Preplanned Studies

Risk Assessment of Cardiovascular Disease in HIV Infected Individuals Receiving Antiretroviral Therapy — Shanghai Municipality, China, 2023

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Summary

What is already known about this topic?

Antiretroviral therapy (ART) is transforming human immunodeficiency virus (HIV) infection into a chronic condition, leading to an altered disease spectrum in patients. The risk of cardiovascular disease (CVD) in HIV-infected individuals are twice that of the general population.

What is added by this report?

This study demonstrates elevated cardiovascular risk among the HIV population. The findings reveal that traditional CVD risk factors are prevalent among people living with HIV but remain inadequately addressed in clinical practice.

What are the implications for public health practice?

These findings underscore both the necessity and urgency of implementing systematic CVD risk screening and intervention programs for HIV population. Furthermore, the study emphasizes the critical need to develop CVD screening tools specifically calibrated for the HIV population in China.

ABSTRACT

Introduction: Cardiovascular disease (CVD) has emerged as a critical determinant of prognosis and quality of life among individuals living with human immunodeficiency virus (HIV). The primary objective of this study is to assess the CVD risk among HIV-infected individuals and determine the proportion of high-risk individuals using multiple evaluation methods.

Methods: A cross-sectional study was conducted among HIV-infected individuals aged 18 years and older who were receiving antiretroviral therapy between April 26, 2023, and December 16, 2023. Participants were categorized into low-risk, intermediate-risk, and high-risk groups for CVD based on six risk assessment tools.

Results: Our analysis revealed that the 5-year overall CVD risk estimates ranged from 2.37% to 2.50%, while the 10-year overall risk estimates spanned from 3.42% to 18.35%, with significant variations observed between subgroups. The proportion of high-risk individuals in the 10-year risk assessment, identified using five different tools, ranged from 7.85% to 31.94%, demonstrating moderate consistency across tools.

Conclusions: The findings underscore the importance of closely monitoring and managing CVD risk in HIV-infected individuals. Given the variability in risk stratification methods, it is imperative to develop an assessment model tailored to the specific characteristics of the Chinese population.

Cardiovascular disease (CVD) has emerged as a critical determinant of prognosis and quality of life among individuals living with human immunodeficiency virus (HIV). Consequently, the screening, prevention, and treatment of CVD have become integral components of comprehensive HIV care (*1*). While risk prediction models and assessment criteria serve as essential tools for CVD primary prevention, their application to HIV-infected individuals presents challenges due to inconsistent results and incomplete consideration of HIV-specific risk factors. We conducted a cross-sectional study of HIV-infected individuals aged 18 years and older who were receiving antiretroviral therapy (ART) at Department of Infection and Immunity of Shanghai Public Health Clinical Center between April 26, 2023, and December 16, 2023. Our analysis revealed 5-year CVD risk estimates ranging from 2.37% to 2.50%, and 10-year risk estimates spanning 3.42% to 18.35%,

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with significant variations observed between subgroups. This study aims to heighten clinician awareness regarding CVD risk in HIV-infected individuals and advocates for the development of tailored assessment tools for this population.

Study participants were screened according to the eligibility criteria of different prediction models, with cases of incomplete data being excluded (Supplementary Figure S1, available at https://weekly.chinacdc.cn/). Demographic and clinical data were collected through questionnaires, including gender, age, region, ethnicity, smoking status, marital status, family history of CVD, antihypertensive medication use, and diabetes mellitus history. Anthropometric measurements were performed on site, including height, weight, waist circumference (measured horizontally at an umbilical level), body mass index (BMI), systolic blood pressure (SBP), and diastolic blood pressure (DBP). Laboratory parameters including total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, triglyceride (TG), and estimated glomerular filtration rate (eGFR) were obtained through standardized testing. Treatment-related data, including regimen details, initial and most recent CD4 counts, ART initiation date, duration of follow-up, and clinical outcomes, were extracted from the treatment database using patient age and treatment identification numbers.

