

# People Living with Human Immunodeficiency Virus in Hadhramout: Clinical Presentation and Outcomes

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## ABSTRACT

**Objective:** The objective of the study was to determine the clinical features and outcome of patients living with human immunodeficiency virus (HIV) in Hadhramout and nearby governorates. **Materials and Methods:** This descriptive study was conducted in the antiretroviral therapy (ART) site at Ibn-Sina General Hospital, Mukalla, Hadhramout governorate. All 145 patients were enrolled in HIV treatment and care program from December 2008 to the end of December 2016 with confirmed HIV test. Data included all personal data, clinical staging, drugs taken, and outcomes. Patients were grouped according to the decades to five groups,  $\leq 15$  years, 16–30 years, 31–50 years, 51–70 years, and  $>70$  years. Cases classify according to the antiretroviral drugs to ART group and Pre-ART group. The relevant data parameters were analyzed using SPSS statistical software version 21 and Excel 10. **Results:** A total of 145 cases, most adults (97.9%), males and females were 104 (71.7%) and 41 (28.3%), respectively. Mean age was 36.46 years and 30–50 years the most affected age group (55.2%). Clinical Stages 3 and 4 were the common presentation in 73.8%, and most cases were from Mukalla city. Of the total cases, 74.5% were on ART 53.1 of them improved, pulmonary tuberculosis was found in 4 cases, and death cases were (18.5%), mostly due to late presentation and non-adherence, and mostly occurred in early 6 months of starting the ART. 37 patients were in a pre-treatment group (21.6%), where the mortality rate is 35.1%, mainly due to loss of follow-up. **Conclusions:** Most cases were adult males, young age and have had late presentation, where mortality is higher in the pre-treatment group due to loss of follow-up and in early 6 months of treatment.

**Key words:** Antiretroviral therapy, deaths, Hadhramout, lost to follow-up, Pre-antiretroviral therapy

## INTRODUCTION

The acquired immunodeficiency syndrome (AIDS) was first recognized in 1981, although the earliest documented case has been traced to a blood sample from 1959. It is caused by the human immunodeficiency virus (HIV-1), which is a member of the Retroviridae family that replicates in CD4 positive cells, which has evolved a number of mechanisms to elude immune control and has thereby prevented effective control of the epidemic.<sup>[1]</sup> HIV-2 causes a similar illness to HIV-1 but is less aggressive and restricted mainly to Western Africa.<sup>[1]</sup>

AIDS remains the second leading cause of disease burden worldwide although downward trends in prevalence are

occurring in several countries, partly as a result of effective prevention measures and partly due to scaling up of antiretroviral access.<sup>[1]</sup> The center for disease control reported a significant increase in morbidity and mortality between 2001 and 2012 in the Middle East and North Africa region.<sup>[2]</sup> Highly active antiretroviral therapy (ART) with three or more drugs has improved life expectancy to near normal in the majority of patients with an 80% reduction of mortality.<sup>[1]</sup>

Early identification of infected persons helps in reducing transmission, preventing complications, and modifying risk behavior.<sup>[3]</sup> Early diagnosis is important for appropriate and effective ART. The number of CD4+T lymphocytes at the time of confirming HIV-1 infection (CD4 - HIV) has

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been suggested to provide useful staging information.<sup>[3]</sup> The stage of disease at diagnosis is influenced by patients' willingness to be tested, their knowledge of the disease, and the effectiveness of the health-care system in finding and contact tracing.<sup>[3]</sup>

Yemen is one of the countries with low prevalence of HIV (0.2%) in the general population, according to 2011 HIV size estimates by national AIDS program (NAP).<sup>[4]</sup> In 2009, the estimated number of people living with HIV (PLHIV) was 23,000, and the cumulative number of HIV reported cases (since the first case in 1987) to 2009 is 2,882.<sup>[5]</sup> There are no available data about the cumulative number of HIV related deaths and orphans. The main mode of HIV transmission was unprotected heterosexual contact 62%, homosexual 7%, and through mother to child transmission 5% and about 24% of the reported cases did not have a mode of transmission reported.<sup>[5]</sup>

In Yemen, there are five sites providing services for PLHIV called ART sites, one of them was at Ibn-Sina general hospital in Al-Mukalla city, capital of Hadhramout governorate, which cover the four governorates of Hadhramout sector (Hadhramout, Shabwa, Al-Mahra, and Socotra). This site is providing voluntary counseling and testing, post-exposure prophylaxis, prophylaxis for opportunistic infections and ART.

