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"STUDY OF CLINICAL PROFILE OF PATIENTS WITH HIV-AIDS ON TENOFOVIR BASED REGIMEN".

Medicine

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ABSTRACT

BACKGROUND: Antiretroviral therapy may cause undesirable change in clinical and laboratorial parameter. This study in ART Centre, government medical college, Bhavnagar concerning to alteration in clinical and laboratory parameters in HIV positive patients. it will help physicians to gain knowledge of these adverse events, with the ultimate goal of improving the tolerability of HIV treatment & promoting the early recognition and reversal of potentially serious adverse events

METHOD: 80 subject were started Tenofovir based Regimen therapy, all study participant had examined into this prospective study, following parameters were collected: age, gender, marital status, general physical examination and Laboratory parameters like CD4+ T cell count, serum Sodium, Potassium, lipid profile, serum creatinine, serum urea, SGPT and SGOT.

RESULT: Common presenting symptoms observed at 0 month were diarrhea (11.25%) >weight loss (15%)>weakness (10%)>fever (6.25%).After 1 month of treatment it has been observed that GIT system involvement was maximum with Nausea being predominant. Majority of patients were symptoms free after 6 months of treatment, 16.45% of study population develop renal dysfunction at the end of 6 months.

CONCLUSION: GIT system is most commonly involved with predominant symptoms nausea after 1 month of tenofovir based regimen therapy. After 6 months of tenofovir based regimen therapy patients' clinical events were improved compare to baseline while Renal and liver dysfunction is prevalent in the study population. There was improvement in CD4+ T cell count at the end of 6 month of treatment.

KEYWORDS

Human immune deficiency virus,National aids control organisation,Antiretroviral therapy,

INTRODUCTION

Antiretroviral therapy has led to significant reduction in the rates of illness and prolongs the life, Despite the positive therapeutic effects, antiretroviral therapy (ART) may cause undesirable change in clinical and laboratorial parameter. Adverse clinical and laboratorial events of ART therapy have a major impact on public health by imposing economic burden on the society and health care systems and may significantly impact patient's quality of life and drug adherence. This study in ART Centre, government medical college, Bhavnagar concerning to alteration in clinical and laboratory parameters in HIV positive patients. it will help physicians to gain knowledge of these adverse events, with the ultimate goal of improving the tolerability of HIV treatment & promoting the early recognition and reversal of potentially serious adverse events.

AIMS & OBJECTIVES:

Study of clinical profile, Biochemical profile and Haematological profile in patients of HIV-AIDS on tenofovir based regimen therapy.

MATERIALS AND METHODOLOGY

During the study course of six months total, 80 subject were taken into study who had newly diagnosed HIV-AIDS and started Tenofovir based Regimen. All study participants were examined into this prospective study. Baseline data including age, gender, marital status and detailed medical history, clinical examinations and relevant investigations were included as part of the methodology. Laboratory parameters like CD4+ T cell count,serum Sodium, Potassium, lipid profile, serum creatinine, serum urea, SGPT and SGOT were obtained at 0 months (baseline) ,1months and 6 months.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria:

- Patients giving informed and written consent
- Age >18 years
- Patients with HIV-AIDS who has newly started Tenofovir based regimen therapy.

Exclusion criteria

- Patient not giving informed and written consent.

Patients age <18 years

Type of study: Prospective study

Sample size : 80

OBSERVATION AND RESULT

80 subjects with newly diagnosed HIV-AIDS patients put on tenofovir based regimen and followed up till period of 6 months. All data was taken at 0 month, 1 month and 6 months during this study.

Table 1 Age distribution of study subjects

	Frequency (N=80)	Percent (100%)
18-30	19	23.8
30-45	36	45
45-60	25	31.2
mean±SD	38.4±10.89	

Out of 80 subjects, 19 subjects fall into 18-30 years age group; 36 falls into 30-45 years; 25 falls into 45-60 years age group with mean age of 38.4±10.89

Chart 1: Age distribution

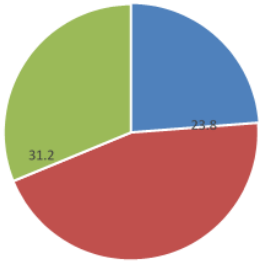


Table 2 Comparison between baseline CD4+ T cell count and outcome after 6 months of tenofovir based regimen therapy.

