

# A Study to Assess the Side Effects of Antiretroviral Therapy with a View to Develop Educational Program Regarding Home Care Management for Prevention of Side Effects of ART Among HIV Positive Patients in ART Clinic at PGIMS, Rohtak

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## Abstract

**Background:** HIV/AIDS poses a growing challenge to public health, leading to additional socioeconomic challenges for individuals, families, communities, and governments across numerous nations. HIV is increasingly recognized as a chronic condition, necessitating individuals living with HIV to manage various symptoms associated with the infection, comorbid conditions, or adverse effects from medications over prolonged durations. Research studies show the side effects of ART, and home care management are the most common issues for people living with HIV/AIDS. So, there is a need to adopt different educational interventions to prevent it. Keeping this in mind, the present study has been adopted to assess the side effects of ART and home care management with a view to developing awareness among HIV/AIDS patients and ensuring a safe and quality life for HIV/AIDS patients. **Objective:** To evaluate the adverse reactions to antiretroviral treatment. **Materials and Methods:** This descriptive study took place at the ART clinic of Pt. BD Sharma, PGIMS, Rohtak, involving a sample of 60 participants. A structured checklist was developed to evaluate the adverse effects of ART in HIV patients, and non-probability convenient sampling was employed. Descriptive statistics were utilised to analyse the gathered data. **Result:** The findings reveal that the majority of patients (19, or 31.7%) belonged to the age group of 26–33 years of age. The majority (56.7%) were male. The majority, 56.7%, had an income of ₹ 10,001–20,000 in the low socioeconomic group. The majority of patients (100%) were receiving the NRTI drug regimen. The majority of the patients (78.3%) had symptoms of fatigue or loss of energy. The majority of patients (71.7%) had symptoms of fever, chills, and sweat. **Conclusion:** This study was useful for assessing the side effects of ART and providing information, education, and communication material for the improvement of home-based care to prevent side effects of ART and improve the quality of life of HIV patients.

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**Keywords:** Side effects, antiretroviral therapy, educational program, home care management, ART, HIV

## INTRODUCTION

Human immunodeficiency virus (HIV) infects and impairs immune system cells, leading to progressive immune system deterioration, known as “immune deficiency.” Opportunistic infections thrive in this weakened immune system. In 2022, over 39 million individuals contracted HIV, resulting in approximately 35 million deaths globally. Of the 37.9 million people living with HIV,

37.5 million were adults, and 1.5 million were children under 15 years old. Additionally, 53% were women and girls. In India, an estimated 24 lakhs (0.22 million males, 0.29 million females) experience side effects from ART, with around 49,976 individuals in Haryana experiencing such effects [1–4].

Antiretroviral medications used to manage HIV fall into three main categories: nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs). Tenofovir (Viread), a nucleotide reverse transcriptase inhibitor (NtRTI), and enfuvirtide (Fuzeon), a recently approved fusion inhibitor, are also available. PIs typically have the most side effects and require strict dosing regimens.

Antiretroviral therapy (ART) can induce various side effects in individuals. Early in the course of most ART regimens, individuals commonly experience mild gastrointestinal symptoms such as bloating, nausea, and diarrhea. These symptoms may be short-lived or persist for the duration of the therapy. Additional frequent side effects include fatigue and headaches, particularly from AZT, and EFV-induced nightmares.

Globally, numerous approaches have been adopted to monitor and manage side effects in HIV-positive individuals, including the utilization of ART. These antiretroviral drugs represent some of the most transformative and effective medical advancements in recent history for treating HIV/AIDS [5–7].

## OBJECTIVE OF THE STUDY

To assess the side effects of ART

## MATERIALS AND METHODS

- *Research Approach:* Quantitative research approach
- *Research Design:* Descriptive cross-sectional research design
- *Study Setting:* ART Clinic PGIIMS, Rohtak
- *Study Size:* 60 samples
- *Study Population:* ART patient

### *Inclusion Criteria*

- HIV patients on antiretroviral medication who are 18 years of age or older.
- Those who are willing to participate.
- Patients who have been taking ART for 3 years.

### *Exclusion Criteria*

- Critically ill patients will not be included.
- Patients who are compromised patients.
- Psychiatric patients
- Terminally ill patients
- Any opportunistic infection was excluded.