This study will highlight the general features, adherence, and outcome for PLHIV in ART site at Ibn-Sina hospital.

## MATERIALS AND METHODS

This descriptive study was conducted at ART site in Ibn-Sina General Hospital for all PLHIV who are enrolled in HIV treatment and care since the start of the program from December 2008 to the end of December 2016.

A total of 145 cases registered including those who were transferred from other sites in the republic. A data collected from electronic records (Tier.net) including age, gender, residency, month of diagnosis, clinical stages on presentation, date of starting ART, and laboratory data. The age further subdivided based on decades into five groups; ≤15 years, 16–30 years, 31–50 years, 51–70 years, and >70 years.

Clinical stages according to the WHO staging<sup>[6]</sup> was used in all cases [Table 1]. All PLHIV were defined as: (i) Pre-ART group included cases on prophylaxis treatment and not started treatment with ART, and (ii) ART group including cases treated with ART drugs and prophylaxis treatment. Treatment with ART was based on the WHO clinical staging and National AIDS program (NAP) policy which includes seven requirements mentioned in Table 2.<sup>[6]</sup>

Lost to follow-up (LTFU) which defined as loss of follow-up for more than 6 months in pre-ART group and not attended three scheduled visits to the site in case of ART group. Dead cases were documented and the duration from diagnosis and started ART and death or loss to follow-up were registered.

**Table 1: The WHO clinical staging of HIV/AIDS cases**

Stage 1 Asymptomatic	Stage 2 Mild disease	Stage 3 Moderate disease	Stage 4 Severe disease (AIDS)
No symptoms	Wt. loss>5–10%	Wt. loss>10%	HIV wasting syndrome
	Sore or cracks around the lip	Oral thrush	Esophageal thrush
Or only persistent generalized lymphadenopathy	Seborrhea	Oral hairy	More than 1 month: Herpes simplex ulceration
	Prurigo	Leukoplakia	Lymphoma
	Herpes zoster	More than 1 month	Kaposi sarcoma
	Recurrent URTI	• Diarrhea	Invasive cervicalcancer
	Recurrent mouth ulcer	• Unexplained fever	Pneumocystic pneumonia
		• Severe bacterial infection	Extrapulmonary TB
		• Pneumonia	Cryptococcal meningitis
		• Muscle infection	Toxoplasma brain abscess
		Pulmonary TB	Visceral leishmaniasis
		TB lymphadenopathy	HIV encephalopathy
		Acute necrotizing ulcerative gingivitis	

HIV: Human immunodeficiency virus, AIDS: Acquired immunodeficiency syndrome

**Table 2: NAP requirements to initiate ART therapy at the ART**

1. HIV infection confirmed by written documentation.
2. Medical eligibility
  - Any clinical Stage 3 or Stage 4 disease, or where CD4 is available, any clinical stage and CD4<350/mm<sup>3</sup>
3. Patient fits criteria to be started on ART at the first-level facility.
  1. Does the patient have a condition requiring referral
    - Severe illness
    - Any condition in Stage 4 with 2 exceptions: Non-severe esophageal thrush or chronic herpes simplex ulcerations?
    - Persistent fever
  2. Is the patient currently on TB treatment?
  3. Is there anemia?
  4. Is there a jaundice or known liver problem?
  5. Chronic illness such as diabetes mellitus, heart or kidney disease?
  6. Injecting drug user, now or past?
  7. Prior ARV use except nevirapine for PMTCT?
4. Any opportunistic infection has been treated/stabilized
5. Patient is ready for ARV therapy
  - Patient understands aRV therapy, possible side effects, limitations, adherence schedule, etc., and wants treatment
  - Patient ready for treatment adherence
  - Patient actively involved in own care
  - Family and/or social support available
  - Treatment supporter if possible
  - No recent non-adherence to care or medication. several visits are required before treatment initiation
  - Barriers to adherence have been addressed such as highly unstable social situation, heavy alcohol dependence or serious psychiatric illness.
6. Supportive clinical team prepared for chronic care
7. Reliable drug supply

NAP: National AIDS control program, HIV: Human immunodeficiency virus, ART: Antiretroviral therapy, MTCT: Mother to child transmission, AIDS: Acquired immunodeficiency syndrome

Laboratory confirmation of HIV infection was based on detection of antibodies by ELISA, and two tested were done, one in hospital lab and another in a central lab. CD4 was not done for most of the cases due to unavailability in our hospital.

