.0377
Follow up	10.6	8.9	0.0029*

Table 4: Comparison Of Blood Sugar Parameter-HbA1c (%)

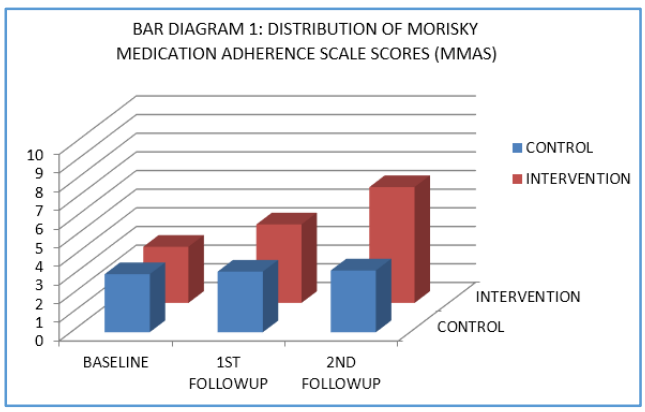
The comparison of HbA1c value between intervention and control group is shown in the table 8 above. The baseline HbA1c value of control group was 10.6 and intervention group was 10.2. The mean follow up value of control group was 10.0, whereas intervention group with a value of 8.9, showed a statistically significant (p=0.0029) betterment HbA1c value.



MMAS	CONTROL (mean±SD	INTERVENTION (mean±SD)	P VALUE
Baseline	3.11±0.12	3.01±0.09	0.6056
1st follow up	3.25±0.21	4.21±0.09	0.0128
2nd follow up	3.31±0.13	6.21±0.26	0.0008*

Table 5: Distribution of Morisky Medication Adherence Scale Scores (MMAS)

* - Statistically significant results, SD-Standard Deviation.



The MMAS scores at base line, first follow up and second follow up was found to be in control group as 3.11±0.12, 3.25±0.21 and 3.31±0.13 respectively and in intervention group 3.01±0.09, 4.21±0.09 and 6.21±0.26 respectively. In the baseline medication adherence p value was found to be 0.6056 which was not significant, followed by first follow-up p value of 0.0128 which is to be statistically significant, further followed by second follow-up p value 0.0008*. Statistical test results showed an extremely significant value at second follow up p value.

In this study during the baseline and first follow up most of the patients showed low adherence value (<6) both in control and intervention group. But in the second follow up most of the patients exhibited an improvement from low adherence to moderate adherence (6-8) in the intervention group, whereas the control group did not exhibit any marked improvement in the adherence level.

DISCUSSION: Diabetes Mellitus is a growing concern as it substantially increases one's risk of developing blindness, end stage renal disease, lower limb amputations, dying from coronary heart disease, cerebrovascular disease, or peripheral vascular disease. The management of DM not only requires the prescription of the appropriate nutritional and pharmacological regimen by the physician but also intensive education and counseling of the patient.[10]

In this study FBS level between control and intervention group was found to be highly significant in the second follow up (117.12±22.31) when compared to first (136.67±35.87) and baseline (146.98±49.78) follow ups. This improvement in the blood sugar level of intervention over the control shows that there is best positive impact on patient. This was similar to the findings of the study conducted by P. H. Patil et al,[11] Mahvash Iram et al,[12] K. V. Ramnath et al[13].

Postprandial blood sugar comparisons between control and intervention group were found to be highly significant in the second follow up (166.32±29.84) when compared to first (191.61±52.15) and baseline (229.42±94.7) follow ups, showing improvement in the blood sugar level. These results correlated with the findings of the study conducted by Shobha Rani et al[12], K.V. Ramnath et al.[13]

A statistically significant (p=0.0029) betterment was observed during final follow up in the intervention group compared to control group. At the final follow up the

intervention group subjects had a total improvement in the glycemic control. These results correlated with the findings of the study conducted by A. Satpute et al[11], Nalini Pais et al.[12]

During the second follow up patients in the intervention group exhibited an improvement from low adherence to moderate adherence, whereas the control group did not show any marked improvement. Statistical test results showed a strong significance at second follow up p value as 0.0008. This clearly showed that there was a good improvement in medication adherence behaviour in intervention group because of educational services when compared to control group. This was similar to the findings of the study conducted by Christian S. Conley et al[13] and K. V. Ramnath et al.[13]

CONCLUSION: The study concludes that there is a stastically significant improvement in the medication adherence level after patient counseling and education. Knowledge about the disease and treatment has improved the patient's adherence to medication. DM is a life long disease and health care providers have almost no control over the extent to which patients adhere to the day-to-day treatment regimen. A prescriptive approach fails in many situations. For long term success of DM self-management education is critical.[14]

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