## RESULT

### Section A: Describing the Frequency and Percentage Distribution of Socio-demographic Variables of Samples

Table 1 depicts that the majority of patients (19, 31.7%) were in the age group of 26–33 years of age. 16 (26.7%) belonged to age group of 34–41 years. 12(20%) belonged to age group of above 50 years. 8(13.3%) samples belonged to age group of 42–49 years. 5(8.3%) belonged to age group of 18–25 years. Majority (56.7%) were male, 47.7% were female, and only 1.7% were transgender. Most of the patients were unmarried, that was 80%, 11.7% were married, 5% were divorced, and 3.3% were

widow/widower. The majority (33.3%) of patients had secondary education. 31.7% of patients had primary education, and 11.7% were undergraduate and above. 23.3% of patients were found illiterate.

The majority (56.7%) had income of ₹ 10,001–20,000 and 20% sample had income between ₹ 20,001 and 30,000. 15% earned less than ₹ 10,000 monthly. 6.7% had income between ₹ 30,001 and 40,000, and 1.7% has income above ₹ 40,001. The majority of patients (100%) were receiving NRTIs drug regimen. No one was receiving NNRTIs, PI, or integrase strand transfer inhibitors.

**Table 1.** Frequency and percentage distribution of socio-demographic variables of the samples.

S.N.	Socio-demographic variables	Category	Frequency (F)	Percentage (%)
1.	Age group (in years)	18–25	05	8.3
		26–33	19	31.7
		34–41	16	26.7
		42–49	08	13.3
		Above 50	12	20.0
2.	Gender	Male	34	56.7
		Female	25	41.7
		Transgender	01	1.7
3.	Marital status	Unmarried	48	80.0
		Married	07	11.7
		Divorced	03	5.0
		Widow/widower	02	3.3
4.	Educational status	Illiterate	14	23.3
		Primary education	19	31.7
		Secondary education	20	33.3
		Undergraduates and above	07	11.7
5.	Income of the family per month (in ₹)	Below 10,000	09	15.0
		10,001–20,000	34	56.7
		20,001–30,000	12	20.0
		30,001–40,000	04	6.7
		Above 40,001	01	1.7
6.	Drug regimen	NRTIs	60	100.0
		NNRTIs	00	00
		PIs	00	00
		Integrase strand transfer inhibitors	00	00
7.	BMI (body mass index)	<18.5 kg per m <sup>2</sup> (underweight)	17	28.3
		18.5–24.9 kg per m <sup>2</sup> (normal)	31	51.7
		25.0–29.9 kg per m <sup>2</sup> (overweight)	12	20.0
		30.0–39.9 kg per m <sup>2</sup> (obese)	00	00
8.	CD4 count	Below 100 cells/mm <sup>3</sup>	07	11.7
		Below 200 cells/mm <sup>3</sup>	09	15.0
		Between 300 and 500 cells/mm <sup>3</sup>	28	46.7
		Above 500 cells/mm <sup>3</sup>	16	26.7
9.	Duration of taking ART (in months)	<6	10	16.7
		6–12	18	30.0
		13–18	07	11.7
		19–24	16	26.7
		25–30	01	1.7
		31–36	08	13.3
10.	Comorbid conditions	Yes	06	10.0
		No	54	90.0
11.	Types of comorbidities	Diabetes mellitus (DM)	01	1.7
		Hypertension (HTN)	03	5.0
		Both DM and HTN	01	1.7
		Thyroid disorders	01	1.7
		Other	54	90.0

In the BMI status of patient, the majority (51.7%) were belonging to normal and 28.3% were belonging to underweight. 20% were belonging to overweight and none of the patient were obese. Majority (46.7%) of patients had CD4 count between 300 and 500 cell/mm<sup>3</sup>. 26.7% patient had above 500 cell/mm<sup>3</sup> and 15% had CD4 count below 200 cell/mm<sup>3</sup>. 11.7% of the sample had below 100 cell/mm<sup>3</sup>.

Majority (30%) of patients had duration of taking ART for 6–12 months. 26.7% of patients were taking ART for 19–24 months, 16.7% sample had taken ART for less than 6 months, 13.3% had for 31–36 months. 11.7% had for 13–18 months and 1.7% had for 25–30 months. Majority (90%) of HIV patients had no comorbid condition. 10% of patients had comorbid condition. Majority (90%) of patients had other types of comorbidity then HTN and DM, and both [8].