Baseline characteristics were summarized using percentages for categorical variables and medians with interquartile ranges (IQRs) for continuous variables. We applied multiple validated atherosclerotic cardiovascular disease (ASCVD) risk assessment tools: The American College of Cardiology/American Heart Association 2013 ASCVD risk score (ACC/AHA-ASCVD) (*2*), the Framingham 2008 ASCVD risk score (FHS-CVD) (*3*), European AIDS Clinical Society (EACS) guidelines (*4*), the Predicting the 10-Year risks of Atherosclerotic Cardiovascular Disease in Chinese Population (China-PAR) (*5*), Data-collection on Adverse Effects of Anti-HIV Drugs (D:A:D) study (*6*), and the Chinese guidelines for lipid management (2023 edition) (*7*). Detailed comparisons of cohort populations, endpoint definitions, and risk stratification criteria across models are provided inSupplementary Table S1 (available at https://weekly.chinacdc.cn/). To ensure standardized comparison, we focused on 10-year risk assessment, excluding lifetime risk calculations. For EACS guidelines, we utilized Version 11.0 recommendations based on the Framingham equation or national guidance, rather than Version 12.0's SCORE-2 model, given our focus on Shanghai's HIV-infected population. Statistical analyses were performed using R (version 4.4.1; R Foundation for Statistical Computing, Vienna, Austria) and the R package 'CVrisk' version 1.1.1 (*8*). For D:A:D risk assessment, we implemented the reduced model and sex-specific adjusted Framingham model to calculate 5-year incidence risk. We conducted subgroup analysis by gender, age group, and diabetes status, computing mean values and 95% confidence intervals (*CI*) for each subgroup, with pairwise t-tests for between-group comparisons. Inter-rater reliability was assessed using Fleiss' kappa, with values interpreted as: 0.00–0.20 (slight), 0.21–0.40 (fair), 0.41–0.60 (moderate), 0.61–0.80 (substantial), and 0.81–1.00 (almost perfect) agreement.

The study comprised 3,815 individuals, with males constituting 93.69% of the cohort and a median age of 44 years (interquartile range: 33–55 years). Among participants, 27.79% (1,060/3,815) were smokers, with a median BMI of 23.04 (interquartile range: 20.83–24.77), and 33.94% (1,295/3,815) were overweight (BMI>24). Dyslipidemia was present in 61.57% (2,349/3,815) of participants, with 22.2% (848/3,815) exhibiting elevated low cholesterol levels. Hypertension affected 27.02% (1,031/3,815) of the cohort, with 42.78% (441/1,031) receiving antihypertensive medication. Treatment records indicated that 96.75% of individuals maintained stable and continuous treatment, while approximately 3% were lost to follow-up, transferred out, or deceased. The majority of participants (85.95%) presented with baseline viral loads below 100,000 copies/mL, and 63.94% maintained baseline CD4 levels exceeding 200 cells/μL, indicating the absence of severe immunosuppression. The most frequently prescribed antiretroviral medications were efavirenz (EFV), lamivudine (3TC), and tenofovir (TDF), with over half of the cohort receiving each of these agents (Table 1).

In the baseline population, 2,893 individuals aged 40-74 years met the age range requirements for all risk assessment tools. The five-year risk assessment revealed an overall population risk of 2.37% (95% *CI*: 2.26%, 2.48%) with the reduced D:A:D model, while the adjusted Framingham model estimated a risk of 2.50% (95% *CI*: 2.38%, 2.62%). The proportion of high-risk

TABLE 1. Demographic,cardiovascular, and HIV-related risk factors and clinical characteristics of the study population (*n*=3,815).