	N	Mean	Std. Dev	P value**
0 month	80	196.46	59.08	<0.0001*
6 months	79	345.54	112.16	

**unpaired t test *statistically significant

The data suggest that there was significant improvement in CD4+ T cell count at the end of 6 month of treatment with tenofovir based regimen therapy and which was statistically significant.

Table 3 Distribution of clinical symptoms in study subjects

System	Symptoms	0 month	1 month	6 month
CNS	Headache	4	5	-
	Convulsion	-	-	1
GIT	Nausea	-	20	3
	Vomiting	-	2	-
	Abdominal pain	-	1	4
	Diarrhea	8	4	-
	Gastritis	-	4	-
	Jaundice	1	1	-
Respiratory	Cough	2	3	4
	Breathlessness	-	-	2
Psychological	Decrease sleep	1	5	-
	Abnormal dream	-	2	-
	Depression	-	-	1
	Decrease concentration	-	1	-
	Insomnia	-	3	-
	Memory loss	-	2	-
Skin	Rashes	-	4	5
	Skin lesion	2	-	-
	Itching	-	-	-
	Hair fall	-	-	1
GUT	Genital ulcer	2	-	-
	Burning micturition	1	-	2
	Decrease urine output	-	1	1
Others	Fever	5	-	-
	Weight loss	12	-	1
	Night sweat	2	-	-
	Lymph node enlargement	1	-	1
	Body ache	2	-	-
	Fatigue	4	1	-
	Weakness	7	2	1
	sore throat	2	-	-
	Oral ulcer	2	2	-
	Decrease appetite	-	1	-
	Muscle wasting	-	-	4
	Pedal edema	-	-	3
	Pallor	-	-	2
	NIL	21	14	45

Table 4 Classification/distribution of clinical events in study subjects

System involvement	0 months (n=80)	1 months (n=80)	6 months (n=79)
CNS	04	06	01
GIT	09	31	09
GUT	04	01	02
Respiratory	02	03	05
Psychological	01	13	01
Skin	03	04	05
Others	36	08	11
NIL	21	14	45

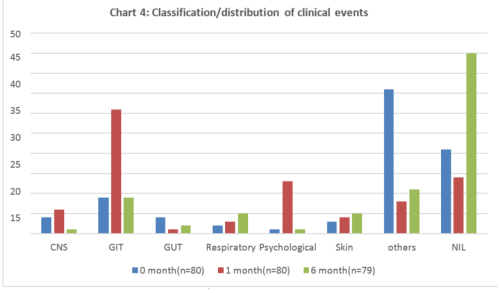


Table 5

SYMPTOMS	0 MONTHS	1 MONTHS	6 MONTHS	P VALUE**
+	59	66	34	<0.0001*
-	21	14	45	

** χ^2 test *significant

In this study, baseline clinical events were taken into consideration before starting tenofovir based regimen therapy and it was observed at 1 month and 6 months during study period. Statistical analysis suggests that there were significant clinical improvements noted at the end of 6 month of tenofovir based regimen.

Table 6 Renal function test

		0 month	1 month	6 month	P value**
Creatinine	Mean	0.86	0.92	1.09	0.0011*
	Sd	0.17	0.33	0.59	
Urea	Mean	33.41	31.93	30.01	0.19
	Sd	6.69	7.93	17.59	

**ANOVA test * statistically significant

Table 7 Distribution of serum creatinine

Serum creatinine	0 month(n=80)	1 month(n=80)	6 month(n=79)
0.7-1.2	79	74	64
>1.2	1	6	15

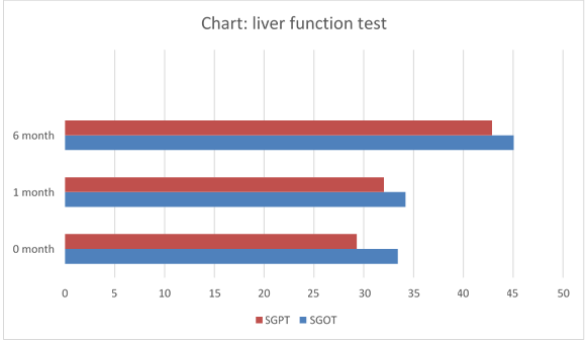
In this study, baseline serum creatinine and blood urea were done before starting tenofovir based regimen therapy and it was repeated at 1 month and 6 months to see the drug effect on kidney function test. Statistical analysis suggests that there is significant effect of tenofovir based regimen therapy on serum creatinine but not significantly effect on blood urea.

