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ORIGINAL RESEARCH

Survival Analysis of Antiretroviral Treatment for PLWH in Sichuan Province, China, 2003-2022: A Large Retrospective Cohort Study

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Background: Sichuan Province was severely affected by the HIV, and there was a scarcity of data regarding the survival time and influencing factors for People Living with HIV/AIDS (PLWH) in Sichuan Province who have received Antiretroviral Therapy (ART). Therefore, it is necessary to conduct a survival analysis for PLWH receiving ART.

Methods: A retrospective cohort study was conducted on PLWH who had received ART≥6 months in Sichuan Province from January 1, 2003, to December 31, 2022. The Kaplan-Meier method was used to calculate median survival time and plot survival curves, while a Cox proportional hazards regression model was applied to analyze factors affecting survival time. Bilateral tests were performed, with P≤0.05 considered statistically significant.

Results: The cumulative survival rates at 1, 3, 5, and 10 years for the 223,386 subjects were 94.54%, 89.07%, 84.82%, and 76.44%, respectively. Multivariate analysis using the Cox regression model indicated lower mortality risks for females (HR=0.59, 95% CI: 0.54–0.65), homosexual transmission (HR=0.43, 95% CI: 0.33–0.55), and baseline BMI≥24 (HR=0.81, 95% CI: 0.72–0.90). Higher mortality risks were associated with age≥50 years at diagnosis (HR=3.21, 95% CI: 2.94–3.50), being unmarried or divorced (HR=1.23, 95% CI: 1.11–1.37), living separately (HR=1.32, 95% CI: 1.22–1.43), baseline BMI <18.5 (HR=1.27, 95% CI: 1.13–1.41), presence of single-drug resistance (HR=1.25, 95% CI: 1.15–1.36), baseline WHO stage IV (HR=1.27, 95% CI: 1.09–1.47), and a diagnosis-to-treatment interval >12 months (HR=1.27, 95% CI: 1.15–1.41). Compared to those with CD4(+) T cell count of 200–350cells/μL, 350–500cells/μL, and >500cells/μL at baseline, individuals with <200cells/μL had higher mortality risks (HR=0.73, 95% CI: 0.67–0.79; HR=0.57, 95% CI: 0.51–0.64; and HR=0.58, 95% CI: 0.51–0.66, respectively).

Conclusion: The survival rate for PLWH receiving ART in Sichuan Province was relatively high. Male gender, age over 50 at diagnosis, being unmarried, divorced, or living separately, presence of single-drug resistance, low baseline BMI, baseline CD4+ T cell <200cells/μL, baseline WHO stage IV, and a diagnosis-to-treatment interval >12 months were risk factors for the survival of PLWH.

Keywords: PLWH, antiretroviral therapy, survival analysis

Introduction

As of the end of 2022, approximately 39 million individuals were living with HIV globally, with 1.3 million new PLWH and approximately 630,000 deaths due to HIV-related illnesses occurring in the same year.[1] In China (excluding Hong Kong, Macao, and Taiwan regions), there were 1.223 million reported cases of PLWH alive at the end of 2022, with 418,000 reported deaths, in 2022, China reported 107,800 new cases of PLWH.[2] ART can enhance the quality of life for PLWH, decelerate the progression of the disease, and diminish the risk of mortality.[3] ART can effectively prevent HIV transmission.[4] China initiated free acquired immunodeficiency syndrome (AIDS) treatment in 2003. The primary AIDS treatment approaches in our country include: 1) Provision of a "baseline" national free medication; 2) Inclusion of

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some ART drugs in medical insurance; 3) Introduction of self-paid medications from international advanced treatment plans. The treatment plan is determined based on the condition of PLWH and the antiviral drugs currently available in our country. All first-line treatment plans include three types of antiviral drugs: two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTIs). If the first-line treatment plan is ineffective, physicians may switch to a second-line treatment plan after a comprehensive evaluation of the patient's condition.[5]

However, it is important to note that ART cannot eradicate HIV. Patients must take antiretroviral therapy drugs for life. Due to the pressure of drug selection, the virus is prone to drug-resistant mutations, which can lead to treatment failure. Antiretroviral treatment failure is an important factor leading to HIV/AIDS death.[6] A substantial body of research[5–7] has demonstrated that, in addition to ART, the survival time of individuals diagnosed with PLWH is associated with a range of demographic characteristics, modes of infection, and disease status at the time of diagnosis.

Sichuan Province is one of the regions most severely affected by AIDS and was also among the first provinces in China to initiate ART.[8] By 2022, the province had been engaged in ART work for a period of 20 years. It is essential to conduct a retrospective analysis of the survival status of patients who have received ART treatment, identify the factors influencing their survival time, and provide a scientific foundation for enhancing the efficacy of ART and the survival rate of PLWH.