Variable	Individuals Included in This Analysis
Demographic characteristics	
Age in years [median (IQR)]	44.07 (33–55)
Male sex (%)	3,536 (93.69)
Southern/Northern region	3,814/1
Urban/Rural address	3,814/1
CVD-related risk factors	
BMI in kg/m^2 [median (IQR)]	23.04 (20.83–24.77)
≥24 (%)	1,295 (33.94)
SBP in mmHg [median (IQR)]	125.64 (116–134)
DBP in mmHg [median (IQR)]	76.51 (70–83)
Hypertension (%)	1,031 (27.02)
Waist circumference in cm [median (IQR)]	81.32 (75–86)
TC in mmol/L [median (IQR)]	4.56 (3.97–5.15)
≥5.2 (%)	909 (23.08)
HDL-C in mmol/L [median (IQR)]	1.21 (0.99–1.37)
<1 (%)	985 (25.82)
LDL-C in mmol/L [median (IQR)]	2.82 (2.27–3.29)
≥3.4 (%)	848 (22.20)
TG in mmol/L [median (IQR)]	2.58 (1.05–2.69)
≥1.7 (%)	1,880 (49.28)
GFR in ml/(min·1.73m^2) [median (IQR)]	94.96 (81–108)
<60 (%)	123 (3.22)
Dyslipidemia (%)	2,349 (61.57)
Smoking (%)	1,060 (27.79)
Family history of CVD (%)	396 (10.38)
Diabetes status (%)	
Not diabetic	3,597 (94.29)
Less than 10 years	132 (3.46)
More than 10 years	86 (2.25)
Use of antihypertensive drugs (%)	441 (11.56)
HIV-related risk Factors	
Current status (%)	
Undergoing treatment	3,691 (96.75)
Lost to follow-up	112 (2.94)
Transferred out	4 (0.01)
Death	8 (0.21)
Baseline viral load in copies/mL (%)	
<100, 000	3,279 (85.95)
100,000–500,000	388 (10.17)
>500,000	148 (3.88)
Baseline CD4+T-Cell count in cells/μL (%)	
<200	1,376 (36.07)
200–350	1,360 (35.65)
351–800	1,036 (27.16)
≥801	43 (1.13)
EFV-based ART	2,129 (55.81)
TAF-based ART	912 (23.91)
TDF-based ART	2,071 (54.29)
INSTI-based ART	1,383 (36.25)
PI-based ART	221 (5.80)
ART duration in weeks	62 (22–105)

Note: Hypertension is defined as blood pressure ≥140/90 mmHg, or in patients with hypertension taking antihypertensive medications.
Abbreviation: CVD=cardiovascular disease; BMI=body mass index; SBP=systolic blood pressure; DBP=diastolic blood pressure; TC=total cholesterol; HDL-C=high-density lipoprotein cholesterol; LDL-C=low-density lipoprotein; TG=triglyceride; GFR=glomerular filtration rate; EFV=efavirenz; TDF=tenofovir disoproxil fumarate; TAF=tenofovir alafenamide; INSTI=integrase strand transfer inhibitor; PI=protease inhibitor.

individuals for 5-year risk ranged from 2.45% (95% *CI*: 1.93%, 3.10%) to 3.39% (95% *CI*: 2.78%, 4.13%). 10-year risk assessment using five different tools demonstrated substantial variation in both mean risk values and high-risk population proportions. The China-PAR identified the smallest proportion of high-risk individuals at 7.85% (95% *CI*: 6.91%, 8.90%), while the FHS-CVD identified the highest at 31.94%. The Chinese guidelines for lipid management, ACC/AHA-ASCVD, and EACS criteria identified high-risk groups comprising 14.86% (95% *CI*: 13.60%, 16.22%), 20.26% (95% *CI*: 18.81%, 21.78%), and 26.58% (95% *CI*: 24.99%, 28.24%) of the population, respectively. The 10-year overall risk estimates spanned from 3.42% (95% *CI*: 3.28%, 3.56%) to 18.35% (95% *CI*: 17.70%, 19.00%). Subgroup analysis revealed statistically significant mean differences within each subgroup across all models (P<0.05). Risk assessment results are summarized in Table 2. Inter-rater reliability assessment of the grading outcomes yielded a Fleiss' kappa coefficient of 0.51. A Wayne diagram (Figure 1A) revealed that 137 (4.7%) individuals were classified as high risk across all 10-year tools. Comprehensive grading analysis and mosaic visualization were performed using 10-year tools (Figure 1B).