Data were analyzed using Microsoft Excel 2010 and SPSS statistical software version 21. The frequencies of different categorical variables were calculated. The median and range were calculated for continuous variables. Patient characteristics were compared using the Chi-square test or Fisher's exact test for categorical variables.

## RESULTS

### Overview of the Problem

A total number of 145 PLHIV registered in the ART site during an 8 years period. Yearly diagnosed cases by gender are shown in Table 3. The cases increased gradually each year and the past 3 years (2014–2016) showed the highest number

of cases had been registered. 33 death cases were reported resulting in a mortality rate of approximately (22.8%) among all documented cases.

### Demographics Features

From all cases reported; 104 (71.7%) were male and 41 (28.3%) were females with male to female ratio of 2.5:1. The mean age when enrolled in ART site was 36.46 years, and the median was 35 years (range 3–83 years). Women were similar to men at diagnosis, mean of 36.12 (standard deviation [SD] ± 15.37) years versus 36.6 (SD ± 11.97) years for men, *P* = 4.88. Most of the cases were adults (97.9%), the most affected age group was from 30 to 50 years (55.2%), and their only 3 cases (2.2%) of children equal or below 15 years of age [Table 4]. One death case was reported in children <15 years of age.

Patients belonging to Hadhramout governorate outnumbered and were 116 (80.0%) followed by 15 patients (10.3%) belonging to

**Table 3: Yearly HIV cases diagnosis by gender**

Year of diagnosis	Male	Female	Total (%)
Before 2009	11	8	19 (22.8)
2009	10	4	14 (9.7)
2010	13	3	16 (11)
2011	14	5	19 (13.1)
2012	3	1	4 (2.8)
2013	9	2	11 (7.6)
2014	15	6	21 (14.5)
2015	12	7	19 (13.1)
2016	17	5	22 (15.2)
Total	104	41	145 (100)

HIV: Human immunodeficiency virus

**Table 4: Distribution of PLHIV according age groups and sex**

Age group	Gender		Total n (%)
	F	M	
≤ 15 years	1	2	3 (2.2)
16–30 years	9	22	31 (21.4)
31–50 years	24	56	80 (55.2)
51–70 years	6	23	29 (20)
>70 years	1	1	2 (1.4)
Total	41	104	145 (100)

PLHIV: People living with human immunodeficiency virus

**Table 5: Distribution of PLHIV in different governorates**

Governorate	Number of patients (%)
Hadhramout	116 (80)
Shabwa	15 (10.3)
Al-Mahra	9 (6.2)
Socotra	2 (1.4)
Others	3 (2.1)
Total	145 (100)

PLHIV: People living with human immunodeficiency virus

Shabwa governorate and 9 patients (6.2%) belong to Al-Mahra governorate. Representatives from other governorates were minimal (3.5%) [Table 5]. Mukalla city, capital of Hadhramout had the largest share of cases compared to other areas of the governorate ( $n = 64$ , 54.7%). Distribution of cases in common affected districts in Hadramout governorate [Figure 1].

### Clinical Features

The most common presentation at the time of diagnosis was Stage 3 ( $n = 87.60\%$ ) followed by Stages 2 and 4 equally represented ( $n = 20$ , 13.8%) and Stage 1 ( $n = 18$ ,

12.4) [Table 6]. The CD4 was done in 15 cases in other governorates, and it was  $<350$  in 13 cases. 4 cases had pulmonary tuberculosis comorbidity. 2 cases were pregnant on diagnosis.

### Classification According to Treatment

Pre-ART group: PLHIV not taken ART called pre-ART group and it was 37 cases (21.6% of all cases), 29 males (78.4%) and 8 females (21.6%). Most of this pre-ART group were present in clinical stage 1 and 2 (64.9%) [Table 6], and their ages at presentation were between 30–50 years old.

ART group: PLHIV who undergone ART were placed in ART group. 108 cases were included in this group approximately (74.5%) of all cases. 75 cases were males (69.4%) and 33 (30.6%) were females. Two of female cases were pregnant. 4 cases had pulmonary tuberculosis. 50% of cases in the ART group belong to the 30–50 years age group. Clinical staging of this group at presentation in order of frequency; Stage 3 ( $n = 78$ , 72.2%), Stage 4 (16, 14.8%), Stage 2 ( $n = 13$ , 12%), and final Stage 1 ( $n = 1$ , 0.9%) [Table 6]. Most cases started on zidovudine, lamivudine, and nevirapine regimen (46.3%) and tenofovir, emtricitabine, and efavirenz (38.9%).