Methods

Study Population

The study subjects were selected from PLWH who had been receiving ART for more than half a year in the comprehensive prevention and control information system for AIDS in China. Inclusion criteria: (1) Cases reported to have current residence in Sichuan Province, aged ≥18 years at diagnosis from January 1, 2003 to December 31, 2022; (2) Receiving ART for more than 6 months during the period from January 1, 2003 to December 31, 2022; (3) Disease type was "laboratory diagnosis" or "clinical diagnosis", excluding those with follow-up status of "no such person" and those with missing key information such as the start time of treatment.

Ethics Statement

All personally identifiable information about the patients in this study had been anonymized. The use of anonymous clinical/demographic and sequence data was reviewed, The study protocol was approved by the Ethics Committee of the Sichuan Center for Disease Control and Prevention (Approval No.: SCCDCIRB 2024–010). Patient informed consent was waived by the ethics committee. The study was conducted following the Helsinki Declaration of 1964.

Methods

A retrospective cohort study method was adopted. The subjects were included in the study cohort after receiving ART for 6 months between January 1, 2003, and December 31, 2022. The follow-up of the cohort ended on December 31, 2022. The outcome event of the study was death from all causes, and the censoring events included loss to follow-up, discontinuation of medication, referral, and ongoing treatment. Survival time was defined as the time from diagnosis to death from all causes or the last follow-up. Basic information and follow-up data of the subjects were collected and analyzed in the Chinese AIDS Comprehensive Prevention and Control Information System, including gender, age, height, baseline weight, marital status, baseline CD4(+) T lymphocyte count, route of infection, death, et al. Body Mass Index (BMI) was calculated as weight (kg) divided by the square of height (m). The classification criteria for baseline BMI values are as follows: underweight if BMI < 18.5, normal if 18.5–24, and overweight if ≥24. Opportunistic infections included tuberculosis, skin lesions, thrush, hairy leukoplakia, persistent diarrhea, persistent or intermittent fever, recurrent severe bacterial infections, disseminated non-tuberculous mycobacterial infections, chronic simple herpes virus infections, shingles, toxoplasmic encephalitis, Kaposi's sarcoma, brain lymphoma, or B-cell non-Hodgkin's lymphoma, etc. Baseline CD4(+) T cell count was the first CD4(+) T cell test result within the first year after diagnosis. Missing values and extreme values for height, weight, and the first CD4(+) T cell count were supplemented with median values.

Statistical Analysis

Using Excel 2016 software to establish a database, the chi-square test was adopted for rate comparison. Descriptive and statistical analyses were performed using R 4.1.3 software, employing univariate and multivariate Cox proportional hazard regression models to analyze factors influencing the mortality risk of research subjects. The Kaplan-Meier curve method was used for the proportional hazard's assumption test of qualitative variables; if there was no obvious crossing between the two curves, the PH assumption was satisfied. The steps for establishing the Cox proportional hazard regression model were as follows: (1) Perform univariate Cox regression analysis on each independent variable, where variables with $P < 0.05$ were included in the multivariate Cox regression analysis. (2) Then, variables were selected using stepwise regression, with an entry test level for independent variables set at 0.05, and a removal test level set at 0.15. Unless otherwise stated, the test level α was set at 0.05.

Results

Baseline Characteristics

As of December 31, 2022, a total of 223,386 cases of PLWH were followed up that met the criteria (Figure 1). The majority were male (71.58%), diagnosed at the age of 18–50 years old (59.05%), married or cohabiting (57.56%), heterosexually transmitted (77.18%), with baseline CD4(+) T cell count of 200–350 cells/μL (36.63%), baseline WHO clinical stage of Stage I (51.41%), and time from diagnosis to start of treatment less than 3 months (66.31%). The cohort experienced a total of 26,630 deaths (11.92%), with an all-cause mortality rate of 2.7 per 100 person-years. The proportion of deaths varied statistically across different genders, ages at diagnosis, marital status, transmission routes, baseline BMI values, baseline CD4(+) T cell counts, WHO clinical stages, and time from diagnosis to start of treatment. As the CD4(+) T cell count gradually decreased, the higher the baseline WHO clinical stage, and the longer the time from diagnosis to start of treatment, the risk of death proportion increased significantly, showing a notable trend relationship (Table 1).