TABLE 2. Risk estimates and high-risk population proportions across assessment models (*n*=2,893) [mean (95% *CI*)].

Subgroup	D:A:D study, mean (95% *CI*)		FHS-CVD, mean (95% *CI*)	China-PAR, mean (95% *CI*)	ACC/AHA-ASCVD, mean (95% *CI*)	EACS, mean (95% *CI*)	Chinese guidelines for lipid management, mean (95% *CI*)
	D:A:D reduced model	5-years Framingham model					
Overall	2.37 (2.26, 2.48)	2.50 (2.38, 2.62)	18.35 (17.70, 19.00)	3.42 (3.28, 3.56)	11.17 (10.67, 11.68)		
Gender							
Female	1.75 (1.54, 1.96)	1.65 (1.42, 1.88)	13.07 (11.58, 14.56)	2.08 (1.83, 2.33)	7.88 (6.65, 9.11)		
Male	2.42 (2.30, 2.54)	2.58 (2.45, 2.70)	18.82 (18.13, 19.52)	3.54 (3.39, 3.70)	11.47 (10.94, 12.00)		
Age, years							
≤40	0.62 (0.59, 0.65)	0.68 (0.65, 0.71)	6.08 (5.85, 6.32)	1.06 (0.96, 1.16)	2.35 (2.20, 2.50)		
41–50	1.48 (1.40, 1.56)	1.56 (1.48, 1.64)	13.27 (12.69, 13.85)	2.20 (2.05, 2.35)	6.07 (5.68, 6.45)		
51–60	3.58 (3.35, 3.81)	3.78 (3.53, 4.04)	28.10 (26.72, 29.48)	5.21 (4.91, 5.51)	16.39 (15.46, 17.31)		
61–70	5.96 (5.56, 6.36)	6.18 (5.77, 6.59)	40.75 (39, 42.51)	8.04 (7.68, 8.40)	30.04 (28.77, 31.31)		
≥71	7.03 (6.12, 7.95)	7.84 (6.76, 8.92)	49.88 (45.58, 54.17)	10.71 (9.67, 11.76)	43.67 (40.51, 46.83)		
Diabetes							
Yes	8.08 (7.17, 9.00)	8.29 (7.38, 9.20)	48.09 (44.54, 51.63)	9.28 (8.45, 10.11)	35.02 (31.87, 38.17)		
No	1.98 (1.90, 2.06)	2.11 (2.01, 2.20)	16.33 (15.75, 16.91)	3.03 (2.90, 3.15)	9.55 (9.13, 9.98)		
High risk Proportion	2.94 (2.37, 3.64)	3.39 (2.78, 4.13)	31.94 (30.25, 33.68)	7.85 (6.91, 8.90)	20.26 (18.81, 21.78)	26.58 (24.99, 28.24)	14.86 (13.60, 16.22)

Abbreviation: CVD=cardiovascular disease; D:A:D=data-collection on adverse effects of anti-HIV drugs study; 5-years Framingham model=the Framingham model calibrated to the D:A:D data; ASCVD=atherosclerotic cardiovascular disease; FHS-CVD=the Framingham 2008 ASCVD risk score; ACC/AHA-ASCVD=the American College of Cardiology/American Heart Association 2013 ASCVD risk score; China-PAR=the predicting the 10-year risks of atherosclerotic cardiovascular disease in the Chinese population; EACS=European AIDS Clinical Society guidelines.