### Outcome

Most cases on ART improved symptomatically, with 77, 53.1% switching to Stage 1 and 6, 4.6% to Stage 2, and 5, 3.4% remaining on Stage 3 and no cases in Stage 4.

For all enrolled cases in the program (pre-ART and ART groups), 25 cases were LTFU and this represented 17.2% of all cases (16 cases were from pre-ART groups and 9 cases from ART group), while 33 (22.8%) were died.

### Deaths Cases

From all death cases, 26 cases (78.8%) males and 7 cases females (21.2%) with male to female ratio 3.7:1. Most of the death cases (75.8%) were on Stage 3 and 4. The duration from diagnosis to death was ranging from days to 89 months, with mean 22.25 (SD + 25.335). There is a significant correlation between duration of disease and deaths ( $P = 0.00$ ) indicating most cases died in earlier 2 years of disease.

Pre-ART group deaths were 13 cases, 10 (76.9%) males and 3 (23.1%) females, with male to female ratio 3.3:1. Most cases in 31–50 years age group (76.9%) [Figure 2] with a mean ( $44 \pm SD 7.439$  years). Most death cases were either loss of follow-up (84.6%) or refuse treatment. Duration from diagnosis to death range from 0 to 62 months with a mean ( $15.23 \pm SD 18.426$ ); with most cases died in the first 2 years from diagnosis (84.6%) with correlation from time of diagnosis and deaths ( $P = 0.000$ ).

Death from ART group outnumbered 20 cases (18.5%), most of death cases were males ( $n = 16$ , 80%) [Table 7] with

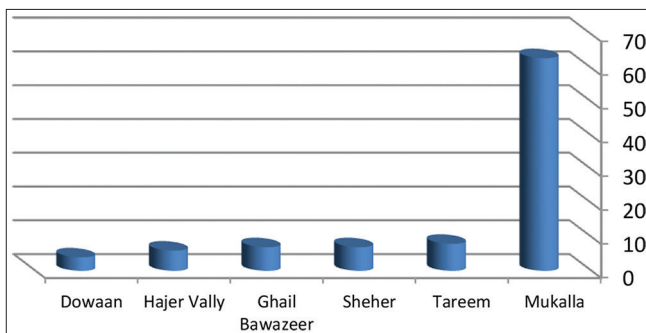
**Table 6: Stages and outcomes of PLHIV**

Data	Pre-ART			ART			Total (%)		
	%	Total	F	M	%	Total		F	M
Stage 1	45.9	17	4	13	0.9	1	1	0	18 (12.4)
Stage 2	18.9	7	2	5	12	13	7	6	20 (13.8)
Stage 3	24.3	9	1	8	72.2	78	22	56	87 (60)
Stage 4	10.8	4	1	3	14.8	16	3	13	20 (13.8)
Loss of follow up	43.2	16	5	11	8.3	9	1	8	25 (17.2)
Deaths	35.1	13	3	10	18.5	20	4	16	33 (22.8)

PLHIV: People living with human immunodeficiency virus, ART: Antiretroviral therapy

**Table 7: Comparison of the clinical and demographic criteria of early versus late deaths**

Data	Early deaths (n=15)	Late deaths (n=5)	P value
Sex	M (13), F (2)	M (4), F (1)	0.75
Age (years)	47 (12–85)	50 (35–56)	0.57
Clinical stages			0.422
Stage 1	0	0	
Stage 2	2 (13.3)	0	
Stage 3	9 (60)	3 (60)	
Stage 4	4 (26.7)	2 (40)	
Duration of disease (months)	17.07 (1–63)	64.50 (41–89)	0.003



**Figure 1:** Distribution of people living with human immunodeficiency virus in common regions in Hadhramout governorate

male to female ratio 4:1. Most cases in age range between 31 and 70 years (95%) [Figure 2] with mean (47.45 ± SD 15.500 years). Factors predisposing to death (based on clinical follow-up of ART team) vary from late stages of starting ART (n = 9.47%), non-adherence (n = 9.37%) which may relate to recurrent LTFU (6 cases), severe depression (3cases), and AID-unrelated causes such as trauma, postsurgical, and sudden death (n = 3.16%) [Figure 3].

Duration from starting ART to dead range from 1 month to 89 months with mean (27.05 ± SD 28.621); and most cases died within <6 months from starting treatment (n = 16.80%) indicating a correlation between adherence to therapy for prolonged period and good response (P = 0.003) [Table 7].