### **Distribution of Socio-demographic Variables**

Figure 1 shows that 31.7% belongs to 26–33 years, 26.7% belongs to 34–41 years, 20% above 50 years, 13.3% belongs to 42–49 years, and 8.3% belongs to 18–25 years.

Figure 2 shows 56.7% belongs to male, 41.7% belongs to female, and 1.7% belongs to transgender.

Figure 3 shows 80% were unmarried, 11.7% were married, and 5% were widow/widower.

Figure 4 shows 33.3% had secondary education, 31.7% had primary education, 23.3% were illiterate, and 2.8% were undergraduate and above.

Figure 5 shows that 56.7% of sample had income ₹ 10,000–20,000, 20% had income between ₹ 20,001 and 30,000, 15% were below ₹ 10,000, 6.7% had income between ₹ 30,001 and 40,000, and 1.7% had income above ₹ 40,001.

Figure 6 shows that 100% receiving NRTIs drug regimen, 0% receiving NNRTIs, PI, and integrase strand transfer inhibitors.

Figure 7 shows that 51.7% belongs to normal, 28.3% belongs to underweight, 20% belongs to overweight, and none of the patients were found obese.

Figure 8 shows that 46.7% of samples had CD4 count between 300 and 500 cell/mm<sup>3</sup>, 26.7% above 500 cell/mm<sup>3</sup>, 15% had below 200 cell/mm<sup>3</sup>, and 11.7% had below 100 cell/mm<sup>3</sup>.

Figure 9 shows that 30% of the sample had duration of taking ART for 6–12 months, 26.7% had taken for 19–24 months, 16.7% had taken for less than 6 months, 13.3% had taken for 31–36 month, 11.7% had taken for 13–18 months, and 1.7% had taken for 25–30 months.

Figure 10 shows that 90% had no comorbid condition, 10% had comorbid condition.

Figure 11 shows that 90% had other types of comorbidity, 5% had HTN, 1.7% had DM, 1.7% had both HTN and DM, and 1.7% had thyroid disorders.

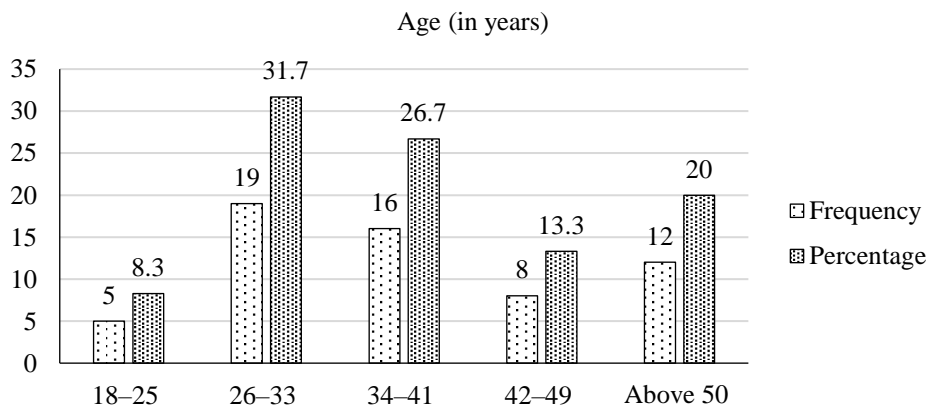
### **Section B: Frequency and Percentage Distribution of Side Effects of ART of Samples**

Table 2 indicates that a significant portion, 78.3%, experienced symptoms related to fatigue or a lack of energy. Conversely, 21.7% of patients reported no such symptoms of fatigue or loss of energy. The majority of 71.7% had symptoms of fever, chills, and sweat, and 28.3% had no symptoms of fever, chills, or sweat. The majority (85% of patients had no symptoms of feeling dizzy or lightheaded. 15% had symptoms of feeling dizzy or lightheaded. The majority (63.3% of patients had no symptoms of pain, numbness, or tingling in their hands or feet, but 36.7% had symptoms of pain, numbness, or