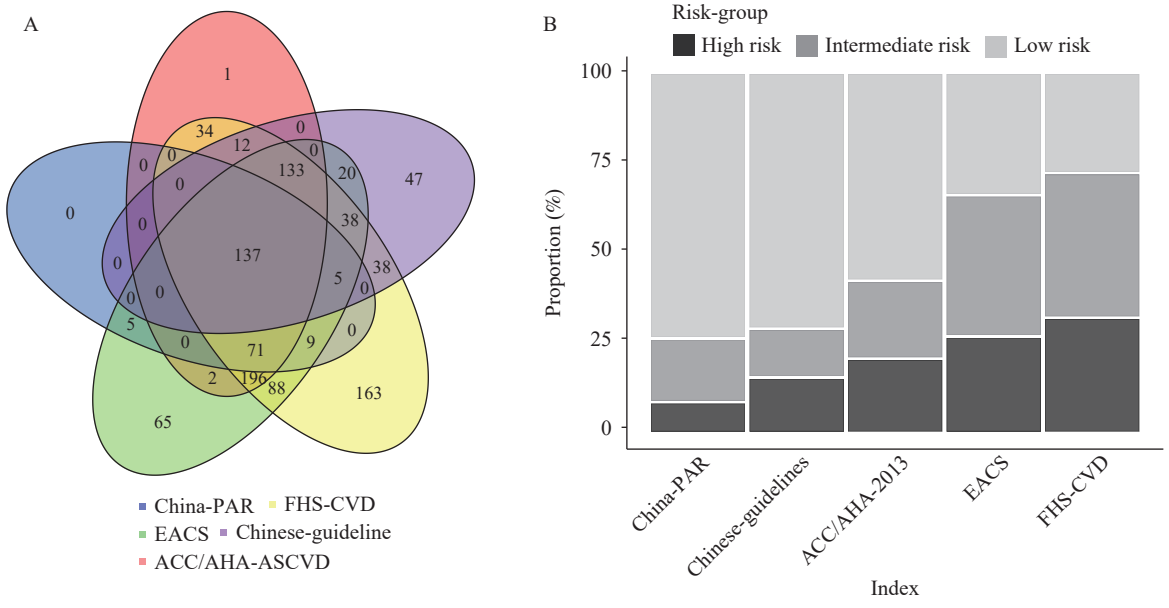

FIGURE 1. Overlap and Distribution of High-Risk Classifications Across Five Assessment Tools: A) Venn diagram showing overlap of high-risk classifications across five assessment criteria; B) Mosaic plot illustrating risk classification distribution under different criteria.
Abbreviation: China-PAR=the predicting the 10-year risks of atherosclerotic cardiovascular disease in Chinese population; EACS=European AIDS Clinical Society guidelines; FHS-CVD=the Framingham 2008 ASCVD risk score; ACC/AHA-ASCVD=the American College of Cardiology/American Heart Association 2013 ASCVD risk score.

DISCUSSION

Our 10-year risk assessment revealed that 7.85% to 31.94% of HIV-infected individuals are at high risk for CVD, highlighting a significant health concern that demands attention. While HIV-infected individuals typically exhibit more traditional risk factors, these alone cannot fully explain their elevated CVD risk (*9*). Therefore, systematic risk screening among the HIV population is crucial. The Chinese guidelines for diagnosis and treatment of HIV infection/AIDS (2024 edition) mandate regular CVD risk assessments, screenings, and preventive interventions for all HIV-infected individuals (*2*). For high-risk individuals, ART regimens should be modified accordingly, with active management of CVD risk factors, including smoking cessation, glycemic control, lipid management, obesity, and hypertension. Among antiviral medications, protease inhibitors and non-nucleoside reverse transcriptase inhibitors have a higher propensity to cause lipid metabolism disorders. Given the high usage rate of EFV observed in our study, individuals on these medications may require ART regimen modifications.