Survival Situation

Among 223,386 HIV/AIDS patients, 190,449 cases (872,600.9 person-years) were under treatment, 1523 cases (4652.1 person-years) discontinued medication, 26,630 cases (78,933.7 person-years) died, 2368 cases (11,749.7 person-years) were lost to follow-up, and 2416 cases (15,220.9 person-years) were transferred out. Among the deceased patients, the shortest survival time was 0.5 years, the longest was 14.4 years, 4327 cases (16.25%) died within one year, and the median survival time was 2.4 years (IQR: 1.3~4.0 years). The median follow-up time for all study subjects was 3.9 years (IQR: 2.4~5.9 years), with an average follow-up time of 4.4 years. The cumulative survival probabilities at 1, 3, 5, and 10

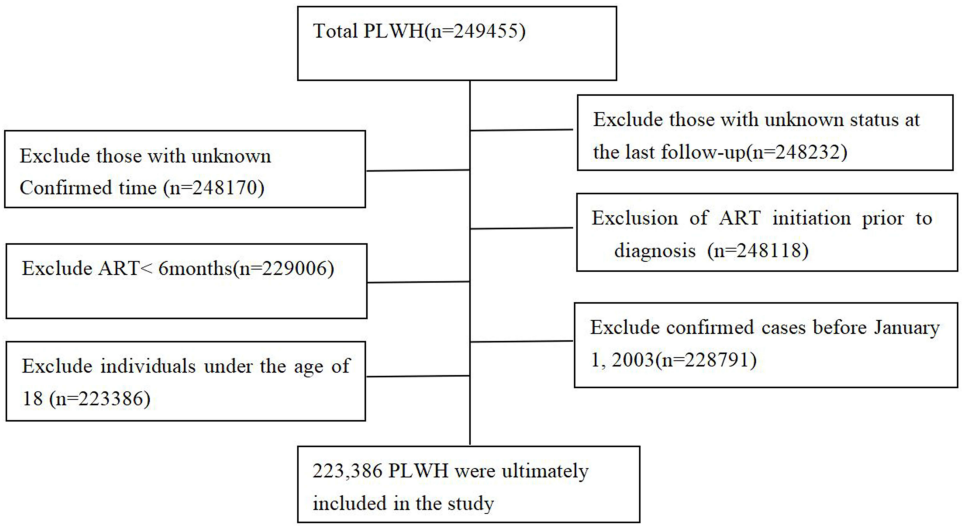

Figure 1 Sampling flowchart.

Table 1 Baseline Characteristics on the Death of PLWH in Sichuan Province 6 Months After Receiving ART, 2003–2022 (n=223386)

Characteristics	Number of people	Composition Ratio (%)	Mortality count	Mortality Rate (%)	Chi-square value
Sex					1368.154*
Male	159911	71.58	21,618	13.52	
Female	63475	28.41	5012	7.90	
Age at diagnosis (Years)					2591.499*
<50	131,916	59.05	11,892	9.01	
≥50	91,470	40.95	14,738	16.11	
Marital Status					1216.537*
Divorced or separated	46496	20.81	7180	15.44	
Widowhood	2936	1.31	359	12.22	
Unmarried	45365	20.31	3627	8.00	
Married or cohabiting	128587	57.56	15,464	12.02	
Unknown	2	–	0	–	
Route of transmission					3798.257*
Heterosexual transmission	172404	77.18	19,995	11.60	
Homosexual transmission	19571	8.76	632	3.23	
Drug injection transmission	21303	9.54	4838	22.71	
Blood transfusion, plasmapheresis transmission	381	0.17	63	16.554	
others	9725	4.35	1101	11.32	
Unknown	2	–	1	–	
Baseline BMI					1530.081*
Normal	165126	74	20,098	12.17	
Overweight	37739	17	2788	7.39	
Thin	20521	9.2	3744	18.24	
Drug resistance profile					38.323*
Single drug resistance	3458	25	911	26.34	
Multidrug resistance	2923	21	713	24.39	
No drug resistance	7692	55	1633	21.23	
Unknown	209313	–	23,373	–	
Baseline CD4+ T cell count (cells/μL)					1485.707Δ*
<200cells/μL	62788	28.11	9950	15.85	
200–350cells/μ	81,817	36.63	9417	11.51	
350–500cell/μL	47475	21.25	4448	9.37	
>500cells/μL	31306	14.01	2815	8.99	
Baseline WHO Staging					1429.058Δ*
I	114847	51.41	11,622	10.12	
II	69405	31.07	8120	11.70	
III	29096	13.02	5064	17.40	
IV	9732	4.36	1647	16.92	
Unknown	306	0.14	177	–	
Time interval from diagnosis to treatment (months)					1897.791Δ*
0–3	148,118	66.31	14,458	9.76	
3–12	33,216	14.87	5080	15.29	
>12	42,052	18.82	7092	16.86	

Note:"Δ"represents the use of the chi-square test for trends. *p value< 0.05.

years were 94.54%, 89.07%, 84.82%, and 76.44%, respectively. Statistically significant differences in survival curves by gender, age at diagnosis, and baseline CD4 level ($\chi 2$=1387.48, P<0.001) ($\chi 2$= 5395.39, P<0.001) ($\chi 2$=1582.858, P<0.001). (Figures 2–5).