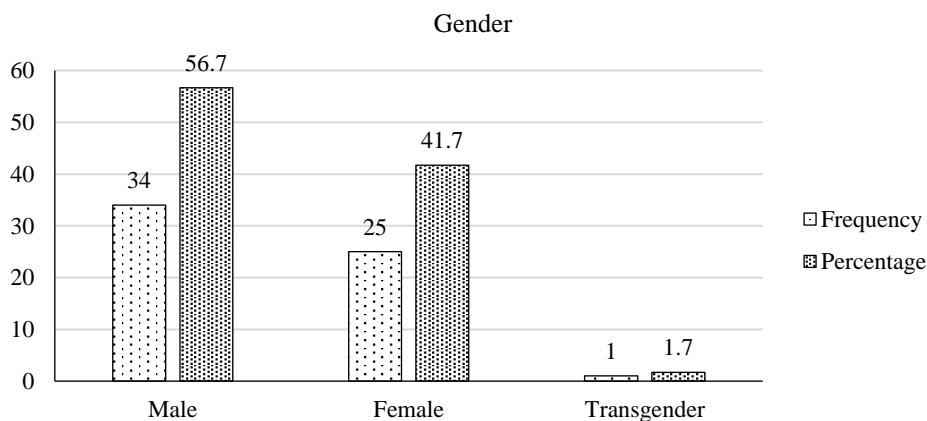
tingling in their hands or feet. The majority, 93.3%, had no symptoms of trouble remembering or amnesia, and 6.7% had symptoms of trouble remembering or amnesia.

The majority (71.7%) of samples had no symptoms of nausea or stomach upset, but 28.3% of samples had symptoms of nausea or stomach upset. Majority (75%) of patients had no symptoms of vomiting, but 25% had symptoms of vomiting. 75% of patients had no symptoms of diarrhoea or loose bowel movements. 25% of patients had symptoms of diarrhoea or loose bowel movements. 71.7% had no symptoms of feeling sad, down, or depressed, but 28.3% had symptoms of feeling sad, down, or depressed. Majority (86.7%) had no symptoms of feeling nervous or anxious. 13.3% had symptoms of feeling nervous or anxious. 80% had no symptoms of difficulty with sleep insomnia, but 20% were found to have symptoms of difficulty with sleep insomnia. 85% had no symptoms of hair loss, changes, or alopecia, but 15% had symptoms of hair loss, changes, or alopecia. 88.3% had no symptoms of change in or loss of sense of taste or ageusia. 11.7% had symptoms of change in/loss of sense of taste/Ageusia.

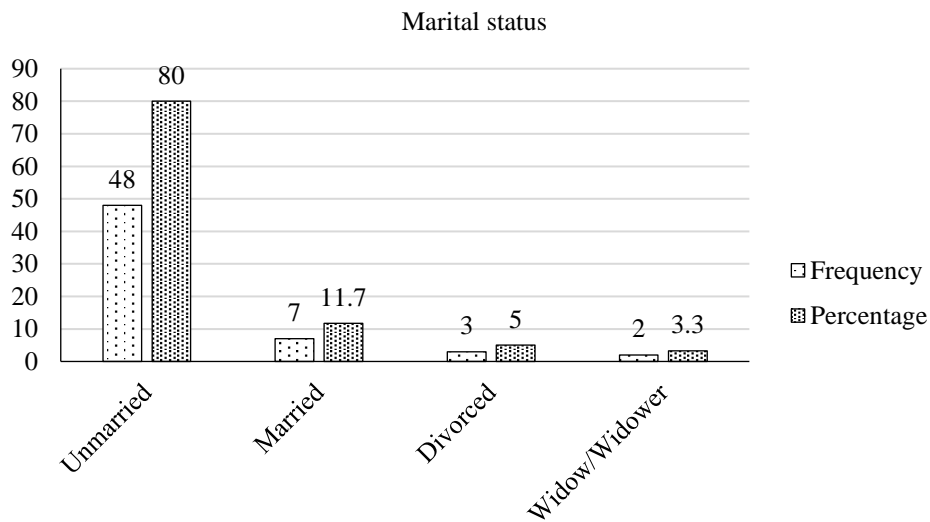
The majority (68.3%) had no symptoms of skin problems (rash, dryness, or itching) and 31.7% had symptoms of skin problems (rash, dryness, itching). 75% had no symptoms of cough or dyspnea. 25% had symptoms of coughing or dyspnea. 55% had no symptoms of headaches. 45% had symptoms of headaches. 46.7% had no symptoms of loss of appetite or anorexia. 53.3% had symptoms of loss of appetite or anorexia. 83.3% had no symptoms of bloating gas in the stomach or indigestion, 16.7% had symptoms of bloating gas in the stomach or indigestion. 98.3% have no symptoms of vivid dreams or narcolepsy. 1.7% had symptoms of vivid dreams or narcolepsy. 100% had no symptoms of seizures [9, 10].