Based on our findings and current guideline recommendations, proactive CVD risk screening, and targeted interventions for the HIV population are imperative. However, our study revealed that fewer than half of hypertensive individuals received antihypertensive treatment, and effective interventions for risk factors such as smoking and dyslipidemia were inadequate. This underscores the need for enhanced primary prevention efforts, particularly in screening high-risk populations and implementing timely antihypertensive and lipid-lowering interventions to reduce CVD risk.

CVD risk screening should be integrated into routine clinical management of HIV, necessitating appropriate screening tools. However, current risk screening tools have significant limitations. General population prediction models show reduced accuracy in HIV-infected individuals due to factors such as drug toxicity and immune reconstitution (*9*). Our study demonstrated poor consistency among the five tools used for 10-year CVD risk assessment in the general population. This inconsistency partly stems from differences in outcome indicators. Most predictive model cohorts were established in the last century, and temporal changes in lifestyle and environmental factors may compromise their current accuracy. In clinical practice, this poor consistency results in different models identifying distinct patient groups for intervention, leading to varied preventive care decisions. Treating HIV-infected individuals as part of the general population for cardiovascular prevention fails to account for the increased CVD risk associated with HIV infection itself. While the D:A:D model was specifically designed for HIV-infected populations, it lacks external validation and excludes the Asian population data. In the absence of an accurate and reliable model, priority should be given to determining the most suitable predictive model for Asian HIV-infected populations and developing a new CVD risk assessment model for HIV-infected individuals. Previous studies have suggested that FHS-CVD is most useful for determining statin eligibility in primary prevention; however, its significant differences in outcome indicators make it generally incomparable with other models (*10*).

Our study has several limitations. First, reliance on voluntary participation in daily follow-up surveys may introduce volunteer bias. Second, identifying valid cases through patient-reported treatment numbers is susceptible to input errors and duplications. Despite manual screening and comparison of treatment records for baseline population data, some missing data persist. Finally, the cross-sectional nature of this baseline survey in an HIV-infected population without a control group precludes comparisons with the general population. Continued follow-up of the study population is necessary to validate these findings, particularly regarding observed outcome events.

In conclusion, our comprehensive evaluation using six risk assessment tools reveals a substantial CVD risk burden among Shanghai's HIV population. The high prevalence of traditional CVD risk factors in this population, coupled with inadequate management, emphasizes the urgent need for systematic screening and intervention programs. Furthermore, our findings underscore the critical importance of developing HIV-specific CVD screening tools tailored to the Chinese population.

Conflicts of interest: No conflicts of interest.