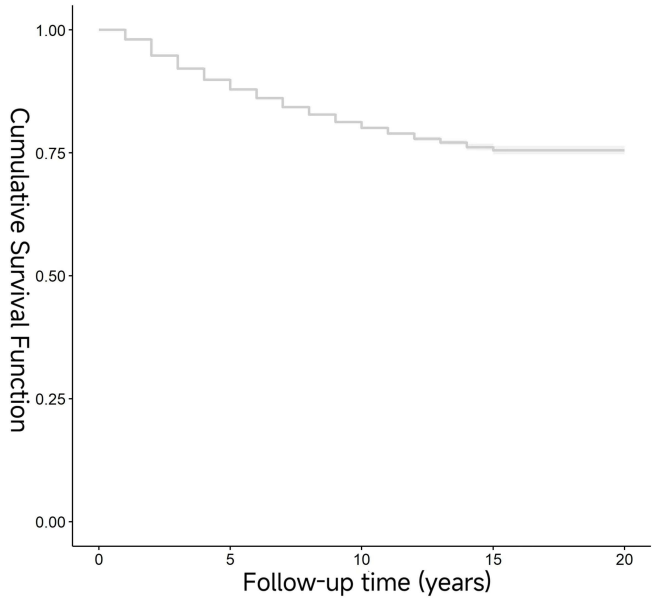

Figure 2 Cumulative Survival Probability of PLWH Receiving Antiviral Therapy for Six Months or More in Sichuan Province, 2003–2022.