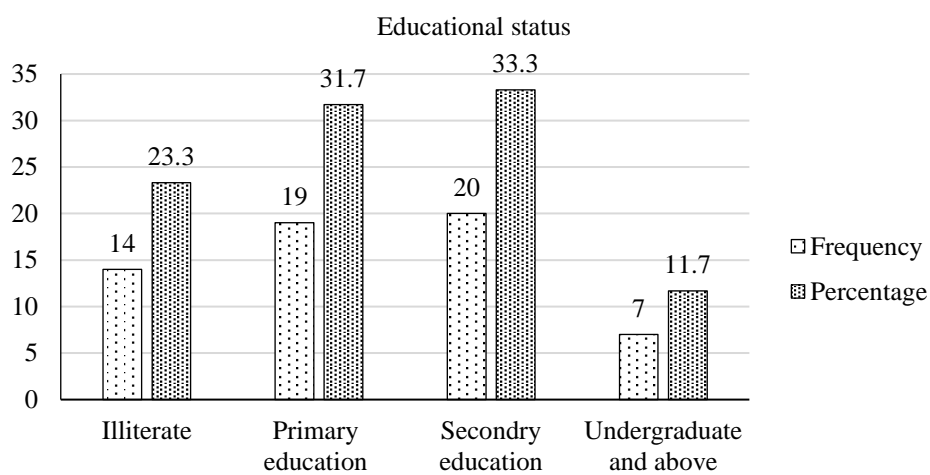
**Figure 1.** Distribution of subjects according to age.



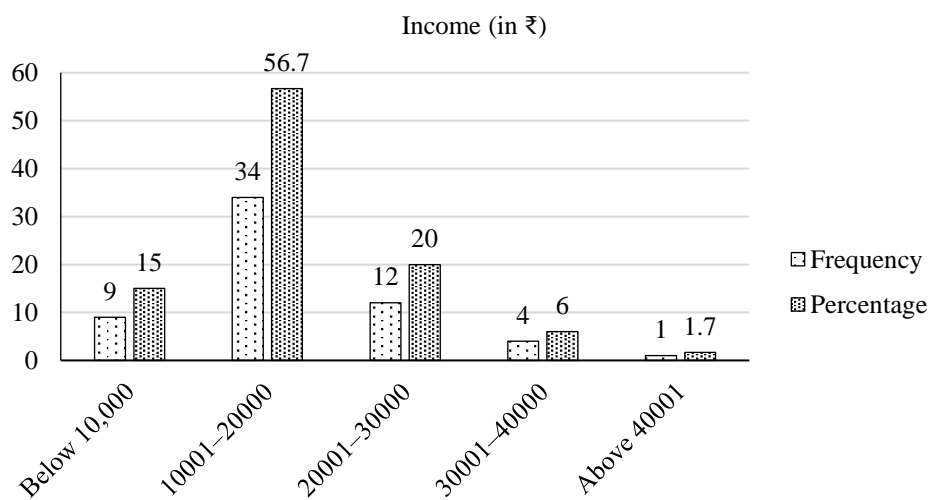
**Figure 2.** Distribution of subjects according to gender.



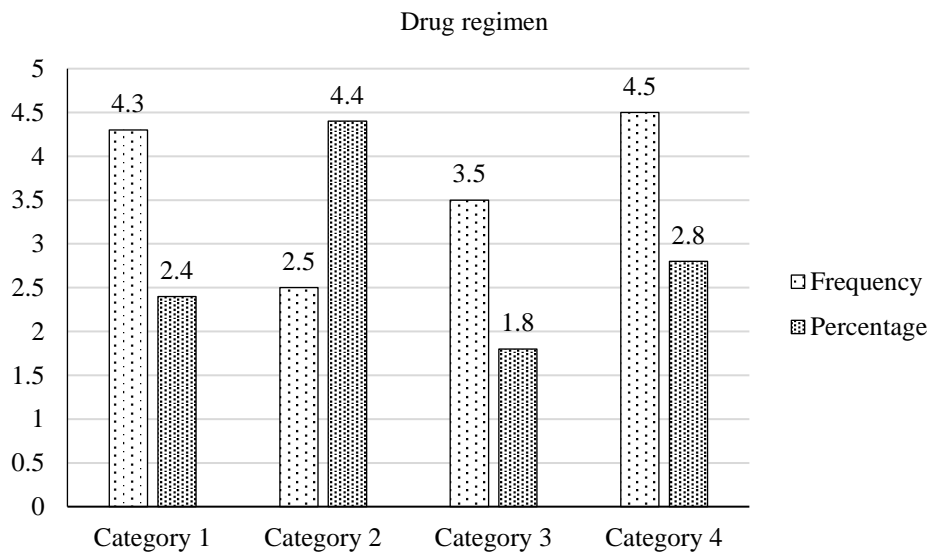
**Figure 3.** Distribution of subjects according to marital status.