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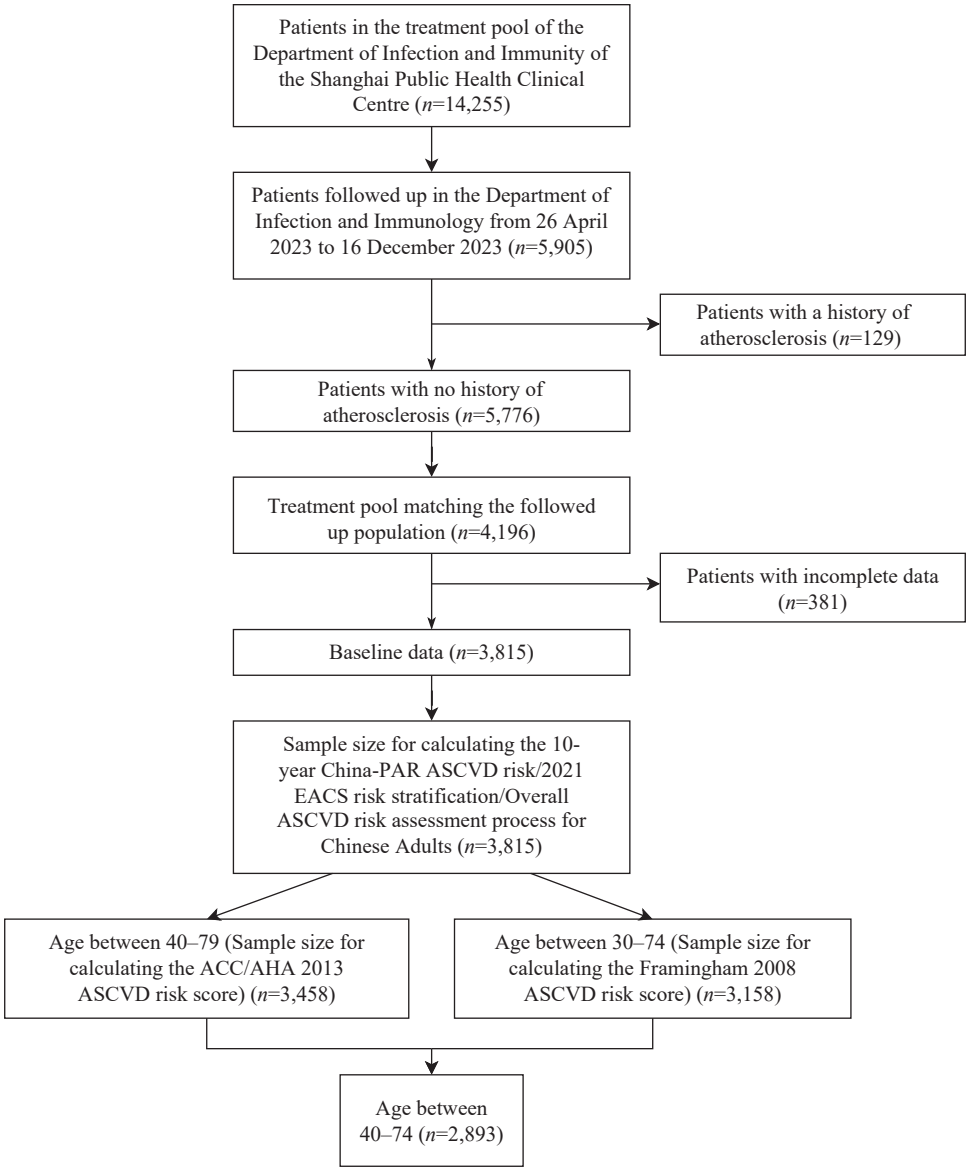
SUPPLEMENTARY MATERIAL



SUPPLEMENTARY FIGURE S1. Flowchart for baseline population selection.
Abbreviation: ACC/AHA=the American College of Cardiology/American Heart Association; ASCVD=atherosclerotic cardiovascular disease.

SUPPLEMENTARY TABLE S1. Basic information about cardiovascular risk assessment models and grading criteria used in this study.