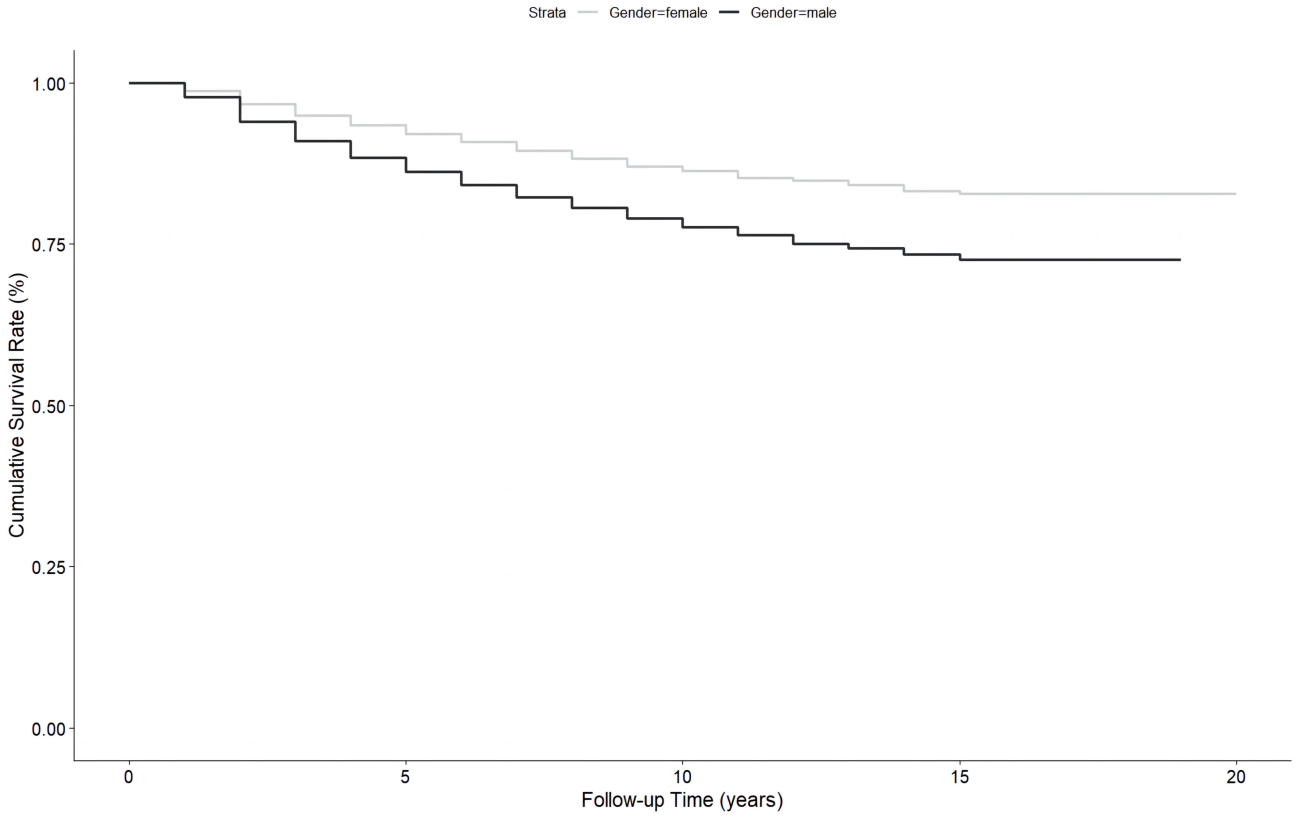

Figure 3 Cumulative Survival Probability of PLWH Receiving ART for Six Months and More by Sex in Sichuan Province, 2003–2022.

Factors Affecting Mortality Risk

The results of the multivariate Cox proportional hazards model analysis show that gender, age at diagnosis, transmission route, baseline BMI value, drug resistance status, baseline CD4(+) T cell count, and WHO clinical stage were factors influencing patient mortality. Among these, the risk of death for females was 0.59 times that of males; the risk of death

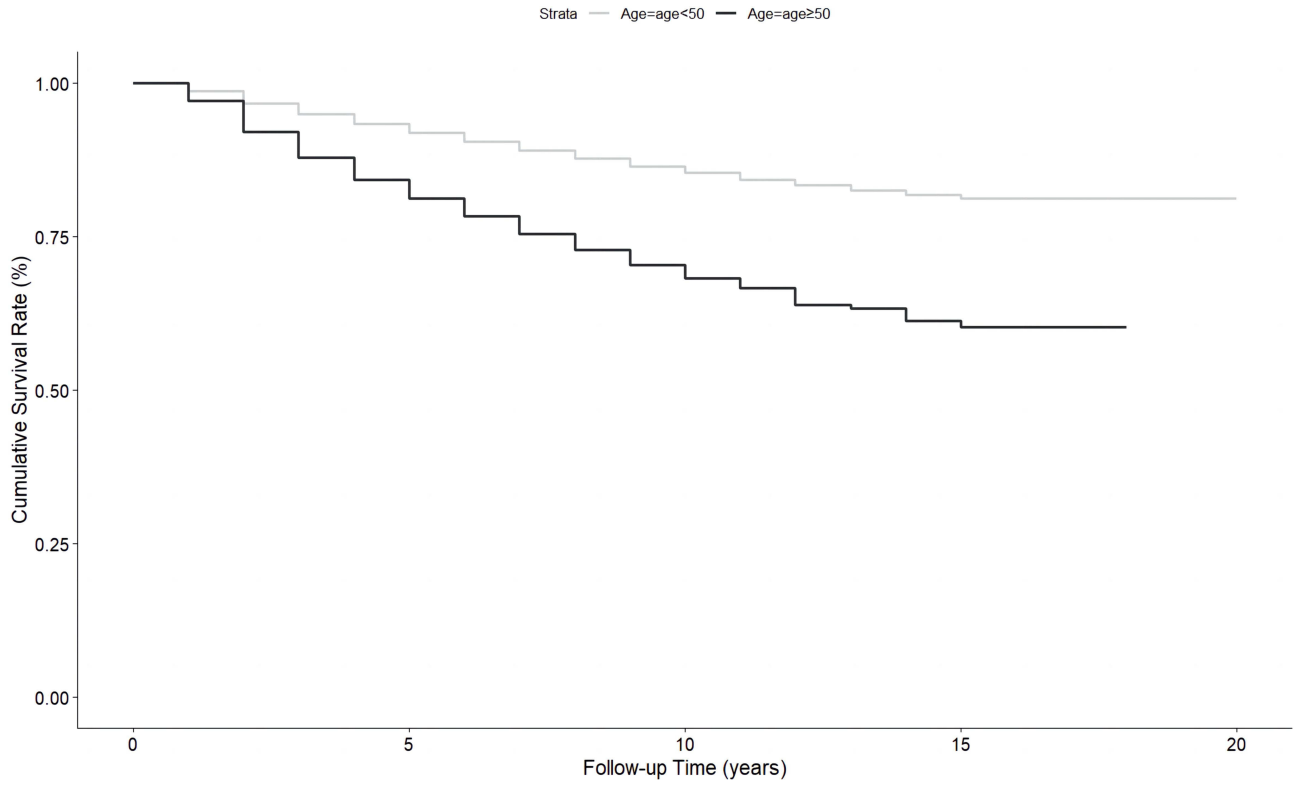

Figure 4 Cumulative survival probability of PLWH receiving ART for six months or more in different age groups in Sichuan Province, 2003–2022.