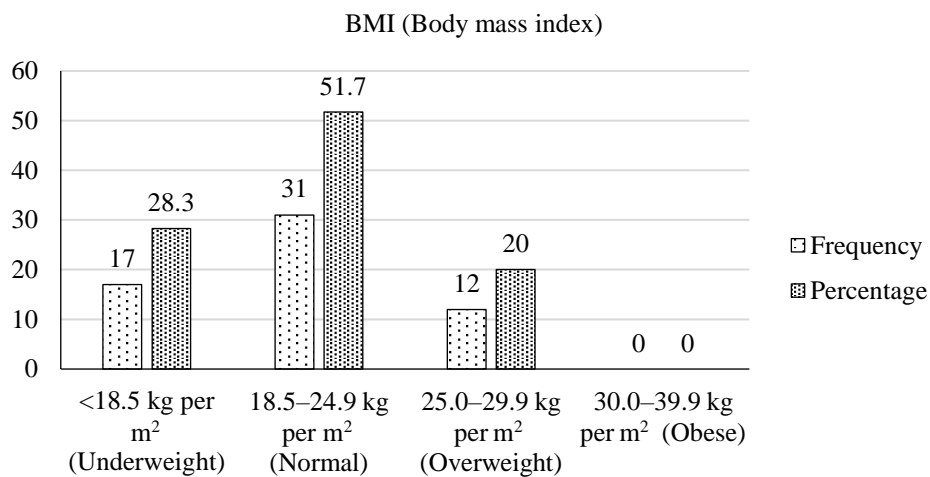
**Figure 4.** Distribution of subjects according to educational status.



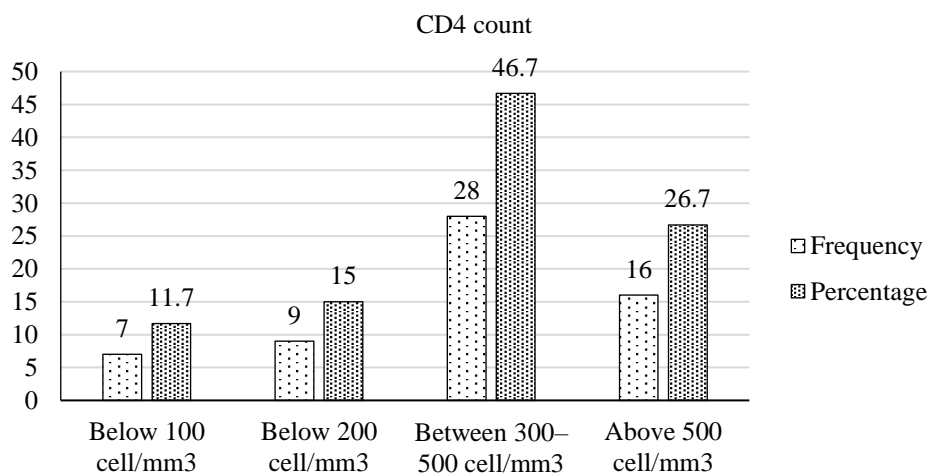
**Figure 5.** Distribution of subjects according to income.