Evaluation criteria	Endpoint definition	Cohort	Follow-up	Assessment results	Criteria for classification
Prediction for ASCVD RISK in China (the China-Par Project)	ASCVD was defined as nonfatal acute MI or CHD death or fatal or nonfatal stroke. Acute MI was identified as a change in biochemical markers of myocardial necrosis accompanied by ischemic symptoms, pathological Q waves, ST-segment elevation or depression, or coronary intervention.18 CHD death included all fatal events resulting from MI or other coronary deaths. Stroke included clinical signs and symptoms of subarachnoid or intracerebral hemorrhage or cerebral infarction, which were rapidly developing signs of focal (or global) disturbances in cerebral function lasting >24 hours without an apparent nonvascular cause.	The China-PAR project used InterASIA (International Collaborative Study of Cardiovascular Disease in Asia) and China MUCA (1998) (China Multi-Center Collaborative Study of Cardiovascular Epidemiology) to develop the Chinese ASCVD risk equations as the derivation cohort. 21,320 participants are included in the project to derive the China-PAR equations	An average follow-up duration of 12.3 years.	Estimation of 10-year and lifetime risk of CVD	Based on the China-PAR equations for risk assessment of ASCVD, those with predicted risks of <5%, 5%–10%, and ≥10% could be classified into categories of low-, moderate-, and high-risk for ASCVD, respectively.
The European AIDS Clinical Society (EACS)					In accordance with the requirements of Version 11.0 of the EACS guidelines, the China-PAR was adopted as the scoring tool, and grading was then conducted based on the EACS grading criteria. Classification criteria include total cholesterol level, LDL cholesterol level, the number of risk factors, and the presence of hypertension.
Chinese guidelines for lipid management (2023)	All fatal and non-fatal acute coronary events and acute stroke events. Acute coronary events included acute myocardial infarction, sudden coronary death, and other coronary deaths and acute stroke events including subarachnoid haemorrhage, intracerebral haemorrhage, or cerebral infarction.	The Chinese Multi-Provincial Cohort Study (CMCS). 21,953 participants aged 35 to 84 years without CVD at the baseline were included.	1992–2010	Estimation of 10-year and lifetime risk of CVD	Classification criteria depend on total cholesterol level, LDL cholesterol level and number of risk factors, and the presence of hypertension.
Framingham 2008 ASCVD risk score	The Framingham Heart Study defines CVD as a composite of CHD (coronary death, myocardial infarction, coronary insufficiency, and angina), cerebrovascular events (including ischemic stroke, hemorrhagic stoke, and transient ischemic attack), peripheral artery disease (intermittent claudication), and heart failure.	In 8,491 Framingham study participants (mean age, 49 years; 4,522 women) who attended a routine examination between 30 and 74 years of age and were free of CVD.	12 years	10-year risk of CVD (We have also adopted the recalibrated 5-year risk of Framingham CVD prediction model in the D:A:D study)	Based on *General Cardiovascular Risk Profile for Use in Primary Care: The Framingham Heart Study*, this project categorized risk levels as 0% to 6%, 6% to 20%, and over 20%

Continued

Evaluation criteria	Endpoint definition	Cohort	Follow-up	Assessment results	Criteria for classification
ACC/AHA 2013 ASCVD risk score	First hard ASCVD events (defined as first occurrence of nonfatal myocardial infarction, CHD death, or fatal or nonfatal stroke)	Provide sex- and race-specific estimates of the 10-year risk of ASCVD for African-American and white men and women 40 to 79 years of age. The final pooled cohorts included participants from several large, racially and geographically diverse, modern NHLBI-sponsored cohort studies, including the ARIC (Atherosclerosis Risk in Communities) study, the Cardiovascular Health Study, and the CARDIA (Coronary Artery Risk Development in Young Adults) study, combined with applicable data from the Framingham Original and Offspring Study cohorts.	>12 years	Estimation of 10-year and lifetime risk of CVD	Predicted risks of <7.5%, 7.5%–20%, and ≥20% could be classified into categories of low-, moderate-, and high-risk for ASCVD, respectively.
The Data-collection on Adverse Effects of Anti-HIV Drugs (D:A:D) study	The study endpoints include all incident cases of MI, stroke, invasive cardiovascular procedures and deaths which were reported to the study co-ordinating office for central validation and coding as detailed previously. Non-fatal MIs not associated with clinical symptoms (silent MIs) were not included.	They conducted a collaborative, observational study of 11 previously established cohorts comprising 23,468 HIV-1–infected patients followed at 188 clinics in 21 countries in Europe, the United States, and Australia.	The median follow-up time was 5.7 (IQR, 2.9–8.8) years	Estimation of 5-year risk of CVD	For each model, they categorized each individua's five-year predicted CVD risk into one of the following categories: <1%, 1%–5%, 5%–10% and >10% five-year CVD predicted risk.

Abbreviation: CHD=congenital heart disease; ASCVD=atherosclerotic cardiovascular disease; MI=myocardial infarction; LDL=low-density lipoprotein; AIDS=acquired immunodeficiency syndrome; CVD=cardiovascular disease.