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CLINICAL STUDY

Survival of people living with HIV after treatment with Traditional Chinese Medicine in Henan province of China: a retrospective cohort study

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Abstract

OBJECTIVE: To provide survival estimates of people living with human immunodeficiency virus (PL-HIV) after treatment with Traditional Chinese Medicine (TCM) in rural China, to identify the prognostic factors at enrollment, and to explore the effectiveness of TCM in treating PLHIV.

METHODS: PLHIV who enrolled in national TCM HIV treatment trial program in October 2004 were analyzed in this study and followed up to October 2010. Survival time was estimated by the Kaplan-Meier curve and hazard ratios, and identifying prognostic factors were computed through Cox proportional hazard models.

RESULTS: A total of 1666 PLHIV were included with 102 591 person-months of follow-up. Overall, 312 (18.7%) patients died. The total mortality rate over the study period was 3.6 per 100 person-years, which was lower than the worldwide rate. The cumulative survival rate was 95.9% at 1 year [95% confidence interval (*Cl*) (94.8-96.8)] and 80.4% at 6 years [95% *Cl* (78.4-82.3)]. Elevated death risks emerged among males, older individuals, and those with lower CD4+ T-cell counts.

CONCLUSION: TCM could increase survival and lengthen the life span of PLHIV in Henan province of China, as shown by our retrospective cohort study. Factors such as sex, age, education, and CD4+ T-cell counts correlated to survival. However, retrospective cohorts bias the data, so more prospective studies should be performed to confirm our primary results.

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Key words: Retrospective studies; HIV; Acquired immunodeficiency syndrome; Survival; Medicine, Chinese traditional

INTRODUCTION

By the end of 2009, the estimated number of people living with human immunodeficiency virus (HIV) in China was 740 000 (560 000-920 000). Among those patients, 105 000 had acquired immune deficiency syndrome (AIDS) (97 000-112 000).1 Since 2003, China has progressively increased funding to support the free combined antiretroviral treatment (cART) plan for people diagnosed with HIV.1 This has resulted in decreased morbidity and mortality, but the prevalence of HIV-related and non-HIV-related diseases and symptoms has increased in HIV-infected patients. These unpredictable or embarrassing symptoms include nausea, diarrhea, fatigue, lipodystrophy, and skin problems, and may result in patients not adhering to the cART.²⁻⁴ The side effects of cART and incurable diseases compel researchers to find new drugs or complementary treatments. One type of complementary and alternative medicine, Traditional Chinese Medicine (TCM), has been used for thousands of years for many diseases, and in the last 30 years has been used to treat HIV. TCM use for HIV/AIDS has been partially shown to reduce plasma HIV viral load, increase CD4+ T-cell counts, promote immunity reconstitution, ameliorate symptoms and signs, improve health-related quality of life (HRQOL), and counteract against the effects of anti-retroviral drugs.5

In 2004, the National Administration of Traditional Chinese Medicine in China started a national TCM HIV treatment trial program (NTCMTP), which eventually provided free TCM treatment to 9267 people living with human HIV (PLHIV) in 17 provinces (autonomous regions and municipalities) by the end of 2009. During the treatment program, PLHIV reported that their clinical symptoms (e.g., fatigue, pain, sleep disturbance, shortness of breath, coughing) were greatly relieved, and opportunistic infections decreased significantly. However, the long-term clinical benefits of TCM treatment for PLHIV are unclear. Therefore, survival analysis of PLHIV after treatment with

TCM was used to explore a possible curative effect. The objective of our analysis was to document the outcome of TCM treatment in terms of survival and its determinants through a retrospective cohort study.

MATERIALS AND METHODS

Context

The Henan NTCMTP center, from which the data in this study was provided, treated the PLHIV in the Henan province of China. All PLHIV in this area comprised mostly one ethnic group, and resided in the countryside. The prevalence of HIV infection caused by paid blood donation was high, and the prevalence in the whole population of this area was 9.1%.9 The infection rate in some villages was up to 35.87%. 10 Because of a lack of a recent negative HIV antibody test date of patients, we had to infer infection date according to the character of the epidemic in each area. Epidemiological study found that HIV transmission was mostly associated with the sale of blood plasma. Illegal blood supply practices started from the end of 1993, peaked in 1994, and were prohibited in March 1995.11 From the date and location of the high risk behavior, such as blood sale or blood transfusion, we inferred the HIV infection date.

Patients

All PLHIV older than 18 years enrolled in NTCMTP in October 2004 were eligible for this retrospective study, and they were followed up to October 2010. Their data were collected at enrollment and monthly thereafter, mainly through a case report form, which included demographic information, laboratory measurements (i.e., CD4 + T-cell counts, whole blood cell counts, urine analysis, liver and renal function, and HIV viral load test results), details of therapy, clinical symptoms, and vital status. Once the PLHIV did not return to get his or her medicine, medical workers would actively visit his or her neighbor or relative to identify whether the patient had died or was lost to follow-up. If patients died of a non-AIDS-defining illness, this was considered "lost to follow-up."

Data analysis

Since the start of the program in this area, all PLHIV data was entered in an ACCESS database. When CD4 + T-cell counts were unavailable, we recorded them as a separate category in the model. Patients infected with HIV through blood sale and blood transfusions were recorded as "blood donor" and "blood recipient." Patients infected with HIV through sexual intercourse or unknown routes were recorded as "others." Survival time was calculated from the date of PLHIV enrolment in NTCMTP to the date of death or October 2010. Survival rate after receiving TCM treatment was estimated by Kaplan-Meier curves. Survival curves

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