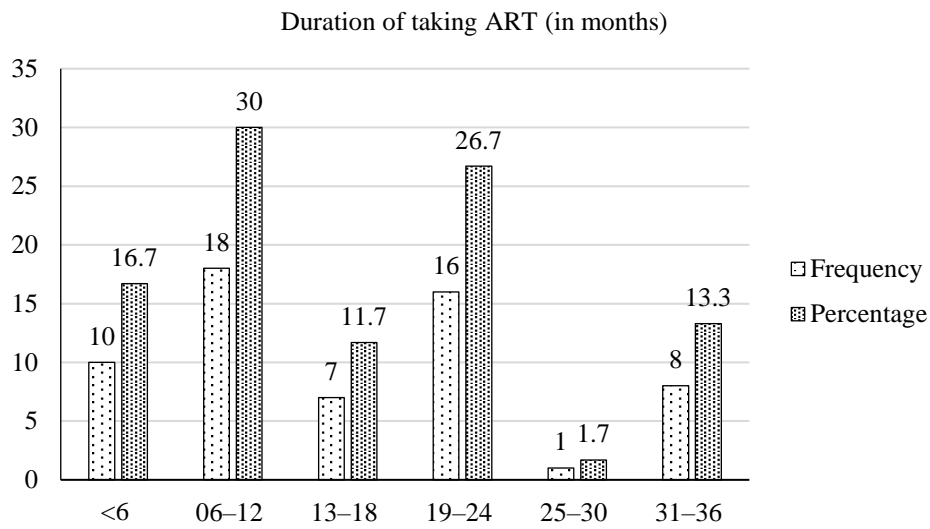
**Figure 6.** Distribution of subjects according to drug regimen.



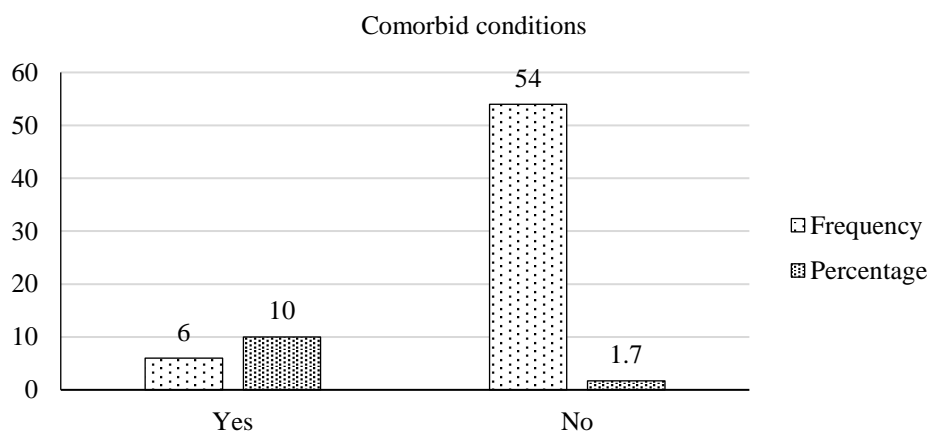
**Figure 7.** Distribution of subjects according to BMI.



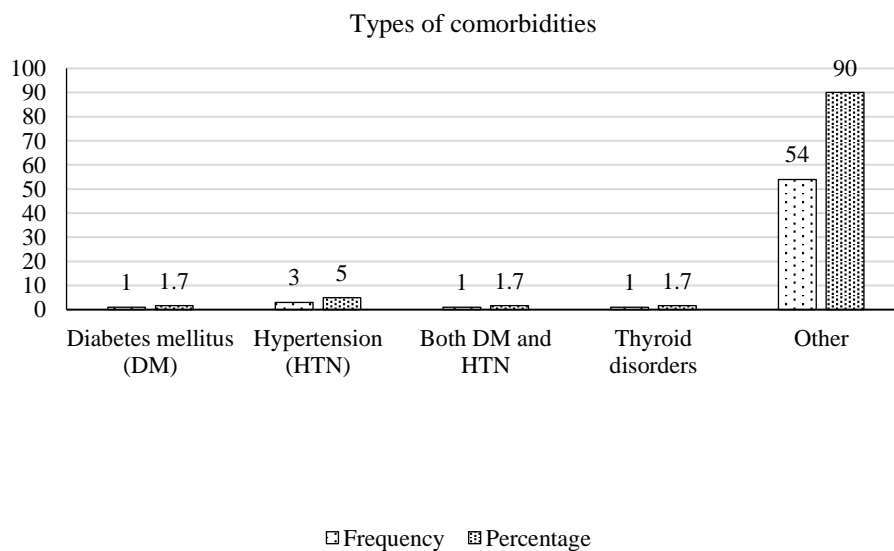
**Figure 8.** Distribution of subjects according to CD4 count.