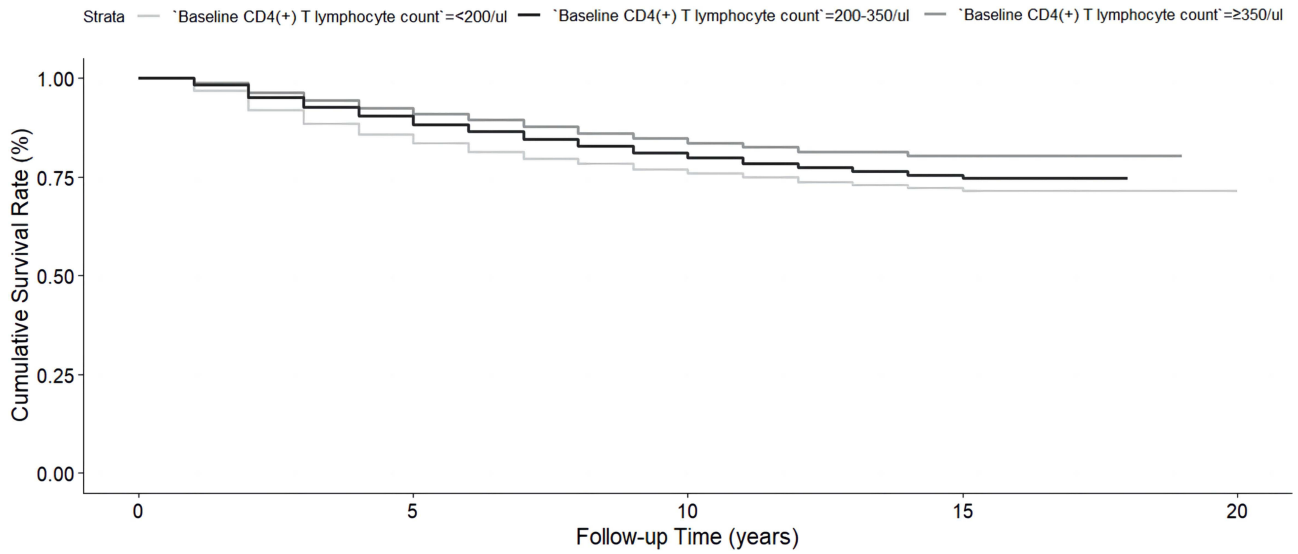

Figure 5 Cumulative survival probability of PLWH receiving ART for six months and more in different CD4(+) T cell level groups in Sichuan Province, 2003–2022.

for those aged ≥50 years at diagnosis was 3.21 times that of those <50 years old; the risk of death for unmarried, divorced, or separated individuals was 1.23 times and 1.32 times that of married or cohabiting individuals, respectively; the risk of death through homosexual transmission was 0.43 times that of heterosexual transmission. The risk of death for those with a BMI in the underweight range was 1.27 times that of those with a normal BMI, while the risk of death for those with a BMI in the overweight range was 0.81 times that of those with a normal BMI; the risk of death with a single drug resistance was 1.25 times that of no drug resistance; the risk of death for baseline CD4(+) T cell counts in the range

of 200–350 cells/μL, 350–500 cells/μL, and ≥500 cells/μL were 0.73 times, 0.57 times, and 0.58 times that of counts <200 cells/μL, respectively; the risk of death for baseline WHO clinical stage IV was 1.27 times that of stage I; the risk of death for those with a diagnosis to treatment interval of more than 12 months was 1.27 times that of those within 0–3 months. (Table 2)

Table 2 Cox Proportional Risk Modeling Analysis of Factors Associated with Survival Time of PLWH on Antiviral Therapy for Six Months and More in Sichuan Province, 2003–2022(n=223386)

