

An open label observational study for Drug adherence in Type 2 Diabetes Mellitus patients

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ABSTRACT

Diabetes mellitus is a heterogeneous group of disorders characterized by abnormalities in carbohydrate, protein, and lipid metabolism. The central disturbance in diabetes mellitus is an abnormality in insulin production or action or both, although other factors can be involved. Medication non-adherence is particularly common among patients with type 2 diabetes and inadequate adherence compromises safety and treatment effectiveness, leading to increased mortality and morbidity.

Key Words: Diabetes mellitus, Insulin, drug adherence

INTRODUCTION

Diabetes mellitus is a heterogeneous group of disorders characterized by abnormalities in carbohydrate, protein, and lipid metabolism. The central disturbance in diabetes mellitus is an abnormality in insulin production or action or both, although other factors can be involved. Diabetes mellitus is a chronic disease and drug adherence is necessary in chronic disease to prevent progression of disease. Drug adherence is the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from the health care provider¹. Medication non-adherence is particularly common among patients with type 2 diabetes and inadequate adherence compromises safety and treatment effectiveness, leading to increased mortality and morbidity². Patients can be intentional as well as unintentional non-adherent to their drug treatment³. Intentional non-adherence is seen as a conscious decision for not taking the drug as prescribed after balancing the pros and cons, whereas unintentional non-adherence is a more passive behavior which is more strongly associated with demographics⁴. Non-adherence is influenced by many factors, including patient and treatment characteristics⁵. The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. The prevalence of diabetes is higher in men than women, but there are more women with diabetes than men. The urban population in developing countries is projected to double between 2000 and 2030. The most important demographic change to diabetes prevalence

across the world appears to be the increase in the proportion of people >65 years of age.⁶

Non-adherence is a barrier to a successful treatment and may result in worsening health status of the patient, eventually causing errors in future treatments. This clinical deterioration may compel the requirements of more drugs, involving the need for further diagnostic procedures, more costly and complex treatments, consultations, the use of emergency services and the increase in hospitalizations⁷.

Specialists often refer to the values of glycated hemoglobin to assess the treatment adherence, which will reflect the degree of control and currently it seems to be the best indicator of the patient's health status. Patients with good metabolic control apparently have good adherence habits.⁸ The index of glycated hemoglobin is therefore considered as the most valid indicator of treatment adherence,⁹ for the patients with a poor metabolic control present superior HbA1c values when compared to the therapeutic target. A low value of HbA1c is a good indicator of the health status and a good treatment adherence. On the other hand, high values of HbA1c are related to weak health, suggesting that there is something wrong in treatment adherence. Treatment adherence among patients with DM-type 2 is strongly influenced by the level of knowledge of the patient, including not only what they know and do not know about the illness, but by misconceptions, beliefs and inaccurate assumptions on the matter.¹⁰ Structured and targeted educational plans play a key role in the adherence level of patients. Kalogianni (2012) believes that it is vital to educate patients and convince them of the benefits of treatment, as well as maintaining a

therapeutic relationship based on communication, trust and motivation.¹¹

AIM OF THE STUDY

To estimate the extend on which patients adhere the physician recommended therapy and how drug adherence is responsible to cure of disease.

Research Method

Study is an open label, single centric, observational, pilot, prospective study which primarily hypothesize that systematic identifications and interventions administered

through continued physician follow-up, patient counseling will improve adherence to therapy and therefore improvement in treatment effectiveness and quality of life in Type 2 Diabetes patients.