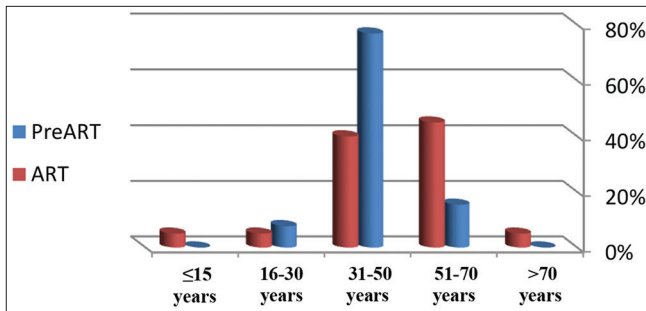
## DISCUSSION

The prevalence of HIV infection among people in the Middle East is relatively lower than other developing countries. However, Yemen, Saudi Arabia, Lebanon, and Libya the incidents of HIV infection were <10%.<sup>[7]</sup>

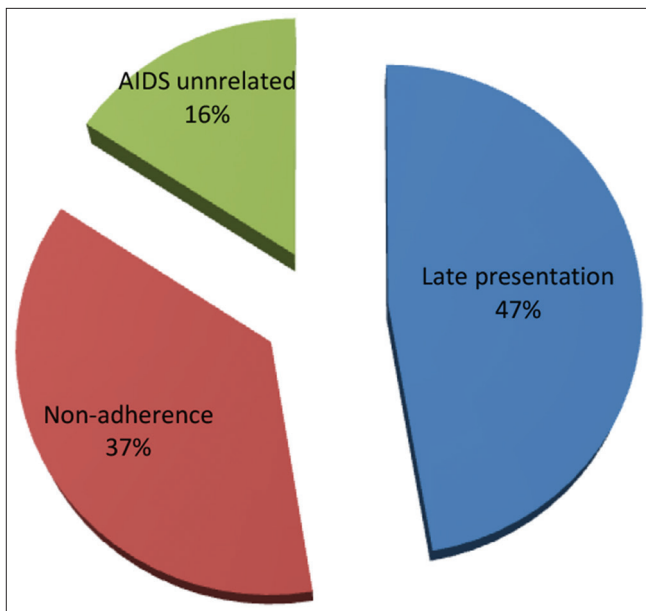
This is a retrospective study of HIV patients at an ART site in Ibn-Sina Hospital, Hadhramout Yemen, over the past 8 years. This site is being a main referral center for HIV infection in Hadhramout district which includes four governorates.

In our study, there were annually increases in the diagnosis of HIV cases which enrolled in ART services and this also seen in Saudi Arabia which is one of the low prevalence countries.<sup>[8]</sup> The majority of cases were males (71.7%) with male:female ratio 2.5:1 and this similar to other studies in Saudi Arabia<sup>[3,9]</sup> and higher than other study among Saudi patient where the ratio (4.4:1).<sup>[8]</sup> The mean and median age of cases was 36.46 and 35 years, which somewhat higher than other studies were done in Saudi Arabia,<sup>[3,10]</sup> and similar to one Austrian study<sup>[11]</sup> with no differences between male and females mean and median ages differ than what seen in Saudi Arabia<sup>[3,10]</sup> where female younger than males. Most cases were adult 97.9% higher than that seen in one Saudi study where adult percent was (80%) in Saudi cases.<sup>[8]</sup>





**Figure 2:** Death cases of antiretroviral therapy (ART) and pre-ART groups according to the age groups



**Figure 3:** Factors predispose to antiretroviral therapy group deaths

Most of our cases were from Hadhramout governorate and its main towns, especially Mukalla city and this perhaps may due to the existence of HIV treatment and care services in Mukalla city - Hadhramout governorate. On the other hand, AIDS-related stigma plays a major role in the access of a patient to services in whole Yemen<sup>[4]</sup>, especially in rural areas. Hadhramout population has somewhat higher education level in comparing to other governorates, and the population of Al-Mahra governorate population mostly treated in neighbor countries especially Oman.

This study showed late stages were the presentation of most cases who enrolled in the ART program (approximately 73.8%) which considered AIDS-defining diseases. This is similar to one study done in Oman<sup>[12]</sup> and differs from studies in Saudi Arabia where the majority was asymptomatic at diagnosis.<sup>[13-15]</sup>

The tuberculosis - HIV coinfection was a well-known entity in different literatures,<sup>[16-18]</sup> and tuberculosis cases were

increases in an era of HIV/AIDS. In our study, there are 4 cases (2.76%) proved has pulmonary tuberculosis out of all cases enrolled in the program. This is in contrast to studies done in Jeddah in Saudi Arabia<sup>[19]</sup> and China<sup>[20]</sup> where the majority of cases has tuberculosis.