Variable	Inclusion Sample Size (Percentage%)	Single Factor Cox Analysis	Multifactorial Cox Analysis
Sex			
Male	159911 (71.58)	–	–
Female	63475 (28.42)	0.56 (0.55–0.58)**	0.59 (0.54–0.65)**
Age at diagnosis (years)			
<50	131,916 (59.05)	–	–
≥50	91,470 (40.95)	2.58 (2.52–2.65)**	3.21 (2.94–3.50)**
Marital Status			
Married or cohabiting	128587 (57.56)	–	–
Unmarried	45365 (20.31)	0.65 (0.63–0.67)**	1.23 (1.11–1.37)**
Divorced or separated	46496 (20.81)	1.44 (1.40–1.48)**	1.32 (1.22–1.43)**
Widowhood	2936 (1.32)	1.00 (0.90–1.11)	1.24 (0.89–1.73)
Route of transmission			
Heterosexual transmission	172404 (77.18)	–	–
Blood transfusion, plasmapheresis transmission	381 (0.17)	0.97 (0.75–1.24)	1.06 (0.50–2.23)
Drug injection transmission	21303 (9.54)	1.43 (1.38–1.47)**	1.04 (0.90–1.18)
Homosexual transmission	19571 (8.76)	0.21 (0.20–0.23)**	0.43 (0.33–0.55)**
others	9725 (4.35)	0.97 (0.91–1.03)	1.11 (0.93–1.32)
Baseline BMI			
Normal	165126 (73.92)	–	–
Overweight	37739 (16.89)	0.67 (0.65–0.70)**	0.81 (0.72–0.90)**
Thin	20521 (9.19)	1.48 (1.43–1.53)**	1.27 (1.13–1.41)**
Drug resistance profile			
No drug resistance	7692 (54.66)	–	–
Single drug resistance	3458 (24.57)	1.38 (1.28–1.50)**	1.25 (1.15–1.36)**
Multidrug resistance	2923 (20.77)	1.09 (0.99–1.19)	1.05 (0.96–1.15)
Baseline CD4+ T cell count (cells/μL)			
<200cells/μL	62788 (28.11)	–	–
200–350cells/μL	81817 (36.63)	0.71 (0.69–0.73)**	0.73 (0.67–0.79,)**
350–500cells/μL	47475 (21.25)	0.56 (0.54–0.58)**	0.57 (0.51–0.64)**
>500cells/μL	31306 (14.01)	0.54 (0.52–0.56)**	0.58 (0.51–0.66)**
Baseline WHO Staging			
I	114847 (51.41)	–	–
II	69405 (31.07)	1.13 (1.10–1.17)**	1.08 (0.99–1.17)
III	29096 (13.02)	1.44 (1.39–1.48)**	1.06 (0.96–1.16)
IV	9732 (4.36)	1.59 (1.51–1.68)**	1.27 (1.09–1.47)*
Time interval from diagnosis to treatment (months)			
0–3	148,118 (66.31)	–	–
3–12	33,216 (14.87)	1.17 (1.14–1.21)**	1.05 (0.96–1.15)
>12	42,052 (18.82)	1.27 (1.24–1.31)**	1.27 (1.15–1.41)**

Notes: *p value< 0.05; **p value< 0.001.

Discussion

This survey found that from 2003 to 2022, the all-cause mortality rate of PLWH in Sichuan Province who received ART for more than half a year was 2.7 per 100 person-years, which was higher than the all-cause mortality rate of the treated population in Guangxi (0.978 per 100 person-years),[9] but lower than that in Guangzhou, Yunnan, Fujian, Henan, and other places (4.00~10.17 per 100 person-years).[10–14] The number of patients who died within one year accounted for 16.25% of the total number of deaths, which may be related to the relatively late diagnosis of some infections,[15] and there were cases where death occurred within one year after diagnosis. He Fang[16] and others analyzed the newly reported PLWH cases aged 50 and above in Sichuan Province from 2015 to 2019 and found that the proportion of late-diagnosed cases were 44.92%, 40.82%, 40.61%, 41.05%, and 39.19%, respectively. This indicates that our province should prioritize the quality of treatment for patients who have been diagnosed at a late stage, in order to enhance their quality of life and extend their survival time. The cumulative survival rates of the study subjects at 1, 3, 5, and 10 years were 94.54%, 89.07%, 84.82%, and 76.44%, respectively. These rates were lower than those in Henan Province,[17] Nanjing City,[18] and Shandong Province,[19] but higher than those in Hubei Province,[20,21] also above the national level.[22]

The findings of this study indicated that several factors, including gender, age at diagnosis, marital status, transmission route, baseline BMI value, drug resistance, baseline CD4(+) T cell count, and WHO clinical staging, were statistically associated with the risk of death in the subjects studied. In terms of gender, women had a lower risk of death than men, which was consistent with domestic related studies.[23,24] Men were less likely to receive antiretroviral treatment than women, started treatment later, and had poorer adherence.[25] In terms of age, the risk of death for those diagnosed at ≥50 years old was 3.21 times that of those <50 years old. On one hand, as lifespan increases, the risk of chronic diseases and tumors becomes higher, and the immune decline caused by HIV infection exacerbates this risk. On the other hand, people aged 50 and above had a slower physical response to AIDS antiretroviral treatment and require more time for immune reconstitution, thus increasing the risk of death. In recent years, among newly detection infections in Sichuan Province and other provinces in China, the proportion of people aged 50 and above had been increasing year by year,[16,26–29] indicating that this group had become a key target for AIDS prevention and control.