Result

DETAIL OF PATIENTS- AGE, SEX, RESIDENCE

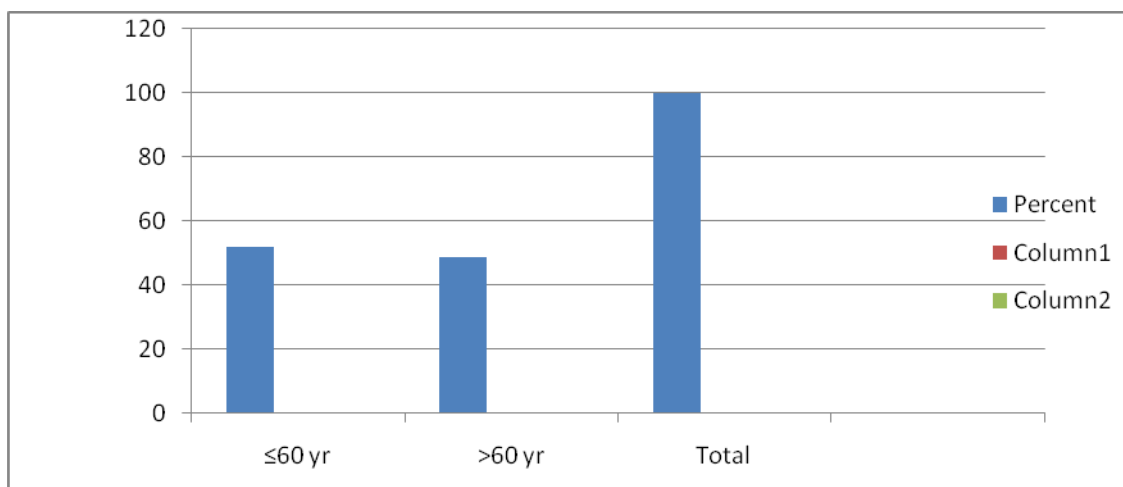
AGE

The age of enrolled 60 patients was ≤60 yr 31 patients (51.6%), >60 yr 29 patients (48.4%). Demographic summary of the patients represented in table (Table 6.1).

Table 1.1: Details- Age of Patients

Age	Frequency	Percent
≤60 yr	31	51.6%
>60 yr	29	48.4%
Total	60	100%

Chart 6.1: Details- Age of Patients



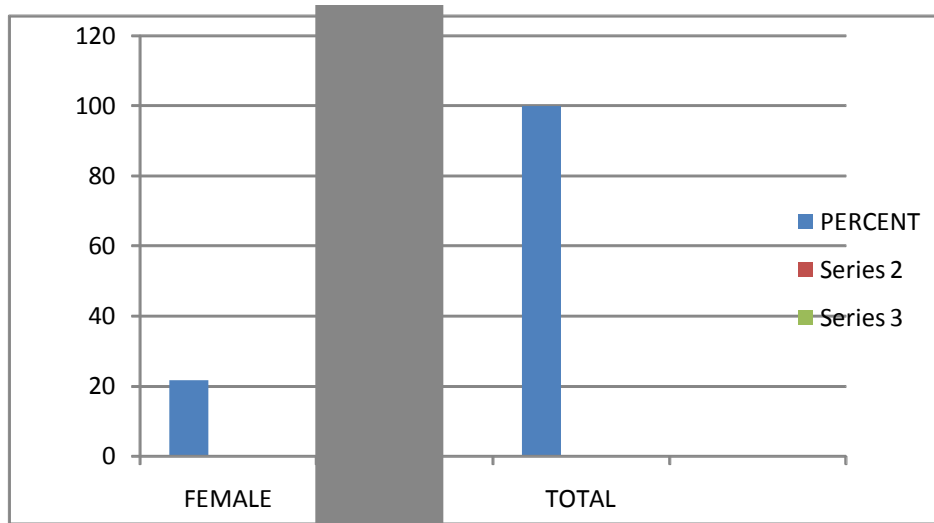
SEX

Out of 60 patients total 13 patients (21.67%) were female and 47 (78.33.%) patients were male, which were enrolled in this study. Detail of patients on the basis of Sex is represented in table (Table 6.2).