Most of PLHIV were under antiretroviral drugs (ART group) (74.6%), while the remaining cases are still in pre-ART group for three different reasons, first: They were in clinical Stages 1 and 2 which were not eligible to start treatment, according to the previous WHO recommendation,<sup>[6]</sup> second: Loss of follow-up which constitute about 43.2% and this possibly due to fear of stigma and discrimination, cost of travelling to site for cases from distant places, low education level and seeking a traditional treatment elsewhere, and third: Feeling healthy and refuse to take the ART. This is also seen in different studies in Asia and Africa.<sup>[21-25]</sup>

From this pre-ART group most cases where either died (35.1%) or LTFU (43.2%) which constitute (78.3%) of all cases, and the remaining cases (8 cases, 21.7%) still not started ART drugs, and for that reasons the outcome was very poor as the studies reported the benefits of early therapy and bad effect of LTFU on outcomes.<sup>[23,26,27]</sup>

The ART group which considered the main group in the site (74.5), the late presentation (Stages 3 and 4) was common in approximately 87%, the most common affected age group was 30–50 years and male were predominant. The drug regimens used were zidovudine, lamivudine, and nevirapine regimen in (46.3%) and tenofovir, emtricitabine, and efavirenzin (38.9%) which recommended by the WHO and NAP and used in different countries<sup>[14]</sup> and improved efficacy in one study done in Sana’a-Yemen.<sup>[28]</sup>

There is a favorable clinical outcome in the ART group, with improvement in about 57.7% of cases, and these were mentioned in literature,<sup>[29,30]</sup> and a major obstacle in this group was the LTFU which constitute about 8.3% of total cases. The causes are the same as mentioned earlier in the pre-ART group, and this problem was seen in different studies, especially in African countries.<sup>[25,27,31]</sup>

Death cases were about 22.8%, and this was similar to a neighboring country (Saudi Arabia).<sup>[10]</sup> Most of the death cases in both groups were found in early 2 years after diagnosis indicating a strong correlation between risk of death and time after diagnosis, and late presentation as one of the major causes of death.<sup>[32]</sup>

The death cases in pre-ART group about 35.8% of all cases in the group, most of them were male in the age group 51–70 years, the majority of them died during the period of LTFU (84.6%), and the others due to late presentation.

Mortality in ART group was about 18.5% of total cases, and most of the cases were male, and this rate is very high in the context of a patient taking ART drugs and higher than African countries.<sup>[33]</sup> This attributed to different factors leading to deaths and the most important causes, according to the clinical judgments were: (a) Late presentation of a large group of patient and this is documented problem leading to death,<sup>[32]</sup> (b) non-adherence to treatment, and this may be due to recurrent LTFU due to effect of depression, stigma, and discrimination, poverty and difficult to reach to the site, beliefs about the necessity of ART, low educational level, and defect in counseling before starting treatment. All these factors are found as barriers to adherence in multiple studies done elsewhere in the world.<sup>[34-42]</sup>

In our study, we found that the majority of death cases in ART group was dying in the first 6 months of starting ART drugs ( $P = 0.003$ ), and the outcome was improved with better adherence and close follow-up, thereafter, indicating longer time spent receiving ART associated with improved survival and deaths mostly from non-AIDs related causes; this finding is also documented in different studies that outcome is sometimes unpredicted in the early period of treatment from 3 months to 3 years mostly in low-income countries in which our country is one of them.<sup>[43-48]</sup>

## CONCLUSIONS

Our study demonstrated that most PLHIV were younger age, mostly males, presented mostly in late stages, with a significant proportion of them LTFU and death. Death cases were improved with prolonged taking ART and with early starting it in asymptomatic patients, and higher efficacy of first-line triple therapy in a higher proportion of cases.

The limitations of our study were mostly unavailability of immunological and virological measures in the form of CD4 and polymerase chain reaction studies for evaluation of cases, staging, and follow their managements accurately.

## ACKNOWLEDGMENTS

We would like to acknowledge ART staff, especially Dr. Nasreen Daakeek for her assistance with the correction of data, and Mr. Abdulla Bazarah and Mr. Fahed Bajar fan who supported and facilitating our job.

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**How to cite this article:** Daakeek AM, Bahashwan AA. People Living with Human Immunodeficiency Virus in Hadhramout: Clinical Presentation and Outcomes. *J Pathol Infect Dis* 2019;2(1):1-9.