**Figure 9.** Distribution of subjects according to duration of ART.



**Figure 10.** Distribution of subjects according to comorbid conditions.



**Figure 11.** Distribution of subjects according to type of comorbidities.



**Table 2.** The frequency and percentage distribution of side effects of ART of the samples.

S.N.	Side effect of ART	Category	Frequency (F)	Percentage (%)
1.	Fatigue/loss of energy	0	13	21.7
		1	47	78.3
2.	Fever, chills, sweat	0	17	28.3
		1	43	71.7
3.	Feeling dizzy/lightheaded	0	51	85.0
		1	09	15.0
4.	Pain, numbness, tingling in hand and feet	0	38	63.3
		1	22	36.7
5.	Trouble remembering Amnesia	0	56	93.3
		1	04	6.7
6.	Nausea/stomach upset	0	43	71.7
		1	17	28.3
7.	Vomiting	0	45	75.0
		1	15	25.0
8.	Diarrhea loose bowel movements	0	45	75.0
		1	15	25.0
9.	Feeling sad/down/depressed	0	43	71.7
		1	17	28.3
10.	Feeling nervous/anxious	0	52	86.7
		1	08	13.3
11.	Difficulty in sleep insomnia	0	48	80.0
		1	12	20.0
12.	Hair loss/changes/alopecia	0	51	85.0
		1	09	15.0
13.	Change in/loss of sense of taste/ageusia	0	53	88.3
		1	07	11.7
14.	Skin problems (rash, dryness, itching)	0	41	68.3
		1	19	31.7
15.	Cough/dyspnoea	0	45	75.0
		1	15	25.0
16.	Headache	0	33	55.0
		1	27	45.0
17.	Loss of appetite/anorexia	0	28	46.7
		1	32	53.3
18.	Bloating gas in stomach/indigestion	0	50	83.3
		1	10	16.7
19.	Vivid dreams/narcolepsy	0	59	98.3
		1	01	1.7
20.	Seizures	0	60	100.0
		1	00	00

## DISCUSSION AND CONCLUSION

The findings reveal that most patients (19, 31.7%) were in the age group of 26–33 years of age. The majority, 56.7%, were male, 47.7% were female, and only 1.7% were transgender. Most of the patients were unmarried; that was 80%. The majority (33.3% of patients) had secondary education. 31.7% of patients had primary education, and 23.3% were found illiterate.

The majority (56.7%) had an income of ₹ 10,001–20,000; the 20% sample had an income between ₹ 20,001 and 30,000; and 1.7% had an income above ₹ 40,001. The majority of patients, 100%, were receiving the NRTI drug regimen.

BMI status of patients: the majority (51.7%) had a normal BMI, and none of the patients were obese. The majority (46.7%) of patients had a CD4 count between 300 and 500 cells/mm<sup>3</sup>. 11.7% of the sample was below 100 cells/mm<sup>3</sup>.

The majority of patients (30%) had been taking ART for 6–12 months. The majority of HIV patients had no comorbid conditions. 10% of patients had comorbid conditions. The result shows that the majority, 78.3%, had symptoms of fatigue and loss of energy. The majority (71.7%) had symptoms of fever, chills, and sweat. The majority (85% of patients) had no symptoms of feeling dizzy or lightheaded. 15% had symptoms of feeling dizzy or lightheaded. The majority (63.3% of patients) had no symptoms of pain, numbness, or tingling in their hands or feet, but 36.7% had symptoms of pain, numbness, or tingling in their hands or feet. The majority, 93.3%, had no symptoms of trouble remembering or amnesia, and 6.7% had symptoms of trouble remembering or amnesia.

A cross-sectional analysis was carried out at the ART center in Aligarh, aiming to evaluate the adverse effects of ART among individuals diagnosed with HIV/AIDS. Utilizing a pre-designed questionnaire, 434 individuals were surveyed. Findings indicated that at the moment of the survey, 18.7% (81/434) of the participants were experiencing side effects, whereas over their lifetime since commencing ART, the prevalence rose to 91.7% (398/434). The most common side effect reported was dizziness, affecting 65.4% of the people living with HIV/AIDS. Additionally, abdominal pain and nausea/vomiting were experienced by 28.4% and 27.2% of the participants, respectively.

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