Table 6.2: Details- Sex of Patients

Sex	Frequency	Percent
Female	13	21.67%
Male	47	78.33%
Total	60	100%

Chart 6.2: Details- Sex of Patients



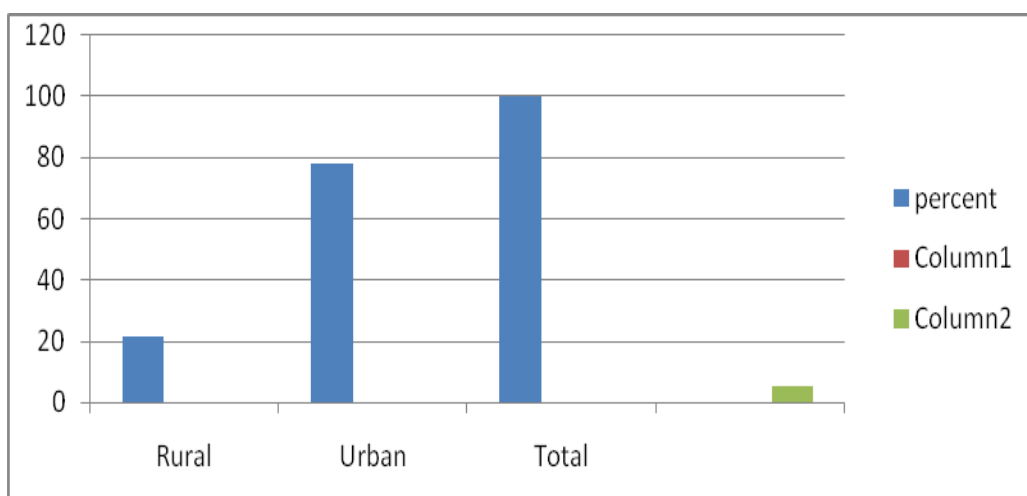
RESIDENCE

Total 47 patients (78.33%) were from urban area and 13 patients (21.67%) were from rural area, involved in this study. Detail of patients on the basis of residence is represented in table (Table 6.3).

Table 6.3: Details- Residence of Patients

Residence	Frequency	Percent
Rural	13	21.67%
Urban	47	78.33%
Total	60	100%

Chart 6.3: Details- Residence of Patients



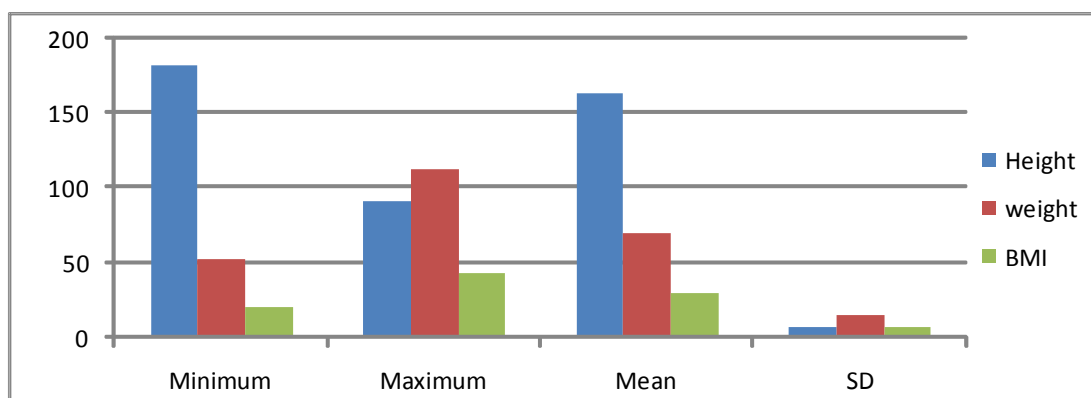
6.1.2 STATISTICAL DETAILS: HEIGHT, WEIGHT AND BODY MASS INDEX

Mean weight of patients was 72.06275 kg (weight male 73.4563 kg and female 70.6692 kg). Mean height of the patients was 164.1000 cms (height-male 158.4190 cms, female 170.3789 cms). Mean Body Mass Index of patients was 29.50695 (BMI male 30.9063 and female 28.1076) in table (Table 6.4).

Table 6.4: Statistical Details- Height, Weight and BMI

	Heights (cms)		Weight (kg)		BMI	
	Male	Female	Male	Female	Male	Female
Minimum	150.00	91.00	52.00	59.05	20.20	24.60
Maximum	175.00	183.00	113.00	92.00	42.80	36.30
Mean	158.4190	170.3789	73.4563	70.6692	30.9063	28.1076
SD	3.92913	9.90398	16.53159	13.57517	6.20530	8.49420

Chart 6.4: Statistical Details- Height, Weight and BMI



BASELINE AND FOLLOW UP VARIABLES STATISTICS

STATISTICS FOR WHOLE POPULATION

	Baseline (MEAN ± SD)	1 st Follow Up	2 nd Follow Up
FBG	150.15 ± 36.03	129.68 ± 34.54	122.25 ± 39.88
PPG	218.66 ± 68.56	185.67 ± 48.94	173.77 ± 51.86
SBP	133.16 ± 12.82	131.12 ± 11.78	130.28 ± 10.14
DBP	84.08 ± 5.32	83.43 ± 5.17	81.66 ± 4.38
BMI	26.86 ± 4.43	26.85 ± 4.29	26.53 ± 4.21
WHR	0.97 ± 0.06	0.97 ± 0.06	0.97 ± 0.06
Adherence	0	92.01 ± 7.43	94.73 ± 4.99