In terms of marital status, unmarried, divorced, or separated patients had a higher risk of death than married patients with spouses, possibly due to the lack of spousal or family care and support, which can improve medication adherence, enhance treatment quality, and thus reduce the risk of death. In terms of transmission routes, homosexual transmission carried a lower risk of death than heterosexual transmission, which was consistent with some domestic studies.[13,30] Homosexual individuals usually had higher education levels, stable work or study environments, relatively good medication adherence,[31] and possibly higher self-health awareness, hence a lower likelihood of death risk. This study founded that baseline BMI was also one of the factors affecting the death of PLWH; The risk of death was lower in those with greater BMI than in those with normal BMI. Reports suggested that overweight PLWH had lower viral loads and higher CD4(+) T lymphocyte levels, which may be related to the higher content of Leptin protein in overweight patients that helped restore immune function.[31,32] Regarding the occurrence of drug resistance, patients with single-drug resistance had a higher risk of death than those without resistance, consistent with the research by Zhou Chang et al.[33] The emergence of HIV drug resistance led to the failure of existing antiretroviral drugs to suppress the virus in patients, causing viral load rebound, CD4 count decline, and opportunistic infections. Without more effective drugs, patients can easily die from opportunistic infections.

The risk of death for baseline WHO clinical stage IV was 1.27 times that of stage I, with patients at this stage experiencing severe immune system damage, low CD4(+) T cell counts, and increased susceptibility to various serious infections and tumors such as Pneumocystis pneumonia, Kaposi's sarcoma, and lymphomas. These diseases were not only difficult to treat but often progress rapidly, leading to an increased risk of death. The mortality risk for populations with a baseline CD4(+) T cell count of <200 cells/μL was higher than those with counts of 200–350 cells/μL, 350–500 cells/μL, and ≥500 cells/μL, with a trend of increasing PLWH mortality rates as baseline CD4(+) T cell counts decrease. The number of CD4(+) T cells is a laboratory indicator crucial for staging HIV infection, predicting disease progression, preventing opportunistic infections, and assessing the effectiveness of antiretroviral therapy.[34] Baseline CD4(+) T cell count results can reflect the immune status at the time of case reporting, especially when the baseline CD4(+) T cell count is <200 cells/μL, significantly impacting treatment and quality of life.[35,36] The influence of baseline WHO clinical staging and CD4(+) T cell count on mortality risk underscores the importance of

early detection in reducing the risk of death. The risk of death was 1.27 times higher for those whose time from diagnosis to initiation of treatment exceeds 12 months compared to those within 3 months, with an increasing trend in mortality rates among PLWH as the duration from diagnosis to treatment initiation increases. Possible reasons include: 1) The longer the time from diagnosis to treatment initiation, the longer the virus replicates in the body, leading to more severe damage to the immune system. 2) If patients did not start ART promptly, they may miss the optimal window to suppress viral replication, resulting in disease progression. 3) As the disease progresses, PLWH may developed more complications such as tuberculosis, pneumonia, cardiovascular diseases, etc, which could further increased the risk of death. Numerous studies[37,38] have shown that early initiation of ART after HIV infection can enhanced the body's immune recovery and improved quality of life.

Limitations

There are some limitations in this study, only the data provided in the AIDS prevention and control information system were analyzed, other such as patients' medication adherence, treatment duration, treatment effect, economic status, psychological factors, family factors, etc. were not analyzed due to the difficulty of obtaining them. Due to the limitations of early medical care, the causes of death in some cases were inaccurate or missing, so this study did not differentiate between AIDS-related deaths and non-AIDS-related deaths, and some studies have shown[12,37–40] that the use of all-cause -of-death analyses may overestimate the risk of patient deaths.

Conclusion

The survival rate for PLWH receiving ART in Sichuan Province was relatively high. Patients who are male, diagnosed at or above the age of 50, unmarried, divorced or separated, with single-drug resistance, baseline BMI indicating underweight, baseline CD4+ T lymphocyte count less than 200 cells/μL, baseline WHO stage IV, and a diagnosis-to-treatment interval greater than 12 months have a higher risk of mortality. This study suggests that healthcare providers need to provide targeted health education and counseling for this population, strengthen compliance education, and improve the quality of treatment to reduce the risk of death. On the other hand, early detection and treatment of PLWH is needed to improve the survival rate of patients.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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