Table 8 liver function test

		0 month	1 month	6 month	P value**
SGOT	Mean	33.42	34.170	45.08	0.055
	Sd	7.205	8.15	58.04	
SGPT	Mean	29.3	32.02	42.88	0.0025*
	Sd	7.11	9.18	43.3	

**ANOVA test * statistically significant

Statistical analysis suggests that there is significant effect of tenofovir based regimen therapy on SGPT level but not any effect on SGOT level.



SUMMARY

The present study was conducted for a period of 6 months with study population of 80 patients at the ART Centre, Government Medical College and Sir Takhtsihji General Hospital, Bhavnagar, Gujarat. Detail history, physical examination was done and patient was investigated with clinical and laboratory parameters. Comparison and statistical analysis were done. Out of 80 patients, 23.8% of subjects belong to age group 18-30 years, 45% patients were in 30-45 years, and 31.2% were in Between 45-60 years age. Majority of patients were in younger age group.. In present study Statistical analysis was done with unpaired t test at the end of 6 months. The data suggest that there was significant improvement in CD4+ T cell count at the end of 6 month of treatment with tenofovir based regimen therapy with P value of diarrhea (11.25%) >weakness (10%)>fever (6.25%). after 1 month of treatment it has been observed that GIT system involvement was maximum. In GIT system, Nausea were predominant. It may be due to adverse event of ART therapy in initial stage of treatment. It was also observed that majority of patients were symptoms free after 6 months of treatment as compared to the baseline clinical symptoms, so it can be assumed that improvement in clinical symptoms due to ART therapy. In present study, common symptom observed at the end of 6 months was skin rashes (5.06%) and common clinical manifestation involvement was general symptoms (11.39 % (Skin rashes >muscle wasting >abdominal pain>cough). In present study, it has been observed that there was rise in serum creatinine level at the end of 6

month of treatment with tenofovir based regimen. In present study, 16.45% of study population develop renal dysfunction at the end of 6 months. Statistical analysis with ANOVA test suggests that there is significant effect of tenofovir based regimen therapy on serum creatinine but not significantly effect on blood urea. In present study, rise in SGPT level at the end of 6 months of treatment with tenofovir based regimen, this regimen has also effect on SGOT level. Statistical analysis done with ANOVA test which suggest that there is significant effect of tenofovir based regimen therapy on SGPT level but not any effect on SGOT level. This rise of serum SGPT and SGOT level may be due to adverse reaction of ART or may be due to HIV infection itself, it has been observed that other parameter like complete blood counts (Hb, TC, PC); serum electrolyte (Na+, K+); lipid profile (TCH, LDL, HDL) were not affected by tenofovir based regimenIn our study Out of 80 subjects, 1 was expired.

CONCLUSION

The study is done to know the effect on clinical profile of tenofovir based regimen therapy in newly diagnosed patients with HIV-AIDS. In our study common presenting symptoms observed at 0 month were diarrhea >weight loss >weakness >fever . After starting tenofovir based regimen therapy it was observed that GIT system is most commonly involved with predominant symptoms nausea after 1 month of tenofovir based regimen therapy. it may be due to adverse event of ART. After 6 months of tenofovir based regimen therapy patients' clinical events were improved compare to baseline while Renal and liver dysfunction is prevalent in the study population. There was significant improvement in CD4+ T cell count at the end of 6 month of treatment with tenofovir based regimen therapy This highlights the critical and underappreciated need to monitor renal and liver function in HIV positive patients attending ART Centre, particularly in this era where tenofovir based regimen is being used in first line ART regimen in majority of patients as recommended by WHO. Early reporting of any adverse event developed after initiation of tenofovir based regimen by Patients is advisable. Frequent screening of renal and liver function at regular intervals is mandatory in tenofovir based regimen when compared to other regimens to avoid the further complications in a HIV patient.

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