BASELINE AND FOLLOW UP VARIABLES STATISTIC

[WHOLE POPULATION (MALE)]

	Baseline (MEAN \pm SD)	1 st Follow Up	2 nd Follow Up
FBG	150.61 \pm 39.380	132.07 \pm 36.760	125.06 \pm 42.344
PPG	216.10 \pm 76.017	190.73 \pm 49.866	177.53 \pm 54.893
SBP	132.17 \pm 11.597	130.36 \pm 11.089	128.96 \pm 7.720
DBP	83.82 \pm 5.130	82.87 \pm 4.513	82.04 \pm 3.670
BMI	26.46 \pm 4.477	26.14 \pm 3.907	25.64 \pm 3.554
WHR	0.98 \pm 0.064	0.98 \pm 0.066	0.97 \pm 0.065
Adherence	0	91.49 \pm 7.75	94.52 \pm 5.22

BASELINE AND FOLLOW UP VARIABLES STATISTICS

[WHOLE POPULATION (FEMALE)]

	Baseline (MEAN \pm SD)	1 st Follow Up	2 nd Follow Up
FBG	148.46 \pm 20.895	117.75 \pm 16.993	108.16 \pm 21.245
PPG	227.92 \pm 29.104	159.75 \pm 36.046	155.00 \pm 29.113
SBP	136.92 \pm 16.525	135.00 \pm 15.118	136.66 \pm 17.511
DBP	85.00 \pm 6.123	86.25 \pm 7.440	80.00 \pm 7.071
BMI	28.31 \pm 4.111	30.46 \pm 4.621	30.98 \pm 4.744
WHR	0.93 \pm 0.068	0.94 \pm 0.070	0.96 \pm 0.062
Adherence	0	94.73 \pm 5.217	95.78 \pm 3.843

BASELINE AND FOLLOW UP VARIABLES STATISTICS

[[AGE ≤60 YR.]]

	Baseline (MEAN ± SD)	1 st Follow Up	2 nd Follow Up
FBG	150.21 ± 43.077	126.04 ± 41.901	118.55 ± 43.980
PPG	204.14 ± 92.522	186.34 ± 50.788	174.00 ± 48.463
SBP	132.14 ± 11.974	132.17 ± 13.802	128.23 ± 7.276
DBP	83.21 ± 4.946	83.26 ± 5.561	82.08 ± 5.822
BMI	28.26 ± 4.995	27.73 ± 4.341	27.00 ± 3.928
WHR	0.97 ± 0.058	0.97 ± 0.055	0.96 ± 0.046
Adherence	0	90.34 ± 8.598	94.41 ± 5.085

BASELINE AND FOLLOW UP VARIABLES STATISTICS

[[AGE >60 YR]]

	Baseline (MEAN ± SD)	1 st Follow Up	2 nd Follow Up
FBG	150.09 ± 29.249	132.76 ± 27.335	125.94 ± 36.225
PPG	231.37 ± 33.694	185.07 ± 48.257	173.55 ± 56.481
SBP	134.06 ± 13.645	130.19 ± 9.846	132.22 ± 12.153
DBP	84.84 ± 5.605	83.60 ± 4.898	81.33 ± 2.968
BMI	25.64 ± 3.517	26.07 ± 4.180	26.05 ± 4.545
WHR	0.97 ± 0.074	0.97 ± 0.078	0.98 ± 0.078
Adherence	0	93.60 ± 5.944	95.06 ± 5.038

CONCLUSION

Study analysis concluded that:

- Female are generally more aware than males for adherence.
- Patients with adherence > 95% showed reduction in FBG and PPG values
- Patients with age group ≤60 show more adherence than older.

Finally it can be concluded that for better control of hyperglycemia and therefore quality of life, patient should have 100% adherence to pharmacotherapy and what advice has been given to him. In my study I enrolled total 60 patients with both old and newly diagnosed Diabetes mellitus condition. I observe that only 84% patients showed adherence to prescribed pharmacotherapy out of total enrolled patients and data also shows that female patients were more aware about adherence. Both Male and female patients got benefit with anti oral hypoglycemic treatment.

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